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

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0394; Project Identifier MCAI–2021–00904–T; Amendment 39–22094; AD 2022–13–08]

RIN 2120–AA64

Airworthiness Directives; De Havilland Aircraft of Canada Limited (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain De Havilland Aircraft of Canada Limited Model DHC–8–401 and –402 airplanes. This AD was prompted by reports of nose wheel steering (NWS) hydraulic motors jamming during pushback or towing. This AD requires doing an inspection to determine the part number and serial number of the NWS hydraulic motor, and re-identifying or replacing the NWS hydraulic motor if necessary. This AD also prohibits the installation of certain NWS hydraulic motors. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 10, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 10, 2022.

ADDRESSES: For service information identified in this final rule, contact De Havilland Aircraft of Canada Limited, Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd@dehavilland.com;* internet *https://dehavilland.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0394.

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–2022–0394; 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: Elizabeth Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2021–28, dated August 5, 2021 (also referred to after this as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain De Havilland Aircraft of Canada Limited Model DHC–8–401 and –402 airplanes. You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0394.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain De Havilland Aircraft of Canada Limited Model DHC–8–401 and –402 airplanes. The NPRM published in the **Federal Register** on April 6, 2022 (87 FR 19813). The NPRM was prompted by reports of NWS hydraulic motors jamming during pushback or towing. The NPRM proposed to require doing an inspection to determine the part number and serial number of the NWS hydraulic motor, and re-identifying or replacing the NWS hydraulic motor if necessary. The NPRM also proposed to prohibit the installation of certain NWS hydraulic motors. The FAA is issuing this AD to address a possible NWS hydraulic motor jam, which could lead to a runway excursion and loss of controllability of the airplane. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from The Air Line Pilots Association, International (ALPA), who supported the NPRM without change.

Conclusion

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

Related Service Information Under 1 CFR Part 51

De Havilland Aircraft of Canada Limited has issued Service Bulletin 84–32–164, Revision A, dated May 13, 2021. This service information describes procedures for doing an inspection to determine the part number and serial number of the NWS hydraulic motor, and re-identifying the redesigned NWS hydraulic motor, or replacing the original NWS hydraulic motor, as necessary.

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

Costs of Compliance

The FAA estimates that this AD affects 52 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 11 work-hours × $85 per hour = $935	$80	Up to $1,015	Up to $52,780.

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:

2022–13–08 De Havilland Aircraft of Canada Limited (Type Certificate Previously Held by Bombardier, Inc.): Amendment 39–22094; Docket No. FAA–2022–0394; Project Identifier MCAI–2021–00904–T.

(a) Effective Date

This airworthiness directive (AD) is effective August 10, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to De Havilland Aircraft of Canada Limited Model DHC–8–401 and –402 airplanes, certificated in any category, serial numbers 4001 and 4003 through 4622 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Unsafe Condition

This AD was prompted by reports of nose wheel steering (NWS) hydraulic motors jamming during pushback or towing caused by worn out piston rod shoes. The FAA is issuing this AD to address a possible NWS hydraulic motor jam, which could lead to a runway excursion and loss of controllability of the airplane.

(f) Compliance

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

(g) Required Actions

Within 12,000 flight hours or 72 months, whichever occurs first after the effective date of this AD: Inspect to determine the part number and serial number of the NWS hydraulic motor, and re-identify or replace the NWS hydraulic motor, as applicable, in accordance with paragraph 3.B. of the Accomplishment Instructions of De Havilland Aircraft of Canada Service Bulletin 84–32–164, Revision A, dated May 13, 2021.

(h) Parts Installation Prohibition

As of the effective date of this AD, no person may install a NWS hydraulic motor, part number (P/N) RS1267–1, P/N RS1267–1 MOD SB 32–13, P/N RS1267–2, P/N RS1267–2 MOD SB 32–13, and P/N RS1267–3, on any airplane.

(i) No Return of Parts

Although De Havilland Aircraft of Canada Service Bulletin 84–32–164, Revision A, dated May 13, 2021, specifies to return certain parts to the manufacturer, this AD does not include that requirement.

(j) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using De Havilland Aircraft of Canada Limited Service Bulletin 84–32–164, dated April 20, 2020.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or De Havilland Aircraft of Canada Limited's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2021–28, dated August 5, 2021, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0394.

(2) For more information about this AD, contact Elizabeth Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone

516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

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

(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) De Havilland Aircraft of Canada Limited Service Bulletin 84–32–164, Revision A, dated May 13, 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact De Havilland Aircraft of Canada Limited, Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd@dehavilland.com;* internet *https://dehavilland.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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

Issued on June 13, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–14280 Filed 7–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31437; Amdt. No. 4016]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 6, 2022. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 6, 2022.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg 29 Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for Part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore— (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on June 24, 2022.

Thomas J Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, CFR part 97, (is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for Part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
11–Aug–22 ..	CA	Susanville	Susanville Muni	2/0125	6/13/22	RNAV (GPS) RWY 29, Amdt 1B.
11–Aug–22 ..	GA	Atlanta	Atlanta Rgnl Falcon Fld	2/0207	5/20/22	ILS OR LOC RWY 31, Amdt 3.
11–Aug–22 ..	ND	Valley City	Barnes County Muni	2/0343	6/17/22	RNAV (GPS) RWY 31, Orig-A.
11–Aug–22 ..	ND	Valley City	Barnes County Muni	2/0344	6/17/22	RNAV (GPS) RWY 13, Orig-A.
11–Aug–22 ..	IL	Chicago	Chicago O'Hare Intl	2/0362	4/28/22	RNAV (GPS) RWY 4R, Amdt 1C.
11–Aug–22 ..	TX	San Angelo	San Angelo Rgnl/Mathis Fld.	2/0594	6/16/22	ILS Y OR LOC Y RWY 3, Amdt 22A.
11–Aug–22 ..	TX	San Angelo	San Angelo Rgnl/Mathis Fld.	2/0596	6/16/22	RNAV (GPS) RWY 3, Amdt 2.
11–Aug–22 ..	TX	San Angelo	San Angelo Rgnl/Mathis Fld.	2/0597	6/16/22	RNAV (GPS) RWY 18, Amdt 1.
11–Aug–22 ..	IA	Sioux City	Sioux Gateway/Brig General Bud Day Fld.	2/0600	5/26/22	RNAV (GPS) RWY 31, Orig-H.
11–Aug–22 ..	IA	Sioux City	Sioux Gateway/Brig General Bud Day Fld.	2/0634	5/26/22	RNAV (GPS) RWY 13, Orig-F.
11–Aug–22 ..	IN	Indianapolis	Indianapolis Downtown	2/0659	5/26/22	COPTER VOR/DME 287, Amdt 2A.
11–Aug–22 ..	IN	Indianapolis	Indianapolis Downtown	2/0666	5/26/22	COPTER RNAV (GPS) 291, Orig-A.
11–Aug–22 ..	PA	Clearfield	Clearfield-Lawrence	2/0679	5/31/22	RNAV (GPS) RWY 30, Amdt 1C.
11–Aug–22 ..	CA	Madera	Madera Muni	2/0701	5/27/22	RNAV (GPS) RWY 12, Amdt 2A.
11–Aug–22 ..	MI	Boyne Falls	Boyne Mountain	2/0705	5/26/22	Takeoff Minimums and Obstacle DP, Amdt 4.
11–Aug–22 ..	SD	Mobridge	Mobridge Muni	2/0709	6/17/22	RNAV (GPS) RWY 30, Amdt 1A.
11–Aug–22 ..	SD	Mobridge	Mobridge Muni	2/0710	6/17/22	RNAV (GPS) RWY 12, Orig-A.
11–Aug–22 ..	CA	Madera	Madera Muni	2/0758	5/27/22	RNAV (GPS) RWY 30, Amdt 2A.
11–Aug–22 ..	TX	Plains	Yoakum County	2/0992	5/27/22	RNAV (GPS) RWY 21, Amdt 1A.
11–Aug–22 ..	FL	Daytona Beach	Daytona Beach Intl	2/1128	5/20/22	RNAV (GPS) RWY 16, Amdt 1D.
11–Aug–22 ..	AL	Brewton	Brewton Muni	2/1132	5/19/22	RNAV (GPS) RWY 24, Orig-B.
11–Aug–22 ..	MD	Baltimore	Baltimore/Washington Intl Thurgood Marshall.	2/1183	5/20/22	RNAV (GPS) RWY 33R, Amdt 4A.
11–Aug–22 ..	KS	Wichita	Colonel James Jabara	2/1185	4/29/22	ILS OR LOC RWY 18, Orig-C.
11–Aug–22 ..	IA	Guthrie Center	Guthrie County Rgnl	2/1189	5/26/22	RNAV (GPS) RWY 36, Amdt 1A.
11–Aug–22 ..	MN	Park Rapids	Park Rapids Muni/ Konshok Fld.	2/1246	3/31/22	ILS OR LOC RWY 31, Amdt 2.
11–Aug–22 ..	TN	Livingston	Livingston Muni	2/1247	6/14/22	RNAV (GPS) RWY 21, Amdt 1B.
11–Aug–22 ..	TN	Livingston	Livingston Muni	2/1251	6/14/22	RNAV (GPS) RWY 3, Amdt 1D.
11–Aug–22 ..	IA	Sioux City	Sioux Gateway/Brig General Bud Day Fld.	2/1252	3/31/22	ILS OR LOC RWY 13, Amdt 3.
11–Aug–22 ..	MO	Cape Girardeau	Cape Girardeau Rgnl	2/1259	6/17/22	RNAV (GPS) RWY 20, Orig-A.
11–Aug–22 ..	TX	Seymour	Seymour Muni	2/1313	4/21/22	RNAV (GPS) RWY 17, Orig-C.
11–Aug–22 ..	WV	Morgantown	Morgantown Muni (Walter L Bill Hart Fld).	2/1475	6/6/22	RNAV (GPS) Z RWY 18, Orig-B.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
11–Aug–22 ..	WV	Morgantown	Morgantown Muni (Walter L Bill Hart Fld).	2/1476	6/6/22	RNAV (GPS) Y RWY 18, Orig-C.
11–Aug–22 ..	WV	Morgantown	Morgantown Muni (Walter L Bill Hart Fld).	2/1477	6/6/22	RNAV (GPS) RWY 36, Amdt 2.
11–Aug–22 ..	WV	Morgantown	Morgantown Muni (Walter L Bill Hart Fld).	2/1478	6/6/22	ILS OR LOC RWY 18, Amdt 13C.
11–Aug–22 ..	OH	Youngstown/Warren	Youngstown/Warren Rgnl	2/1508	6/15/22	VOR-A, Orig-B.
11–Aug–22 ..	NV	Las Vegas	Harry Reid Intl	2/1517	4/6/22	VOR RWY 26L/R, Amdt 4A.
11–Aug–22 ..	PA	State College	University Park	2/1546	5/19/22	ILS OR LOC RWY 24, Amdt 9C.
11–Aug–22 ..	TN	Clarksville	Outlaw Fld	2/1552	5/20/22	RNAV (GPS) RWY 17, Amdt 1B.
11–Aug–22 ..	NM	Albuquerque	Double Eagle II	2/1705	4/22/22	ILS OR LOC RWY 22, Amdt 3.
11–Aug–22 ..	TX	Ingleside	Mccampbell-Porter	2/1719	6/9/22	RNAV (GPS) RWY 13, Amdt 1A.
11–Aug–22 ..	SC	Rock Hill	Rock Hill/York County/ Bryant Fld.	2/1789	5/23/22	RNAV (GPS) RWY 20, Amdt 1A.
11–Aug–22 ..	NY	White Plains	Westchester County	2/1867	6/14/22	RNAV (RNP) Z RWY 16, Orig-C.
11–Aug–22 ..	KS	Topeka	Topeka Rgnl	2/2088	6/2/22	RNAV (GPS) RWY 3, Amdt 1B.
11–Aug–22 ..	TX	Edinburg	South Texas Intl At Edinburg.	2/2377	4/4/22	RNAV (GPS) RWY 32, Orig-A.
11–Aug–22 ..	NJ	Atlantic City	Atlantic City Intl	2/2600	6/14/22	RADAR 1, Amdt 16.
11–Aug–22 ..	NY	Rochester	Frederick Douglass/Greater Rochester Intl.	2/2768	5/20/22	Takeoff Minimums and Obstacle DP, Amdt 8.
11–Aug–22 ..	FL	Melbourne	Melbourne Orlando Intl	2/2785	5/23/22	VOR RWY 9R, Amdt 21B.
11–Aug–22 ..	IL	Taylorville	Taylorville Muni	2/3006	4/4/22	Takeoff Minimums and Obstacle DP, Orig.
11–Aug–22 ..	MS	Natchez	Hardy-Anders Fld/Natchez-Adams County.	2/3142	4/26/22	ILS OR LOC RWY 13, Amdt 2B.
11–Aug–22 ..	MS	Natchez	Hardy-Anders Fld/Natchez-Adams County.	2/3143	4/26/22	RNAV (GPS) RWY 18, Amdt 1B.
11–Aug–22 ..	MS	Natchez	Hardy-Anders Fld/Natchez-Adams County.	2/3144	4/26/22	RNAV (GPS) RWY 31, Amdt 1C.
11–Aug–22 ..	MS	Natchez	Hardy-Anders Fld/Natchez-Adams County.	2/3145	4/26/22	RNAV (GPS) RWY 36, Amdt 1C.
11–Aug–22 ..	MS	Natchez	Hardy-Anders Fld/Natchez-Adams County.	2/3146	4/26/22	VOR RWY 18, Amdt 11.
11–Aug–22 ..	MO	Warrensburg	Skyhaven	2/3380	6/9/22	RNAV (GPS) RWY 1, Amdt 1.
11–Aug–22 ..	MO	Warrensburg	Skyhaven	2/3381	6/9/22	RNAV (GPS) RWY 19, Amdt 1.
11–Aug–22 ..	MO	Warrensburg	Skyhaven	2/3382	6/9/22	VOR–A, Amdt 3A.
11–Aug–22 ..	IN	Washington	Daviess County	2/3525	4/6/22	Takeoff Minimums and Obstacle DP, Orig-A.
11–Aug–22 ..	NY	Sidney	Sidney Muni	2/3580	5/23/22	RNAV (GPS) RWY 25, Amdt 1A.
11–Aug–22 ..	KS	Newton	Newton-City-County	2/3665	6/6/22	ILS OR LOC RWY 17, Amdt 4B.
11–Aug–22 ..	LA	Alexandria	Alexandria Intl	2/3701	4/6/22	RNAV (GPS) RWY 32, Amdt 1B.
11–Aug–22 ..	LA	Alexandria	Alexandria Intl	2/3702	4/6/22	VOR/DME RWY 32, Amdt 1B.
11–Aug–22 ..	TX	Baytown	Baytown	2/4057	6/17/22	RNAV (GPS) RWY 32, Orig-A.
11–Aug–22 ..	KY	Greenville	Muhlenberg County	2/4191	6/13/22	RNAV (GPS) RWY 6, Orig-C.
11–Aug–22 ..	KY	Greenville	Muhlenberg County	2/4192	6/13/22	RNAV (GPS) RWY 24, Amdt 1D.
11–Aug–22 ..	OH	Carrollton	Carroll County-Tolson	2/4452	4/27/22	VOR–A, Amdt 1B.
11–Aug–22 ..	TX	Port Lavaca	Calhoun County	2/4928	6/8/22	RNAV (GPS) RWY 32, Orig-A.
11–Aug–22 ..	TX	Port Lavaca	Calhoun County	2/4929	6/8/22	RNAV (GPS) RWY 14, Amdt 2A.
11–Aug–22 ..	GA	Canton	Cherokee County Rgnl	2/5042	5/20/22	RNAV (GPS) RWY 5, Amdt 1B.
11–Aug–22 ..	PA	State College	University Park	2/5073	5/19/22	RNAV (GPS) RWY 24, Amdt 1A.
11–Aug–22 ..	TX	Mexia	Mexia-Limestone County	2/5213	5/19/22	Takeoff Minimums and Obstacle DP, Orig.
11–Aug–22 ..	AR	Texarkana	Texarkana Rgnl-Webb Fld	2/5214	6/6/22	Takeoff Minimums and Obstacle DP, Amdt 4.
11–Aug–22 ..	IL	Kewanee	Kewanee Muni	2/5215	5/18/22	Takeoff Minimums and Obstacle DP, Orig-A.
11–Aug–22 ..	WI	Madison	Blackhawk Airfield	2/5226	6/8/22	Takeoff Minimums and Obstacle DP, Amdt 2.
11–Aug–22 ..	IA	Emmetsburg	Emmetsburg Muni	2/5535	4/8/22	RNAV (GPS) RWY 13, Orig-B.
11–Aug–22 ..	IL	Chicago/Lake In The Hills	Lake In The Hills	2/5551	4/13/22	RNAV (GPS) RWY 8, Orig-B.
11–Aug–22 ..	NY	New York	Laguardia	2/5738	6/14/22	RNAV (GPS) RWY 13, Amdt 1A.
11–Aug–22 ..	MI	St Ignace	Mackinac County	2/5771	6/9/22	RNAV (GPS) RWY 25, Orig-B.
11–Aug–22 ..	MI	St Ignace	Mackinac County	2/5772	6/9/22	RNAV (GPS) RWY 7, Orig-B.
11–Aug–22 ..	OH	London	Madison County	2/5895	6/9/22	RNAV (GPS) RWY 27, Orig-A.
11–Aug–22 ..	OH	London	Madison County	2/5896	6/9/22	RNAV (GPS) RWY 9, Orig-A.
11–Aug–22 ..	GA	Savannah	Savannah/Hilton Head Intl	2/6225	5/31/22	RNAV (GPS) RWY 19, Amdt 2A.
11–Aug–22 ..	AR	Ash Flat	Sharp County Rgnl	2/6306	6/16/22	RNAV (GPS) RWY 22, Orig-B.
11–Aug–22 ..	AR	Ash Flat	Sharp County Rgnl	2/6309	6/16/22	RNAV (GPS) RWY 4, Orig-B.
11–Aug–22 ..	MI	Holland	West Michigan Rgnl	2/6311	6/9/22	RNAV (GPS) RWY 8, Amdt 2D.
11–Aug–22 ..	MN	Winona	Winona Muni-Max Conrad Fld.	2/6313	6/9/22	ILS Z OR LOC Z RWY 30, Orig-B.
11–Aug–22 ..	PA	Bellefonte	Bellefonte	2/6346	6/14/22	VOR–A, Amdt 2.
11–Aug–22 ..	PA	Bellefonte	Bellefonte	2/6350	6/14/22	RNAV (GPS) RWY 25, Orig-A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
11–Aug–22 ..	MO	Potosi	Washington County	2/6395	6/13/22	RNAV (GPS) RWY 2, Amdt 2D.
11–Aug–22 ..	NY	New York	Laguardia	2/6432	5/23/22	LOC RWY 31, Amdt 3D.
11–Aug–22 ..	TN	Cleveland	Cleveland Rgnl Jetport	2/6434	5/23/22	RNAV (GPS) RWY 3, Amdt 2B.
11–Aug–22 ..	TX	Longview	East Texas Rgnl	2/6980	4/14/22	ILS OR LOC RWY 13, Amdt 13C.
11–Aug–22 ..	VA	Winchester	Winchester Rgnl	2/7007	4/15/22	Takeoff Minimums and Obstacle DP, Amdt 1.
11–Aug–22 ..	TX	Dallas	Dallas Love Fld	2/7201	5/6/22	RNAV (GPS) Y RWY 31R, Amdt 3A.
11–Aug–22 ..	GA	Columbus	Columbus	2/7223	6/15/22	Takeoff Minimums and Obstacle DP, Amdt 7A.
11–Aug–22 ..	IN	Terre Haute	Sky King	2/7394	4/14/22	Takeoff Minimums and Obstacle DP, Amdt 5.
11–Aug–22 ..	MN	Elbow Lake	Elbow Lake Muni—Pride Of The Prairie.	2/7716	4/14/22	RNAV (GPS) RWY 14, Orig-B.
11–Aug–22 ..	MN	Elbow Lake	Elbow Lake Muni—Pride Of The Prairie.	2/7717	4/14/22	RNAV (GPS) RWY 32, Orig-B.
11–Aug–22 ..	IN	Plymouth	Plymouth Muni	2/8093	5/26/22	RNAV (GPS) RWY 28, Orig-A.
11–Aug–22 ..	IN	Plymouth	Plymouth Muni	2/8101	5/26/22	VOR RWY 28, Amdt 11A.
11–Aug–22 ..	IN	Shelbyville	Shelbyville Muni	2/8105	3/24/22	VOR RWY 19, Amdt 1C.
11–Aug–22 ..	IN	Rensselaer	Jasper County	2/8390	4/18/22	Takeoff Minimums and Obstacle DP, Amdt 1.
11–Aug–22 ..	KY	Williamsburg	Williamsburg-Whitley County.	2/8395	4/19/22	VOR RWY 20, Orig-E.
11–Aug–22 ..	MI	Rogers City	Presque Isle County	2/8425	6/16/22	RNAV (GPS) RWY 9, Orig-A.
11–Aug–22 ..	MI	Rogers City	Presque Isle County	2/8426	6/16/22	RNAV (GPS) RWY 27, Orig.
11–Aug–22 ..	WY	Evanston	Evanston-Uinta County Burns Fld.	2/8599	6/15/22	RNAV (GPS) RWY 23, Amdt 4.
11–Aug–22 ..	WY	Evanston	Evanston-Uinta County Burns Fld.	2/8600	6/15/22	ILS OR LOC/DME RWY 23, Amdt 1.
11–Aug–22 ..	WY	Evanston	Evanston-Uinta County Burns Fld.	2/8603	6/15/22	VOR/DME RWY 5, Orig.
11–Aug–22 ..	IN	Columbus	Columbus Muni	2/8619	4/18/22	RNAV (GPS) RWY 14, Amdt 1C.
11–Aug–22 ..	MA	Hyannis	Cape Cod Gateway	2/8625	6/15/22	RNAV (GPS) RWY 24, Amdt 1A.
11–Aug–22 ..	MA	Hyannis	Cape Cod Gateway	2/8630	6/15/22	ILS OR LOC RWY 15, Amdt 5A.
11–Aug–22 ..	MA	Hyannis	Cape Cod Gateway	2/8634	6/15/22	RNAV (GPS) RWY 6, Orig-B.
11–Aug–22 ..	IA	Dubuque	Dubuque Rgnl	2/8655	4/27/22	RNAV (GPS) RWY 31, Orig-A.
11–Aug–22 ..	MA	Hyannis	Cape Cod Gateway	2/8669	6/15/22	RNAV (GPS) RWY 15, Orig-C.
11–Aug–22 ..	MA	Hyannis	Cape Cod Gateway	2/8673	6/15/22	VOR RWY 6, Amdt 10.
11–Aug–22 ..	MA	Hyannis	Cape Cod Gateway	2/8679	6/15/22	RNAV (GPS) RWY 33, Orig-C.
11–Aug–22 ..	NM	Silver City	Grant County	2/8752	6/16/22	VOR–A, Amdt 7C.
11–Aug–22 ..	MI	Marlette	Marlette Township	2/8776	5/27/22	RNAV (GPS) RWY 28, Amdt 2.
11–Aug–22 ..	GA	Fort Stewart (Hinesville) ..	Wright AAF (Fort Stewart)/Midcoast Rgnl.	2/8905	5/20/22	RNAV (GPS) RWY 33R, Amdt 1A.
11–Aug–22 ..	GA	Fort Stewart (Hinesville) ..	Wright AAF (Fort Stewart)/Midcoast Rgnl.	2/8914	5/20/22	NDB RWY 33R, Orig-C.
11–Aug–22 ..	GA	Fort Stewart (Hinesville) ..	Wright AAF (Fort Stewart)/Midcoast Rgnl.	2/8918	5/20/22	RNAV (GPS) RWY 6L, Amdt 1.
11–Aug–22 ..	MI	Hancock	Houghton County Meml	2/8925	6/10/22	RNAV (GPS) RWY 31, Orig-A.
11–Aug–22 ..	MI	Hancock	Houghton County Meml	2/8928	6/10/22	LOC BC RWY 13, Amdt 12A.
11–Aug–22 ..	MI	Hancock	Houghton County Meml	2/8930	6/10/22	ILS OR LOC RWY 31, Amdt 15A.
11–Aug–22 ..	MD	Easton	Easton/Newnam Fld	2/8978	6/2/22	RNAV (GPS) RWY 4, Amdt 1A.
11–Aug–22 ..	VA	Melfa	Accomack County	2/9065	5/19/22	LOC RWY 3, Amdt 1A.
11–Aug–22 ..	VA	Melfa	Accomack County	2/9066	5/19/22	RNAV (GPS) RWY 3, Amdt 2A.
11–Aug–22 ..	VA	Melfa	Accomack County	2/9067	5/19/22	VOR RWY 3, Amdt 2A.
11–Aug–22 ..	CO	Denver	Colorado Air And Space Port.	2/9098	6/13/22	RNAV (GPS) RWY 17, Amdt 1C.
11–Aug–22 ..	KS	Topeka	Topeka Rgnl	2/9492	6/2/22	VOR/DME OR TACAN RWY 3, Amdt 6C.
11–Aug–22 ..	LA	Ruston	Ruston Rgnl	2/9585	5/9/22	NDB RWY 18, Orig-F.
11–Aug–22 ..	LA	Ruston	Ruston Rgnl	2/9586	5/9/22	RNAV (GPS) RWY 18, Orig-C.
11–Aug–22 ..	TX	Tyler	Tyler Pounds Rgnl	2/9588	6/10/22	RNAV (GPS) RWY 31, Amdt 3.
11–Aug–22 ..	TX	Tyler	Tyler Pounds Rgnl	2/9589	6/10/22	VOR RWY 31, Amdt 3A.
11–Aug–22 ..	IL	Champaign/Urbana	University Of Illinois/Willard.	2/9696	5/9/22	RNAV (GPS) RWY 22, Amdt 1A.
11–Aug–22 ..	CO	Leadville	Lake County	2/9702	5/25/22	RNAV (GPS) RWY 16, Amdt 1.
11–Aug–22 ..	SD	Wagner	Wagner Muni	2/9753	6/10/22	RNAV (GPS) RWY 27, Orig-B.
11–Aug–22 ..	SD	Wagner	Wagner Muni	2/9755	6/10/22	RNAV (GPS) RWY 9, Orig-B.
11–Aug–22 ..	ME	Augusta	Augusta State	2/9785	6/15/22	RNAV (GPS) RWY 35, Orig-C.
11–Aug–22 ..	NY	Saratoga Springs	Saratoga County	2/9793	6/15/22	VOR/DME–A, Amdt 1B.
11–Aug–22 ..	MN	Elbow Lake	Elbow Lake Muni—Pride Of The Prairie.	2/9838	4/20/22	Takeoff Minimums and Obstacle DP, Orig.
11–Aug–22 ..	TX	Denton	Denton Enterprise	2/9877	6/2/22	RNAV (GPS) RWY 36L, Orig.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
11–Aug–22 ..	KS	McPherson	McPherson	2/9884	4/27/22	Takeoff Minimums and Obstacle DP, Amdt 2.
11–Aug–22 ..	FL	Arcadia	Arcadia Muni	2/9891	5/23/22	Takeoff Minimums and Obstacle DP, Orig.
11–Aug–22 ..	TX	Houston	William P Hobby	2/9938	3/29/22	RNAV (GPS) RWY 13R, Amdt 1C.

[FR Doc. 2022–14279 Filed 7–5–22; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31436; Amdt. No. 4015]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 6, 2022. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 6, 2022.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg 29 Room 104, Oklahoma City, OK 73169. Telephone (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers or aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the typed of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for Part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close

and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore-(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on June 24, 2022.

Thomas J Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for Part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 11 August 2022

Selma, AL, KSEM, ILS Y OR LOC Y RWY 33, Amdt 1
Selma, AL, KSEM, ILS Z OR LOC Z RWY 33, Amdt 3
Little Rock, AR, KLIT, ILS OR LOC RWY 4L, Amdt 26C
San Francisco, CA, ILS OR LOC RWY 28L, ILS RWY 28L (SA CAT II), Amdt 27C
Waverly, IA, C25, RNAV (GPS) RWY 29, Orig-A
Chicago/Rockford, IL, KRFD, Takeoff Minimums and Obstacle DP, Amdt 1
Columbus, IN, KBAK, ILS OR LOC RWY 23, Amdt 8B
Louisville, KY, KSDF, ILS OR LOC RWY 17R, Amdt 4A
Louisville, KY, KSDF, ILS OR LOC RWY 35L, ILS RWY 35L (SA CAT I), ILS RWY 35L (CAT II), ILS RWY 35L (CAT III), Amdt 4A
Louisville, KY, KSDF, RNAV (GPS) Y RWY 17L, Amdt 1G
Greenville, ME, 52B, Takeoff Minimums and Obstacle DP, Amdt 3A
Sanford, ME, KSFM, Takeoff Minimums and Obstacle DP, Amdt 3B
Fairmont, MN, KFRM, ILS OR LOC RWY 31, Amdt 2
Cassville, MO, 94K, RNAV (GPS) RWY 9, Amdt 1B
Cassville, MO, 94K, RNAV (GPS) RWY 27, Orig-B
Maxton, NC, KMEB, RNAV (GPS) RWY 23, Amdt 2A
Newark, NJ, KEWR, VOR RWY 11, Amdt 2G
Wellsville, NY, KELZ, RNAV (GPS) RWY 10, Amdt 2
Wellsville, NY, KELZ, RNAV (GPS) RWY 28, Amdt 2
Painesville, OH, 2G1, Takeoff Minimums and Obstacle DP, Amdt 3A
Youngstown/Warren, OH, KYNG, ILS OR LOC RWY 32, Amdt 27E
Portland, OR, KHIO, VOR–C, Amdt 1B, CANCELLED
Corry, PA, 8G2, RNAV (GPS) RWY 14, Amdt 1B
Nashville, TN, KJWN, ILS OR LOC RWY 20, Amdt 2B
Atlanta, TX, KATA, Takeoff Minimums and Obstacle DP, Amdt 3
Canadian, TX, KHHF, Takeoff Minimums and Obstacle DP, Amdt 3B
Carthage, TX, 4F2, RNAV (GPS) RWY 17, Orig-C
Carthage, TX, 4F2, RNAV (GPS) RWY 35, Orig-C
College Station, TX, KCLL, ILS OR LOC RWY 35, Amdt 14B
Dumas, TX, KDUX, VOR/DME–A, Amdt 6A, CANCELLED
Salt Lake City, UT, KSLC, ILS OR LOC RWY 34R, ILS RWY 34R (SA CAT I), ILS RWY 34R (CAT II), ILS RWY 34R (CAT III), Amdt 4E
Phillips, WI, KPBH, RNAV (GPS) RWY 24, Orig-D

Effective 8 September 2022

Gulkana, AK, PAGK, RNAV (GPS) RWY 15L, Orig-A
Gulkana, AK, PAGK, RNAV (GPS) RWY 33R, Orig-A
Kivalina, AK, PAVL, RNAV (GPS) RWY 30, Amdt 1C
Huntsville, AL, KHSV, ILS OR LOC RWY 18L, Amdt 6
Huntsville, AL, KHSV, ILS OR LOC RWY 36R, Amdt 5
Huntsville, AL, KHSV, RNAV (GPS) RWY 18L, Amdt 3
Huntsville, AL, KHSV, RNAV (GPS) RWY 36R, Amdt 4
Tuscaloosa, AL, KTCL, ILS OR LOC RWY 4, Amdt 15
Tuscaloosa, AL, KTCL, Takeoff Minimums and Obstacle DP, Amdt 3
Danville, AR, 32A, RNAV (GPS) RWY 29, Orig, CANCELLED
Colorado Springs, CO, KCOS, VOR RWY 17L, Orig
Algona, IA, KAXA, VOR/DME–A, Amdt 7C, CANCELLED
Eagle Grove, IA, KEAG, VOR/DME–A, Amdt 2A, CANCELLED
Pocahontas, IA, KPOH, VOR/DME RWY 30, Amdt 4C, CANCELLED
Webster City, IA, KEBS, VOR/DME RWY 14, Amdt 5, CANCELLED
Carmi, IL, KCUL, RNAV (GPS) RWY 18, Orig-A
Chicago, IL, KORD, RNAV (GPS) RWY 9R, Amdt 6
Chicago, IL, KORD, RNAV (GPS) Z RWY 27L, Amdt 6
Evansville, IN, KEVV, ILS OR LOC RWY 22, Amdt 24
Seymour, IN, KSER, RNAV (GPS) RWY 5, Amdt 2
Seymour, IN, KSER, RNAV (GPS) RWY 23, Amdt 3
Seymour, IN, KSER, Takeoff Minimums and Obstacle DP, Amdt 1
Goodland, KS, KGLD, Takeoff Minimums and Obstacle DP, Amdt 6
Baltimore, MD, KBWI, ILS OR LOC RWY 28, Amdt 17A
Auburn/Lewiston, ME, KLEW, Takeoff Minimums and Obstacle DP, Amdt 6
Big Rapids, MI, KRQB, RNAV (GPS) RWY 27, Orig-A
Caro, MI, KCFS, Takeoff Minimums and Obstacle DP, Amdt 3
Grand Rapids, MI, KGRR, ILS OR LOC RWY 26L, Amdt 21C
Morris, MN, KMOX, RNAV (GPS) RWY 14, Amdt 2
Morris, MN, KMOX, RNAV (GPS) RWY 32, Amdt 2
Morris, MN, KMOX, Takeoff Minimums and Obstacle DP, Amdt 1
Morris, MN, KMOX, VOR RWY 14, Amdt 2
Morris, MN, KMOX, VOR RWY 32, Amdt 6
Mount Olive, NC, W40, VOR–A, Amdt 2A, CANCELLED
New York, NY, KLGA, LDA–A, Amdt 2F, CANCELLED
Akron, OH, KAKR, Takeoff Minimums and Obstacle DP, Amdt 2A
La Grande, OR, KLGD, NDB–B, Amdt 2A
Philipsburg, PA, Mid-State, Takeoff Minimums and Obstacle DP, Amdt 2A
San Angelo, TX, KSJT, RADAR 1, Amdt 1C
Temple, TX, KTPL, ILS OR LOC RWY 16, Amdt 14
Temple, TX, KTPL, RNAV (GPS) RWY 16, Amdt 3
Temple, TX, KTPL, RNAV (GPS) RWY 34, Amdt 3
Temple, TX, KTPL, Takeoff Minimums and Obstacle DP, Amdt 4A
Luray, VA, KLUA, NDB–A, Amdt 7C
West Dover, VT, 4V8, RNAV (GPS) RWY 1, Orig-B, CANCELLED
West Dover, VT, 4V8, Takeoff Minimums and Obstacle DP, Amdt 2, CANCELLED
Pasco, WA, KPSC, ILS OR LOC RWY 21R, Amdt 13C

Pasco, WA, KPSC, VOR RWY 30, Amdt 5C
Richland, WA, KRLD, LOC RWY 19, Amdt 9A

Rescinded: On June 13, 2022 (87 FR 35650), the FAA published an Amendment in Docket No. 31431, Amdt No. 4011, to Part 97 of the Federal Aviation Regulations under section 97.29, 97.33, and 97.37. The following entries for Roseburg, OR, and for Temple, TX, effective July 14, 2022, are hereby rescinded in their entirety:

Roseburg, OR, KRBG, Takeoff Minimums and Obstacle DP, Amdt 7A
Temple, TX, KTPL, ILS OR LOC RWY 16, Amdt 14
Temple, TX, KTPL, RNAV (GPS) RWY 16, Amdt 3
Temple, TX, KTPL, RNAV (GPS) RWY 34, Amdt 3
Temple, TX, KTPL, Takeoff Minimums and Obstacle DP, Amdt 4A

[FR Doc. 2022–14278 Filed 7–5–22; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2020–0730, EPA–R05–OAR–2020–0731; FRL–9629–02–R5]

Air Plan Approval; Michigan; Emissions Statement Program and Base Year Emissions Inventory

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is partially approving portions of State Implementation Plan (SIP) revisions submitted by the State of Michigan on December 18, 2020. Specifically, EPA is approving the 2015 ozone National Ambient Air Quality Standards (NAAQS) base-year emissions inventory for Detroit area as meeting the requirements of the Clean Air Act (CAA). EPA is also approving revisions to Michigan's emissions statement program as meeting the requirements of the CAA.

DATES: This final rule is effective on July 6, 2022.

ADDRESSES: EPA has established dockets for this action under Docket ID No. EPA–R05–OAR–2020–0730 and EPA–R05–OAR–2020–0731. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (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 either through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19. We recommend that you telephone Eric Svingen, Attainment Planning and Maintenance Section, at (312) 353–4489 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Eric Svingen, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–4489, *svingen.eric@epa.gov.*

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

I. Background Information

On March 14, 2022 (87 FR 14210), EPA proposed to approve portions of a December 18, 2020, submittal from the Michigan Department of Environment, Great Lakes, and Energy (EGLE) as meeting the applicable requirements for a base year emissions inventory under CAA section 182(a)(1) for the Detroit nonattainment area for the 2015 ozone NAAQS, as well as portions of a separate December 18, 2020, submittal from EGLE as meeting the applicable requirements under CAA section 182(a)(3) for an emissions statement program. An explanation of the CAA requirements, a detailed analysis of the revisions, and EPA's reasons for proposing approval were provided in the notice of proposed rulemaking (NPRM), and will not be restated here. The public comment period for this proposed rule ended on April 27, 2022.

In the March 14, 2022, NPRM, EPA proposed to take additional actions, including a determination that the Detroit area has met the requirements for redesignation to attainment under section 107(d)(3)(E) of the CAA the CAA. EPA's proposed actions received six comments, three of which are adverse. All of the comments relate to EPA's proposal to redesignate the area. None of the comments relate to EPA's proposal to approve the Detroit area base-year emissions inventory or the revisions to Michigan's emissions statement program. All of the comments received are included in the docket for this action.

We do not consider these comments to be germane or relevant to EPA's proposal to approve the Detroit area base year emissions inventory and revisions to the emissions statement program, and therefore not adverse to this action. The comments lack the required specificity to this action and the relevant requirements of CAA section 110. Moreover, none of the comments address a specific regulation or provision in question, or recommend a different action. Therefore, we are finalizing this action as proposed. Should EPA take final action on the other actions proposed in the March 14, 2022, NPRM, including a determination that the Detroit area has met the requirements for redesignation to attainment, then EPA would address the adverse comments at that time.

II. Final Action

EPA is approving portions of Michigan's December 18, 2020, submittals as meeting the base year emissions inventory and emissions statement requirements of sections 182(a)(1) and 182(a)(3), respectively.

Specifically, EPA is also approving EGLE's request to make several revisions to Michigan's SIP. EPA is removing from the SIP Section 5 of Act 348 of 1965, as amended. EPA is approving into the SIP Section 5503 of Act 451 of 1994, as amended, effective March 30, 1995. EPA is removing from the SIP the 1993 Michigan Air Pollution Reporting forms and reference tables, and EPA is approving into the SIP several updated forms: the 2020 version of AQD–013, the 2019 version of MAERS form SB–101 Submit, the 2019 version of MAERS form S–101 Source, the 2019 version of MAERS form A–101 Activity, the 2019 version of MAERS form EU–101 Emission Unit, and the 2019 version of MAERS form E–101 Emissions. EPA is removing from the SIP the 1993 MAERS general instructions, and EPA is approving into the SIP the January 2020 MAERS User Guide. Finally, EPA is approving into the SIP the 2017 base year inventory for the Detroit nonattainment area (Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, and Wayne Counties) for the 2015 ozone NAAQS.

In accordance with 5 U.S.C. 553(d) of the Administrative Procedure Act (APA), EPA finds there is good cause for this action to become effective immediately upon publication. The immediate effective date for this action is authorized under 5 U.S.C. 553(d)(1) of the APA, which provides that rulemaking actions may become effective less than 30 days after publication if the rule grants or

recognizes an exemption or relieves a restriction, and section 553(d)(3), which allows an effective date less than 30 days after publication as otherwise provided by the agency for good cause found and published with the rule.

The purpose of the 30-day waiting period prescribed in section 553(d) is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996); *see also United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). However, when the agency grants or recognizes an exemption or relieves a restriction, affected parties do not need a reasonable time to adjust because the effect is not adverse.

This action, however, does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. Rather, this action relieves Michigan of various requirements for the Detroit area. In addition, EPA has determined that this action removes from the SIP the 1993 versions of several forms, reference tables, and general instructions, which are no longer used by EGLE. Instead, upon the effective date of this action, the SIP would be updated to require the 2019 or 2020 versions of these forms, reference tables, and general instructions. These versions are currently used by EGLE and aid sources in completing required submittals via electronic format. For these reasons, EPA finds good cause under 5 U.S.C. 553(d) for this action to become effective on the date of publication of this action.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Michigan Regulations described in Section II of this preamble and set forth in the amendments to 40 CFR part 52 below. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov,* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

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

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

This action is subject to the Congressional Review Act, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 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, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 29, 2022.

Cheryl Newton,

Deputy Regional Administrator, Region 5.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. Section 52.1170 is amended:
■ a. In the table in paragraph (c), under ''State Statutes'', by revising the entries for ''Act 348 of 1965, as amended'' (with a State effective date of 1990) and ''Act 451 of 1994, as amended''; and
■ b. In the table in paragraph (e):
■ i. By revising the entry for ''Information supporting emissions statement program''; and
■ ii. Under ''Emissions Inventories'' by adding an entry for ''2015 8-hour ozone 2017 base year'' before the entry for ''1997 annual $PM_{2.5}$ 2005 base year''.

The revisions and addition read as follows:

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

§ 52.1170 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MICHIGAN REGULATIONS

Michigan citation	Title	State effective date	EPA approval date	Comments
*	*	*	*	*
State Statutes				
*	*	*	*	*
Act 348 of 1965, as amended.	Air Pollution Act	1990	7/6/2022, [INSERT **Federal Register** CITATION].	Only section 14a.
Act 451 of 1994, as amended.	Natural Resources and Environmental Protection Act.	3/30/1995	7/6/2022, [INSERT **Federal Register** CITATION].	Only sections 324.5003, 324.5524 and 324.5525.
*	*	*	*	*

* * * * *

(e) * * *

EPA-APPROVED MICHIGAN NONREGULATORY AND QUASI-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
*	*	*	*	*
Information supporting emissions statement program.	Statewide	12/18/2020	7/6/2022, [INSERT **Federal Register** CITATION].	2020 version of AQD–013, 2019 version of MAERS form SB–101 Submit, 2019 version of MAERS form S–101 Source, 2019 version of MAERS form A–101 Activity, 2019 version of MAERS form EU–101 Emission Unit, 2019 version of MAERS form E–101 Emissions, January 2020 MAERS User Guide.
*	*	*	*	*
Emissions Inventories				
*	*	*	*	*
2015 8-hour ozone 2017 base year.	Detroit area (Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, and Wayne Counties).	12/18/2020	7/6/2022, [INSERT **Federal Register** CITATION].	
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[FR Doc. 2022–14321 Filed 7–5–22; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2020–0063; FF09E22000 FXES1113090FEDR 223]

RIN 1018–BD83

Endangered and Threatened Wildlife and Plants; Reclassification of Smooth Coneflower From Endangered To Threatened With a Section 4(d) Rule

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), reclassify smooth coneflower (*Echinacea laevigata*) from endangered to threatened (''downlist'') under the Endangered Species Act of 1973, as amended (Act), due to improvements in the species' overall status since the original listing in 1992. This action is based on a thorough review of the best available scientific and commercial information, which indicates that smooth coneflower is not currently in danger of extinction throughout all or a significant portion of its range, but it is still likely to become so in the foreseeable future. We are also finalizing a rule under section 4(d) of the Act that provides for the conservation of smooth coneflower.

DATES: This rule is effective August 5, 2022.

ADDRESSES: Public comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *https://www.regulations.gov at* Docket No. FWS–R4–ES–2020–0063.

FOR FURTHER INFORMATION CONTACT: Pete Benjamin, Field Supervisor, U.S. Fish and Wildlife Service, Raleigh Ecological Services Field Office, 551–F Pylon Drive, Raleigh, NC 27606; telephone (919) 856–4520. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species may warrant reclassification from endangered to threatened if it no longer meets the definition of endangered (in danger of extinction throughout all or a significant portion of its range). Smooth coneflower is listed as endangered, and we are reclassifying smooth coneflower as threatened (*i.e.,* ''downlisting'' the species) because we have determined it is not currently in danger of extinction. Reclassifying a species under the Act can only be accomplished by issuing a rule through the Administrative Procedure Act rulemaking process.

What this document does. This rule reclassifies smooth coneflower from endangered to threatened on the Federal List of Endangered and Threatened Plants (List), with a rule issued under section 4(d) of the Act, based on the species' current status, which has been improved through implementation of conservation actions.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We may reclassify a species if the best available commercial and scientific data indicate the species no longer meets the applicable definition in the Act. We have determined that smooth coneflower is no longer in danger of extinction and, therefore, does not meet the Act's definition of an endangered species, but the species does meet the Act's definition of a threatened species because there are not enough permanently protected or managed populations to ameliorate ongoing habitat loss, degradation, and fragmentation from development. Existing management and regulatory mechanisms are not sufficient to protect the species from these threats such that it is not in danger of extinction within the foreseeable future.

Peer review and public comment. During the proposed rule stage, we sought the expert opinions of four appropriate specialists regarding the proposed reclassification rule. We received responses from two peer reviewers, which informed our determination. Information we received from peer review is incorporated into this final rule. We also considered all comments and information we received from the public during the comment period, but none of these changed our determination.

Previous Federal Actions

Please refer to the proposed downlisting rule for smooth coneflower published on June 24, 2021 (86 FR 33159), for a detailed description of previous Federal actions concerning this species.

Summary of Changes From the Proposed Rule

In preparing this final rule, we reviewed and fully considered all comments we received during the comment period from the peer reviewers and the public on the proposed rule to reclassify smooth coneflower. Minor, nonsubstantive changes and corrections are made throughout this document in response to comments. However, the information we received during the peer review and public comment period on the proposed rule did not change our analysis, rationales, or determination for either reclassifying the smooth coneflower as a threatened species under the Act or the 4(d) rule for the species.

I. Final Reclassification Determination

Background

A thorough review of the taxonomy, life history, ecology, and overall viability of smooth coneflower is presented in the recovery plan (Service 1995, entire), the 5-year review (Service 2011, entire), and the proposed downlisting rule (86 FR 33159; June 24, 2021). Smooth coneflower is a perennial herb in the aster family (Asteraceae). It was first described as *Brauneria laevigata* by Boynton and Beadle in 1903, from material collected in South Carolina (SC) in 1888. It was transferred to the genus *Echinacea* in 1929 (Small 1933, p. 1421; McGregor 1968, p. 120). Smooth coneflower grows up to 1.5 meters (59 inches (in)) tall from a vertical root stock; stems are smooth, with few leaves. Flower heads are usually solitary and are composed of ray flowers and disk flowers. The ray flowers (petal-like structures on composite flower heads) are light pink to purplish, strongly drooping, and 5 to 8 centimeters (cm; 1.9 to 3.1 in) long. Disk flowers (tiny tubular flowers in the central portion of composite flower head) are about 5 millimeters (mm) (0.2 in) long. Flowering occurs from May through July, and fruits develop from late June to September (Gaddy 1991, p. 18). Sexual reproduction results in a gray-brown, oblong-prismatic achene (dry, one-seeded fruit). Asexual reproduction in the form of short clonal rhizomes make new rosettes in both

garden and wild settings (Kunz 2018, pers. comm.). Smooth coneflower is dependent on insect pollinators for cross pollination. While skippers, butterflies, and wasps are frequent floral visitors, bees are believed to be the most effective pollinators (Gadd 2006, p. 15; Collins and Fore 2009, pp. 452–454).

In this rule, we follow guidance for defining element occurrences (EOs) and populations described by NatureServe (2002, pp. 10–11; NatureServe 2004, pp. 6, 14). We define an EO as any current (or historical) location where smooth coneflower occurs (or occurred), regardless of the spatial relationship with other EOs. We define a population as either a stand-alone EO isolated by distance of unsuitable habitat (separated from other EOs by 2 kilometers (km) (1.2 miles (mi)) or more), or as a principal EO. A principal EO is two or more EOs located less than or equal to 2 km (1.2 mi) from each other, with suitable habitat in between them. For the purposes of evaluating the recovery of this species, it is most appropriate to consider populations rather than individual EOs.

At the time of listing in 1992, smooth coneflower had 21 extant populations (57 FR 46340; October 8, 1992). When the recovery plan was written in 1995, there were 24 known populations rangewide, with an additional 3 populations in SC that were considered of cultivated origin at that time but are now believed to be natural populations, for a total of 27 populations (Service 1995, p. 2). New smooth coneflower occurrences have been discovered since the time of listing. Current State Natural Heritage Program database records document 44 extant populations of smooth coneflower (table 1).

TABLE 1—TOTAL NUMBER OF EXTANT POPULATIONS OF SMOOTH CONEFLOWER THAT OCCUR IN EACH STATE WITHIN THE RANGE OF THE SPECIES

[Georgia Department of Natural Resources (GADNR) 2019, unpaginated; North Carolina Natural Heritage Program (NCNHP) 2019, unpaginated; South Carolina Heritage Trust Program (SCHTP) 2019, unpaginated; Virginia Division of Natural Heritage (VADNH) 2018, unpaginated; White 2018, p. 6]

State	Number of extant populations
Virginia (VA)	15
North Carolina (NC)	6
South Carolina (SC)	12
Georgia (GA)	11
Totals	44

At the time of listing in 1992, all of the known smooth coneflower populations occurred in the piedmont or mountain physiographic provinces of GA, SC, NC, and VA. Since listing, new populations have been found in the inner coastal plain/sandhills region of SC (White 2018, p. 4) and the coastal plain of GA (Moffett 2018, pers. comm.).

Smooth coneflower is typically found in open woods, glades, cedar barrens, roadsides, clear cuts, dry limestone bluffs, and power line rights-of-way (ROWs). The species is usually found on magnesium- and calcium-rich soils associated with amphibolite, dolomite, or limestone (in VA); gabbro (in NC and VA); diabase (in NC and SC); marble, sandy loams, chert, and amphibolites (in SC and GA); and shallow soils with minor bedrock exposures (in GA) (Service 1995, pp. 2–3; White 2018, p. 4; GADNR 2019, unpaginated). The healthiest smooth coneflower populations are managed with prescribed fire or mechanical thinning, which provides smooth coneflower plants abundant sunlight and little competition from other plant species (Gaddy 1991, p. 1).

Land managers and biologists have routinely monitored smooth coneflower populations since before the species was listed in 1992. Monitoring at most populations usually involves a flowering stem count, while each rosette of leaves is counted at some sites. Flowering stem counts are generally the most common survey method because they require less time and biologists generally agree that plants produce no more than one flowering stem per growing season, making this method a conservative count of how many plants actually exist at a site. Basal rosettes and plants in vegetative state (non-flowering) can be very hard to find and count in dense herbaceous vegetation (NC Plant Conservation Program (NCPCP) 2018, unpaginated; White 2018, entire).

The species displays a relatively high level of genetic diversity based on analyses across the range of populations (Peters et al. 2009, pp. 12–13). There is also significant population genetic differentiation and a majority of the genetic variance is attributed to variation within populations, suggesting that populations may be adapting to local environments (Apsit and Dixon 2001, entire). Because this genetic variation exists, all populations should be maintained to conserve genetic diversity since each population contains only a subset of the total genetic variation. Regional population differentiation may be important in the selection of material to establish new populations, which suggests that, for greatest success, reintroduction projects use local source material (Apsit and Dixon 2001, p. 76).

Recovery

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species, unless we determine that such a plan will not promote the conservation of the species. Under section 4(f)(1)(B)(ii), recovery plans must, to the maximum extent practicable, include objective, measurable criteria which, when met, would result in a determination, in accordance with the provisions of section 4 of the Act, that the species be removed from the List.

Recovery plans provide a roadmap for us and our partners on methods of enhancing conservation and minimizing threats to listed species, as well as measurable criteria against which to evaluate progress towards recovery and assess the species' likely future condition. However, they are not regulatory documents and determinations with respect to the species' status must be made consistent with section 4(a)(1) of the Act. A decision to revise the status of a species, or to delist a species, is ultimately based on an analysis of the best scientific and commercial data available to determine

whether a species is no longer an endangered species or a threatened species, regardless of whether that information differs from the recovery plan.

There are many paths to accomplishing recovery of a species, and recovery may be achieved without all of the criteria in a recovery plan being fully met. For example, one or more criteria may be exceeded while other criteria may not yet be accomplished. In that instance, we may determine that the threats are minimized sufficiently, and that the species is robust enough that it no longer meets the definition of an endangered species or a threatened species. In other cases, we may discover new recovery opportunities after having finalized the recovery plan. Parties seeking to conserve the species may use these opportunities instead of methods identified in the recovery plan. Likewise, we may learn new information about the species after we finalize the recovery plan. The new information may change the extent to which existing criteria are appropriate for identifying recovery of the species. The recovery of a species is a dynamic process requiring adaptive management that may, or may not, align with all criteria provided in a recovery plan.

Recovery Criteria

The Smooth Coneflower Recovery Plan was approved by the Service on April 18, 1995 (Service 1995, entire). It includes recovery criteria intended to indicate when threats to the species have been addressed to the point the species may no longer meet the definition of an endangered species or threatened species and describes actions or tasks necessary to achieve those criteria.

The recovery plan identifies five downlisting criteria for smooth coneflower (Service 1995, p. 12):

1. Twelve (12) geographically distinct, self-sustaining populations are protected across the species' range, including populations in at least two counties in VA, two counties in NC, two counties in SC, and one county in GA;
2. At least nine of these populations must be in areas within the species' native ecosystem (not in gardens or similar artificial settings) that are in permanent conservation ownership and management;
3. Managers have been designated for each protected population;
4. Management plans have been developed and implemented for each protected population; and
5. Populations have been maintained at stable or increasing levels for 5 years.

The recovery plan also identifies the following five delisting criteria for smooth coneflower (Service 1995, p. 12):

1. Fifteen (15) geographically distinct, self-sustaining populations are protected across the species' range, including populations in at least two counties in VA, two counties in NC, two counties in SC, and one county in GA;
2. At least nine of these populations must be in areas within the species' native ecosystem (not in gardens or similar artificial settings) that are in permanent conservation ownership and management;
3. Managers have been designated for each protected population;
4. Management plans have been developed and implemented for each protected population; and
5. Populations have been maintained at stable or increasing levels for 10 years.

Downlisting/Delisting Criteria 1 and 2 (Twelve (12) or Fifteen (15) Protected Self-Sustaining Populations in Native Ecosystem)

Both criteria 1 and 2 for downlisting and delisting have been met. We currently know of 44 extant populations throughout the species' range. Of those 44, 16 populations ranked with excellent to good viability are found in areas where the habitat is under protective status (like a National Forest). As of 2019, 33 smooth coneflower populations are either on Federal lands or are in conservation ownership (9 in GA, 5 in NC, 12 in SC, and 7 in VA), 16 of which are ranked A (excellent viability; see tables 2 and 3, below), AB (excellent/good viability), or B (good viability) by their respective State Natural Heritage Programs (4 in GA, 3 in NC, 5 in SC, and 4 in VA). These populations are considered protected because they occur on several National Forests managed by the U.S. Forest Service (USFS), as well as lands owned and managed by State agencies, The Nature Conservancy (TNC), U.S. Army Corps of Engineers (USACE), U.S. Department of Energy (USDOE), and U.S. Department of Defense (DOD). Management plans in existence for many of these populations are detailed below.

TABLE 2—STATE DISTRIBUTION, HERITAGE PROGRAM RANK, OWNERSHIP, AND AVAILABILITY OF MANAGEMENT PLAN FOR THE HIGHLY RESILIENT, PROTECTED POPULATIONS

State	Population name	Heritage rank*	Ownership	Management plan?
GA	GA-A	AB	Federal	yes.
GA	GA–B	B	Federal	yes.
GA	GA–C	B	Federal	yes.
GA	GA–D	B	Federal	yes.
NC	NC–A	A	Federal, State	no.
NC	NC–B	A	State	yes.
NC	NC–C	B	Federal	no.
SC	SC–A	AB	Federal	yes.
SC	SC–B	B	Federal	yes.
SC	SC–C	A	Federal, State	yes.
SC	SC–D	A	Federal	yes.
SC	SC–E	AB	Federal	yes.
VA	VA–A	A	State	yes.
VA	VA–B	A	Private	yes.
VA	VA–C	AB	State	no.
VA	VA–D	AB	State	yes.

*Heritage Ranks: A = excellent viability; AB = excellent/good viability; B = good viability.

With regard to the requirement in criterion 1 that populations be self-sustaining, we evaluated the resiliency of each population by looking at the ranks as assigned by the State Natural Heritage Programs. These 16 protected populations are ranked either A, AB, or B (six are ranked A, five are ranked AB, and five are ranked B (see tables 2 and 3)). These 16 highly resilient populations (*i.e.,* those that have good to excellent viability scores (Table 3)) are scattered across the range of the species, including one county in GA (Stephens), two counties in NC (Durham and Granville), two counties in SC (Barnwell and Oconee), and three counties in VA (Franklin, Halifax, and Montgomery). These populations span mountain, piedmont, and coastal plain physiographic provinces.

TABLE 3—SMOOTH CONEFLOWER RANKING CRITERIA

Heritage rank	Viability	Number of plants	Size and type of habitat	Management regime
A	Excellent	>1,000; flowering annually	>5 acres (>2 hectares); open glade or prairie remnant.	open (disturbed) from periodic fires, optimal soil conditions.
B	Good	100–1,000; most flowering annually.	1–5 acres; open glade or prairie remnant.	mostly open by periodic fires or other disturbance.
C	Fair	10–100; 50% or fewer flowering annually.	any size glade or prairie remnant; or isolated roadside or utility ROW with remnant glade or prairie flora.	limited.
D	Poor	<10; may not fewer flower annually.	remnant glades or isolated ROWs	limited.

All of these populations occur in the species' natural ecosystem, which includes habitats such as open woodlands, glades, cedar barrens, and other habitat that is usually (but not always) found on magnesium- and calcium-rich soil. For many of the larger A- and B-ranked populations, the site ranks have not changed significantly over recent years.

The remaining 28 extant populations are ranked C (fair viability), D (poor viability), or E (extant, but their viability has not been assessed). A rank of X is given to sites considered to be extirpated, where evidence indicates that the species no longer exists in that location. A rank of H is given to sites considered to be historical, where recent field information verifying the continued existence of the population is lacking. We estimated that C-, D-, and E-ranked populations have low resiliency, and sites ranked H or X were not evaluated for resiliency because plants have not been found at those sites in recent years.

Downlisting/Delisting Criterion 3 (Managers Have Been Designated for Each Protected Population)

We verified ownership and management status of each of the 16 highly resilient, protected populations on Federal, State, and private conservation lands, to ensure that a land manager responsible for overseeing the management of smooth coneflower has been assigned. The four highly resilient populations in GA are managed by the USFS (Chattahoochee-Oconee National Forest) with assistance from the Atlanta Botanical Garden, State Botanical Garden of Georgia, and Georgia Department of Natural Resources (GADNR). The three highly resilient populations in NC are managed by the North Carolina Department of Agriculture and Consumer Services (NCDACS) Research Stations Division, North Carolina Plant Conservation Program (NCPCP), USACE, and NC Botanical Garden (NCBG). In SC, most of the highly resilient populations occur on the Sumter National Forest, and four of the five highly resilient populations are managed by the Sumter National Forest, with one of those sites being co-owned and managed by South Carolina Heritage Trust Program (SCHTP) as a Heritage Trust Preserve. The other highly resilient population, at the Savannah River Site, is owned by the USDOE and managed by the USFS. In VA, the four highly resilient populations are managed by the Virginia Division of Natural Heritage (VADNH), USFS (George Washington National Forest), and TNC.

Site managers have been identified for all 16 highly resilient populations identified under criteria 1 and 2 above; therefore, we consider this criterion to have been met.

Downlisting/Delisting Criterion 4 (Management Plans Implemented)

Because smooth coneflower requires early to mid-successional habitat, all highly resilient populations have received and will require some form of management in perpetuity to help maintain habitat in the right balance so that populations can thrive. Management techniques include the use of prescribed fire, well-timed mowing, mechanical clearing (including the use of chain saws to cut trees), and herbicides (selectively applied to cut stumps to prevent regrowth). All of these management actions have been implemented separately or in combination to sustain suitable habitat for smooth coneflower. Of the 16 highly resilient populations considered in criteria 1 and 2, 13 of them can be considered to be included in management plans. However, these plans vary in scope and level of specificity toward smooth coneflower, and most plans are outdated. Only six of the plans are specific to the management of smooth coneflower, while the others address the overall management of an entire site but include some actions that may be beneficial to smooth coneflower. Of the six plans that are specific to the management of smooth coneflower, four were developed in the mid-1990s, and two were developed in the early 2000s. In the past 20 years, we have learned a lot about how to best manage the species with fire, as well as how to manage for invasive species. Many of these management practices (*e.g.,* conducting prescribed burns or mechanical clearing every 3 to 5 years, or controlling invasive species) need to be incorporated into older management plans.

Management plans exist for three of the four highly resilient smooth coneflower populations in VA, although new information about fire intervals could improve management of several sites (*e.g.,* VA–A, VA–B, and VA–D) (Heffernan et al. 2002, pp. 1–2; SanJule 2007, p. 5; USDA Forest Service 2014, entire). In NC, the site of the largest smooth coneflower population (NC–B) has been actively managed using prescribed fire, mowing, and other mechanical means as recommended by species experts (Barnett-Lawrence 1994, pp. 18–20, appendix 10; Barnett-Lawrence 1995, pp. 18–19; NCNHP 1996, unpaginated), but two of the

highly resilient populations lack management plans altogether. In SC, all highly resilient populations occurring on the Sumter National Forest in SC (SC–A, SC–B, SC–C, and SC–D) are managed by prescribed fire and mechanical clearing. While the Sumter National Forest Revised Land and Resource Management Plan is from 2004, this plan directs the USFS to maintain or restore at least eight self-sustaining populations of smooth coneflower (USDA Forest Service 2004, pp. 2–9; Roecker 2001, entire), a practice that is in effect today. In GA, the USFS adequately uses prescribed fire, mechanical clearing, and herbicide application to maintain open, glade-like woodland habitat for smooth coneflower and associated species at highly resilient populations (GA–A, GA–B, GA–C, and GA–D).

In summary, 13 of the 16 highly resilient (A-, AB-, and B-ranked) smooth coneflower populations are included in management plans, but only 6 of them specifically address smooth coneflower management. These plans vary in level of detail, scope, and time commitment, and several need to be updated with improved fire management and invasive species management practices. We find that the implementation of regular, dedicated management for the highly resilient populations is the reason these smooth coneflower populations are large, healthy, and viable, and contribute toward the recovery of the species. However, the Service considers criterion 4 for smooth coneflower to have been only partially met because not all populations have management plans, and several of the existing plans are out of date. The Service has developed a template management plan that land managers can use as a guide when developing or updating rare species management plans, particularly those that focus on smooth coneflower management, and we will be working toward getting all plans established and updated as part of our ongoing recovery work.

Downlisting/Delisting Criterion 5 (Stable or Increasing Populations for 5 or 10 Years)

Land managers conduct site visits to their respective smooth coneflower populations on a regular basis to assess population size and health and to determine what management actions, if any, are needed. Monitoring generally involves a flowering stem count, which is a conservative count of how many plants exist at a site (NCPCP 2018, unpaginated; White 2018, entire).

Virginia smooth coneflower populations occur on USFS, TNC, and Virginia Department of Conservation and Recreation (VADCR) lands. These sites have been monitored by their respective land managers and researchers over the last 30 years. Because several of the smooth coneflower preserves in VA are large in size, a complete census has not been conducted every year, although the sites have been monitored during regular management activities. All four highly resilient populations in VA are considered stable over the 30+ years they have been monitored.

Land managers in NC have collected monitoring data on their smooth coneflower populations for decades. Of the high resiliency smooth coneflower populations in North Carolina, one has been increasing over the 14-year monitoring period, and two are stable over the 31-year monitoring period (NCPCP 2018, unpaginated).

South Carolina sites on the Sumter National Forest and a State-owned Heritage Preserve have been monitored since 1990 (White 2018, p. 6, table 1). A recent status survey of all of the smooth coneflower sites in SC determined that since 2006, trends indicated that for the most resilient SC smooth coneflower populations, four appear to be increasing in size, and one is considered stable, for at least the past 14 years.

All four of the highly resilient smooth coneflower populations in GA occur on the Chattahoochee-Oconee National Forest in northeastern GA. Biologists with the USFS, State Botanical Garden of Georgia, Atlanta Botanical Garden, GADNR, and Georgia Plant Conservation Alliance have visited these populations on a regular basis since the species was proposed for listing in 1991 and a Statewide status survey was conducted in 2000 (Sullivan 2000, entire). Monitoring data are intermittent, but the four highly resilient populations have been considered stable for the past 20 years since the Statewide status survey (Suiter 2020, pers. comm.).

Without more detailed data, it is difficult to determine specific trends, but based on our analysis of monitoring data and recent observations, we conclude that all of the 16 A-, AB-, and B- ranked (good to excellent resiliency) protected populations have been stable or increasing for more than 10 years; therefore, we consider this recovery criterion to have been met.

Summary

The implementation of recovery actions for smooth coneflower has significantly reduced the risk of extinction for the species. As indicated above, many smooth coneflower populations are protected on public (Federal and State) and private lands, such as TNC preserves in VA. The most highly resilient smooth coneflower populations (*i.e.,* those considered contributing to species' recovery) are considered stable or increasing. Current information indicates that smooth coneflower is more abundant, and its range is somewhat larger, than when the species was listed. However, management plans for all protected populations are lacking, as only six specifically focus on management for smooth coneflower. Many of the existing management plans are out of date, from the 1990s and early 2000s, or are not being currently implemented.

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects. We consider these same five factors in reclassifying a species from endangered to threatened (50 CFR 424.11(c)). Even though we are not delisting the species at this time, we also consider the risk to the species if it were not listed under the Act to better understand the species' future without the protections of the Act.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Summary of Biological Condition and Threats

When we published the final rule to list smooth coneflower as an endangered species (57 FR 46340; October 8, 1992), the identified threats (factors) were the absence of natural disturbance (fire and/or grazing), highway construction and improvement, gas line installation, and residential and industrial development (Factor A); collecting (Factor B); beetle damage (Factor C); inadequacy of existing State regulatory mechanisms (Factor D); and low genetic variability, herbicide use, and possible encroachment of exotic species (Factor E).

The following analysis evaluates these previously identified threats, any other threats currently facing the species, and any other threats that are reasonably likely to affect the species in the foreseeable future, including cumulatively or synergistically.

Habitat Degradation or Loss Due To Development and Absence of Natural Disturbance

Smooth coneflower plants require open, sunny conditions to survive. Without regular disturbance such as fire, woody shrubs and trees create a dense canopy that prevents sunlight from reaching the forest floor where this herbaceous species occurs. Smooth coneflower is intolerant of dense shade and tends to die out after a few years of shady conditions.

Smooth coneflower occurrences on private land are vulnerable to habitat loss due to degradation, which results from fire suppression or the absence of other disturbances that maintain the habitat in an open state. For example, in Rockingham County, NC, a small smooth coneflower population occurred on private land in an open woodland between a highway and a railroad track. The lack of management or fire resulted in the site becoming overgrown, and no plants have been observed there in recent years. To encourage smooth coneflower growth, the site needs fire or mechanical disturbance in order to remove woody vegetation and open the forest floor to sunlight (NCNHP 2019, unpaginated).

Development projects, such as residential and commercial construction and highway and utility construction and maintenance, pose a threat to smooth coneflower populations by clearing areas where the species occurs, thereby destroying populations. Further, development in close proximity to smooth coneflower populations may preclude the ability to use fire as a management tool at nearby protected populations because of the threat of fires escaping the management area and objections to smoke blowing into developed areas. For example, a smooth coneflower population on a small parcel of USFS land in Habersham County, GA, has declined over recent years due the difficulty in managing fire on a parcel surrounded by private property. The lack of management has resulted in the growth of woody plants that have shaded smooth coneflower plants and resulted in this population's decline (Radcliffe 2019, pers. comm.). As residential and commercial development continue to occur in the suburbs of Durham, NC, it will become harder to manage some of the adjacent smooth coneflower sites with fire (Starke 2019, pers. comm.).

While we are not aware of any smooth coneflower populations that have been destroyed due to residential or commercial development since the species was listed, this threat remains a concern. Recently, a new subpopulation of smooth coneflower was discovered on a property in Durham County, NC, that is slated for development. If a rare plant survey had not been conducted and these plants discovered, they would have been destroyed by the development of the site (Starke 2019, pers. comm.). There are likely additional undiscovered populations of smooth coneflower that are subject to destruction.

Development pressure based on urbanization predictions from the SLEUTH urban growth model indicate that all of the NC counties, more than half of the SC counties, and both of the northeastern GA counties of occurrence for smooth coneflower will exhibit high (greater than 90 percent) growth trends over the next 20 to 30 years as part of the ''southern megalopolis,'' or giant urban sprawl area in the Southeast (Terando et al. 2014, p. 3; Databasin 2014, entire). Smooth coneflower populations that occur on private lands in these counties will continue to face threats from development and land conversion in the foreseeable future. Most of the VA counties of occurrence are outside the boundaries of the

southern megalopolis and the VA urban crescent in the eastern part of the State (Databasin 2014, entire).

Smooth coneflower occurs on roadsides and utility ROWs throughout the range of the species. These populations are vulnerable to management practices that could negatively impact or destroy them. Herbicides, which are typically harmful to all plants, are often used to manage vegetation along road shoulders and in utility ROWs. Herbicide damage can be temporary or permanent depending on the herbicide used and the rate of application. Although dormant season (winter) mowing is generally not problematic for disturbance-dependent species, as it helps reduce competition and maintain sites in an open condition, any mowing that occurs during the growing season but before plants produce mature seeds is considered harmful because it arrests seed development and reproductive potential for that year. Smooth coneflower plants growing on a utility ROW in Granville County, NC, were accidentally sprayed with herbicides, killing many plants in this population (NCNHP 2019, unpaginated). Herbicide damage to smooth coneflowers has also occurred at the Savannah River Site in SC, but the population was able to recover (White 2018, Appendix 3, entire). Roadside and utility ROW occurrences are difficult to manage in an early successional state without harming smooth coneflower plants. For example, woody species encroachment has caused the decline of some smooth coneflower sites that occur in ROWs in Durham County, NC. In some cases, it is possible to manage lands adjacent to ROW populations by, for example, removing woody species to create suitable habitat for the species, encouraging the plant to gradually occupy habitat away from the ROW; however, adjacent, protected land does not always exist (Stark 2019, pers. comm.). In the status survey of smooth coneflower populations in SC, (White 2018, appendix 3, entire) indicates that many populations still face competition by woody species, the presence of invasive species, and road ROW maintenance.

The protection of some smooth coneflower populations has been accomplished through active management and reducing the impacts of development. These efforts are critical to the long-term survival of this species. Recognizing the importance of long-term management of smooth coneflower populations, management plans that incorporate the use of prescribed fire and/or mechanized vegetation control have been prepared for several populations. The Service is working with many landowners that have smooth coneflower populations to complete or update management plans for their populations, as most management plans were first developed in the 1990s and early 2000s and need to incorporate new fire management and invasive species management practices. In 2018, we provided land managers with a management plan outline to facilitate the completion of thorough management plans. Due to greater awareness of the important role of fire in natural systems, prescribed fire and mechanical thinning are now regularly used as management tools on National Forests, military bases, nature preserves, and other protected lands where smooth coneflower occurs. Land managers such as the USFS, DOD, USACE, and Savannah River Site, among others, use prescribed fire on a 2- to 4-year interval as a management tool to control woody vegetation that might otherwise shade this disturbance-dependent species. For sites that are not managed intentionally for smooth coneflower, management practices will likely continue even if the species is not listed under the Act, primarily because the active management benefits the overall habitat and meets the management objectives of the landowner. In general, the management benefits smooth coneflower, and without it, the habitat conditions for smooth coneflower would likely degrade and we would need to reassess the status of the species under the Act. For the most part, management plans for many of the protected populations of smooth coneflower have been in place for several years, but we do not know if management actions would change for these populations if the species were not listed.

While development pressure on smooth coneflower populations on private lands remains, the threat of development for the most highly resilient populations is reduced, as they occur only on protected lands. As discussed earlier, many smooth coneflower populations occur on Federal lands, such as those owned or managed by the USFS (George Washington and Jefferson National Forests in VA, Sumter National Forest in SC, and Chattahoochee-Oconee National Forest in GA), USACE (Falls Lake), DOD (Fort Stewart and Fort Jackson Army Bases), and USDOE (Savannah River Site). These populations are protected on Federal lands from the threats of ecological succession or destruction due to development, primarily because Federal partners are vested in the protection of the species under their management plans. Some smooth coneflower sites occur on active military bases with limited public access, such as Fort Jackson and Fort Stewart Army Bases, providing further protection of these populations. Likewise, the Savannah River Site, a former nuclear weapons facility, is closed to the public, and no development or construction is allowed in the areas where smooth coneflower occurs. This USDOE site, designated as a National Environmental Research Park, is managed by the USFS. Several other populations are permanently protected on non-Federal lands by the VADNH, NCDACS, NCPCP, TNC, and Mecklenburg County (NC) Parks and Recreation Department.

In response to impacts to populations of smooth coneflower in roadside and utility ROWs, State departments of transportation and utility companies, such as Duke Energy and Georgia Power, now have management agreements or memoranda of understanding with State wildlife agencies, State Natural Heritage Programs, the USFS, and other landowners to protect and manage smooth coneflower populations on their ROWs in a way that is protective of the species.

While significant progress has been made to address the protection and management of many smooth coneflower populations, development pressure and management challenges associated with adjacent development continue to pose a threat to unprotected smooth coneflower populations. Populations that occur on private lands face threats from development and land conversion. Additionally, protected populations adjacent to private land can be difficult to manage with prescribed fire due to concerns of neighbors. Without proper management, woody vegetation could grow up and shade a smooth coneflower population to the point of causing decline or eradication in less than 10 years. Long-term management is still of concern to the Service, as several populations are not specifically considered in management plans nor have commitments to be managed into the future. Maintenance activities pose a threat to smooth coneflower populations that occur on roadside and utility ROWs. Despite agreements with State and Federal agencies to conduct ROW maintenance in a way that is protective of rare plants, accidents happen frequently. These sites are mowed or sprayed with herbicide on an irregular basis with varying levels of impacts.

Collection

When we published the final rule to list smooth coneflower as an endangered species (57 FR 46340; October 8, 1992), there was concern that populations might be decimated by collectors interested in exploiting this species for the horticulture and pharmaceutical trades. We expected that publicity might generate increased demand for this species in the nursery trade. However, the final listing rule also mentioned that smooth coneflower, although offered for sale by a few native plant nurseries, was not a significant component of the commercial trade in native plants (57 FR 46340, October 8, 1992, p. 46341). Currently, we are not aware of any plant nurseries that offer this species for sale, likely a result of the prohibitions on collecting endangered plants such as smooth coneflower. The only incidents of poaching known to the Service occurred at one site in GA. Flowers were broken off smooth coneflower plants at one of the roadside sites on Currahee Mountain, GA (Alley 2018, pers. comm.). While there is potential that specialty nurseries would be interested in selling this species in the future, the Service concludes that the demand for wild-collected plants is low, as other species in the genus *Echinacea* can be readily propagated using common horticultural techniques.

The concern in the final rule (57 FR 46340; October 8, 1992) that this species would be collected for the pharmaceutical trade was based on observations of over-collection of other species of *Echinacea* in the midwestern United States for use in medicinal products. However, the rule also stated that ''devastation'' of smooth coneflower populations for the commercial pharmaceutical trade has not yet been documented (57 FR 46340, October 8, 1992, p. 46342). Despite the concerns, in the 27 years that smooth coneflower has been listed, the Service has not been aware of any incidents of poaching this species for use in medicinal products. Because plants in the genus *Echinacea* are still used for medicinal purposes, the threat of this activity remains, but the probability is low due to relatively small population sizes compared to other species in the genus *Echinacea* that grow in midwestern States. Moreover, land managers have not reported poaching as a significant threat to their smooth coneflower populations because other species of *Echinacea* are so much more numerous.

Various types of academic research have been conducted on smooth coneflower since the species was listed in 1992. These studies involved the collection of leaves, stems, flowers, and seeds for laboratory experiments or the collection of voucher specimens for herbaria. The North Carolina Botanical Garden (NCBG), State Botanical Garden of Georgia, and Atlanta Botanical Garden have collected smooth coneflower seeds over the years to be used in restoration projects in their respective States. These botanical gardens follow the Center for Plant Conservation guidelines for seed collection and minimize impacts to populations, a protocol that is followed for all species, regardless of whether the species is federally listed or not (Kunz 2018, pers. comm.). We evaluated these projects before they were initiated and determined that the level of collection was unlikely to pose any potential threat of overutilization for the species. We do not find that any of these research or seed banking projects have had long-term negative effects on smooth coneflower. If the species were not listed, we do not anticipate a significant increase in collection pressure, given current lack of poaching and low interest in the species.

We conclude that collection is not a major threat to the continued existence of smooth coneflower, as long as any future collection follows best conservation practices described in Menges et al. (2004, entire) and by the Center for Plant Conservation Best Practices.

Damage Due to Herbivory by Beetles and Deer

When we listed smooth coneflower as an endangered species (57 FR 46340; October 8, 1992), leaf beetles in the family Chrysomelidae had been observed on smooth coneflower in NC, but their effects were unknown. As mentioned in the 2011 5-year review, a nonnative longhorn beetle (*Hemierana marginata;* family Cerambycidae) was identified at some smooth coneflower populations in NC. This beetle chews into the flowering stem and causes flowers to die before producing viable seeds. While this longhorn beetle has been reported from a few smooth coneflower populations in two NC counties, healthy smooth coneflower populations remain at these sites. Therefore, we conclude that the nonnative longhorn beetle is not a threat at this time.

White-tailed deer (*Odocoileus virginianus*) have been documented browsing on the flower heads of smooth coneflower, but deer herbivory on the leaves has not been observed (Starke 2019, pers. comm.). No other herbivory has been observed. Based on the best available information at this time, we conclude that neither deer browsing nor any other herbivory is causing population-level effects to smooth coneflower.

State Regulatory Protections

Smooth coneflower is listed as ''State Endangered'' by the GADNR. The relevant State law (Rules and Regulations of the State of Georgia, Subject 391–4–10, Protection of Endangered, Threatened, Rare, or Unusual Species) prohibits, among other things, the transfer of a State-listed plant from one property to another without the written permission of the landowner where the species was found. Violations of this law constitute a misdemeanor. In addition, the Georgia Environmental Policy Act (GA Code, title 12, chapter 16, article 1) requires the assessment of major proposed agency impacts on biological resources. Georgia's Wildflower Preservation Act of 1973 (GA Code, title 12, chapter 6, article 3) protects rare plants. However, the Georgia Wildflower Preservation Act does not protect plants on private property. Regardless, nearly all known smooth coneflower populations in GA occur on Federal lands such as the Chattahoochee-Oconee National Forest and DOD (Department of the Army) installations such as Fort Stewart (Moffett 2018, pers. comm.). As discussed above (see *Habitat Degradation or Loss Due to Development and Absence of Natural Disturbance*), Federal lands provide some protection to smooth coneflower populations by limiting public access and reducing the threat of development, as well as ensuring agency-specific management plans.

Smooth coneflower is listed as ''endangered'' in NC by the NCPCP and protected by the Plant Protection and Conservation Act of 1979 (NC General Statutes, chapter 106, article 19B). This law prevents the removal of State-listed plants from the land without written permission of the landowner. However, it does not regulate destruction or mandate protection. It authorizes the NCPCP to establish nature preserves for protected species and their habitats. To that end, the NCPCP owns and manages several tracts of land as preserves for the protection of smooth coneflower and other associated rare plants.

The Virginia Endangered Plant and Insect Species Act (Code of Virginia, title 3.2, chapter 10), as amended, provides for the official listing and recovery of endangered and threatened plant and insect species in VA. The VADNH lists smooth coneflower as ''threatened'' in the State (VA Administrative Code, title 2, agency 5,

chapter 320, section 5–320–10 (2VAC5–320–10); Townsend 2018, p. 16). Virginia law prohibits the removal and sale or gifting of State-listed plant species from land other than a person's own land. The VADCR owns three natural area preserves that protect populations of smooth coneflower. The Virginia Endangered Plant and Insect Species Act has not played a major role in safeguarding smooth coneflower populations (Townsend 2019, pers. comm.).

Smooth coneflower is on the South Carolina Department of Natural Resources' list of rare, threatened, and endangered species of SC (SCHTP 2018, unpaginated); however, neither the law that authorizes the creation of this list, nor any other State law, provides general protection to listed plants in SC.

Populations of smooth coneflower are more abundant and widely distributed than when it was listed as an endangered species in 1992. It is also listed as endangered or threatened by three of the four States where it occurs (GA, NC, and VA). However, protection of this and other State-listed species on private land is challenging. State prohibitions against taking are difficult to enforce and do not cover adverse alterations of habitats such as exclusion of fire. As previously mentioned in this rule, the majority of the highest ranked populations (Ranks A, AB, and B) occur on protected Federal lands and other conservation properties.

Genetics

The final rule listing smooth coneflower as an endangered species (57 FR 46340; October 8, 1992) stated that, at that time, the remaining smooth coneflower populations contained few individual plants and there may have been low genetic variability within populations, making each remaining population important. However, we now know that smooth coneflower displays a relatively high level of diversity (Peters et al. 2009, entire). Thus, populations may be able to respond to selection pressures due to continued genetic exchange sustained by the outcrossing mating system of the species.

Encroachment From Invasive Species

Encroachment by nonnative, invasive plants poses a threat to some smooth coneflower populations, especially those occurrences located on highway ROWs or in utility line easements (such as power lines). These disturbed habitats often include nonnative species, some of which can become invasive. Invasive species change the floristic composition of these areas, compete for nutrients, limit germination of seeds (by changing or eliminating that niche/microenvironment), and may shade out smooth coneflower plants. Another impact is the use of herbicides on invasive species that has the secondary effect of killing smooth coneflower. Smooth coneflower populations face threats by nonnative, invasive plants such as Japanese honeysuckle (*Lonicera japonica*), Sericea lespedeza (*Lespedeza cuneata*), shrubby lespedeza (*Lespedeza bicolor*), Japanese stiltgrass (*Microstegium vimineum*), and autumn olive (*Elaeagnus umbellata*) (White 2019, entire).

Climate Change

Based on observations of climatic conditions over a period of approximately 20 years, there is some biological and historical evidence to indicate that smooth coneflower is adapted to persist with the range of potential effects of climate change, including more frequent droughts (below average rainfall over a time period greater than the historical range of variability) and increased average maximum temperatures. Smooth coneflower is typically found in open, sunny areas with little to no shade and high sun exposure. These sites often occur in fairly xeric conditions such as open woods, glades, barrens, roadsides, clear cuts, dry limestone bluffs, and road and power line ROWs. Even though smooth coneflower populations in NC experienced severe droughts in 2007 and 2010, dry conditions did not negatively influence flower production (NCPCP 2018, entire). All natural populations in NC have survived through drought years and recovered. Despite some drought years, smooth coneflower populations in SC have generally experienced positive trends over the last 20 years, indicating that the species is not negatively affected by droughts (White 2018, entire). Smooth coneflower plants have sustained populations for years on dry clay road cuts (White 2019, pers. comm.). Adaptations to survive in sunny areas likely benefit this species during drought conditions. Further, the perennial growth habitat and underground rhizomes likely allow smooth coneflower to be more resilient to drought conditions.

To generate future climate projections across the range of smooth coneflower, we used the National Climate Change Viewer (NCCV), a tool developed by the U.S. Geological Survey (USGS) that allows the user to view climate projections at the State, county, and watershed level (Alder and Hostetler 2017, entire). The model simulates the response of the water balance to changes in temperature and precipitation in the climate models (30 separate models developed by the National Aeronautics and Space Administration). The NCCV also provides access to comprehensive summary reports for States, counties, and watersheds.

Using the NCCV and using representative concentration pathways (RCP) greenhouse gas emission scenarios (RCP 4.5 and 8.5) as possible outcomes, we calculated projected annual mean changes for maximum air temperature and precipitation for the period 2050–2074 in VA, NC, SC, and GA. Based on these results, all four States within the range of smooth coneflower will be subjected to higher maximum air temperatures (annual mean increase of 1.9–2.2 degrees Celsius (°C) (3.4–4.0 degrees Fahrenheit (°F)) for RCP 4.5; 2.7–3.2 °C (4.9–5.8 °F) for RCP 8.5) and slightly higher precipitation (annual mean increase of 0.57–0.74 centimeters (cm)/month (mo) (0.22–0.3 inches (in)/mo) for RCP 4.5; 0.51–0.76 cm/mo (0.2–0.3 in/mo) for RCP 8.5) relative to 1981–2010 (Alder and Hostetler 2017, entire). In general, across the species' range for both RCP 4.5 and 8.5, runoff is expected to remain at a similar levels or decrease slightly; soil water storage is expected to decrease slightly, and evaporative deficit will increase slightly (Alder and Hostetler 2017, entire). Because the average annual increase in precipitation is predicted to be only slightly higher, the increased evaporative deficit and the loss in runoff and soil storage is primarily a result of higher maximum and minimum air temperatures. Despite the slight increase in predicted precipitation, the coincident warming means that habitats are unlikely to maintain their current levels of moisture and will become slightly drier.

To evaluate the vulnerability of smooth coneflower to the effects of climate change, we also used NatureServe's Climate Change Vulnerability Index (CCVI) (Young et al. 2015, entire), a climate change model that uses downscaled climate predictions from tools such as Climate Wizard (Girvetz et al. 2009, entire) and combines these with readily available information about a species' natural history, distribution, and landscape circumstances to predict whether it will likely suffer a range contraction and/or population reductions due to the effects of climate change. The tool gauges 20 scientifically documented factors and indicators of these components, as well as documented responses to climate change where they exist. The CCVI

generated a vulnerability rating of ''moderately vulnerable'' for smooth coneflower, suggesting that the species' abundance and/or range extent is likely to decrease slightly by 2050. Factors influencing the species' moderate vulnerability include its restricted dispersal ability, anthropogenic barriers, predicted land use changes, dependence on a specific disturbance regime (often fire), and restriction to uncommon geological features.

Although the model suggested that smooth coneflower is sensitive to climate change and could be adversely affected in future years, there are a number of weaknesses associated with the CCVI (Anacker and Leidholm 2012, pp. 16–17). The specific weaknesses identified are: (1) The CCVI is weighted too heavily towards direct exposure to climate change (projected changes to future temperature and precipitation conditions that have high levels of uncertainties); (2) some important plant attributes are missing (mating system and pollinator specificity); (3) it is very difficult to complete scoring for a given species because some information is simply lacking; (4) some scoring guidelines are too simplistic (Anacker and Leidholm 2012, pp. 16–17); and (5) the model does not account for impacts to species' vital rates.

Topographic complexity is a potential complementary factor in assessing vulnerability to climate change (Anacker and Leidholm 2012, pp. 12–16). Within smooth coneflower's range, the Appalachian and Allegheny mountains are predicted to have slightly higher temperature changes as a result of climate change than the piedmont and coastal plain counties, so smooth coneflower populations in the mountains on the north end of the range may be more vulnerable when compared to those that occur, for example, in the coastal plain.

In summary, while smooth coneflower is considered moderately vulnerable to range contraction from future climate change, the predicted temperature and precipitation changes for both moderate (RCP 4.5) and extreme (RCP 8.5) scenarios indicate only slightly hotter and drier conditions by 2074. Thus, smooth coneflower is expected to have little to no change for any populations due to drought or temperature changes that are predicted for the future. Therefore, we conclude that climate change is not likely a major factor affecting the species' resiliency into the foreseeable future.

Stochastic Events

Stochastic events (environmental and genetic stochasticity) do not appear to be adversely affecting populations of smooth coneflower. Environmental stochasticity refers to variation in recruitment and mortality rates in response to weather, disease, competition, predation, or other factors external to the population. While drought and the timing and amount of rainfall are likely important factors in seed germination and establishment of smooth coneflower, we do not have any evidence of how these factors directly affect this species. Smooth coneflower soil seed banks are low to nonexistent, which could exacerbate the potential effects of stochastic events because the species does not have the seed bank to rely on for future recruitment (Walker 2009, p. 12); however, we have not yet observed that the low seedbank has affected highly resilient populations. With regard to genetic stochasticity, smooth coneflower populations have significant levels of population diversity and exhibit substantial population genetic differentiation (Peters et al. 2009, p. 12) (see *Genetics,* above), as such any genetic stochasticity such as allee effects or genetic bottlenecks are not likely. Based on the best available information, we conclude that environmental and genetic stochasticity do not pose a threat to smooth coneflower.

Cumulative Effects

The cumulative effects of encroaching development adjacent to protected sites and the management challenges that accompany that threat will continue to affect the species into the future. Increasing development adjacent to protected sites will likely lead to decreases in managing with prescribed burning in the future, which may or may not be replaced with adequate and appropriate habitat management by other means that are more expensive than managing with fire. The type of development also factors into management ability and flexibility, with major roads and places with vulnerable populations weighing more heavily on the decision of if/when to burn than other types of development.

Summary of Comments and Recommendations

In the proposed rule published on June 24, 2021 (86 FR 33159), we requested that all interested parties submit written comments on the proposal by August 23, 2021. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. A newspaper notice inviting general public comment was published in the public notice section of USA Today on July 12, 2021. We did not receive any requests for a public hearing. We received four public comments, primarily in support of our proposed downlisting of smooth coneflower, during the proposed rule's public comment period, but none raised issues substantial enough to change our conclusions from the proposed rule.

Peer Reviewer Comments

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought peer review of the proposed reclassification rule. The Service sent the proposed rule to four independent peer reviewers who had expertise in smooth coneflower ecology and the threats to its habitat. We received responses from two of the peer reviewers.

We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the information contained in the proposed reclassification rule. The peer reviewers generally concurred with our methods and conclusions, and provided additional information, clarifications, and suggestions to improve the final rule. Peer reviewer comments are addressed in the following summary and were incorporated into this final rule, as appropriate.

(1) Comment: One peer reviewer indicated that the studies we cited for information on reproductive biology seem to conflict, stating that while one cited study includes butterflies as pollinators, another more correctly identifies butterflies as visitors collecting nectar, not as effective pollinators.

Our Response: These two statements in the proposed rule were somewhat confusing. Based on the literature cited, skippers, butterflies, and wasps are frequent floral visitors; however, bees are believed to be the most effective pollinators (Gadd 2006, p. 15; Collins and Fore 2009, pp. 452–454). We have made minor edits to this final rule to clarify this distinction.

(2) Comment: One peer reviewer suggested that we provide reference to best management practices for the downlisting/delisting criterion 4 (management plans implemented). They also suggested that we comment on where outdated management plans fall short of current knowledge (*e.g.,* updated fire frequency, timing, etc.).

Our Response: In the proposed rule and this final rule, we include best management practices where we indicate that smooth coneflowers require early to mid-successional habitat provided via management techniques that include the use of prescribed fire on 3- to 5-year rotations, or well-timed mowing or mechanical clearing, and the control of invasive species with herbicides selectively applied to cut stumps to prevent growth. We assert that maintaining open habitat (through prescribed fire or mechanical clearing) and invasive species control are important management practices that are critical to the long-term survival of smooth coneflower and have included reference to these practices in this final rule. We also note that the Service is working with land managers to update management plans by providing a template as a guide including how to best manage smooth coneflower with fire and for invasive species, which will help improve the seven generic management plans and the six outdated management plans mentioned above in *Downlisting/Delisting Criterion 4 (Management plans implemented).*

(3) Comment: One peer reviewer stated that our conclusion regarding collection threat has some flaws, noting that the proposed rule indicated that the incidence of collection was limited and the Service indicated that the collection that did take place was conducted using very conservative practices. The peer reviewer suggested that the conclusion should be revised to state that overcollection is not a major threat as long as any future collection follows best conservation practices.

Our Response: Limited collection of smooth coneflower has occurred over time, but has been minimal in scope and not been a major threat to the species. Any future collection efforts should follow best conservation practices, as described in Menges et al. (2004) and by Center for Plant Conservation Best Practices. We noted in the proposed rule and reiterate in this final rule that overcollection has not been documented for the species (see *Collection,* above).

(4) Comment: One peer reviewer commented that the climate models we used do not account for impacts to the species' vital rates (*i.e.,* changes in survivorship/mortality, fecundity). The peer reviewer indicated that vital rates can be broadly used to look at range contraction but have long been used with metrics like population viability analyses to determine persistence/threat of individual sites/populations. However, the peer reviewer agreed that based on the information in the proposed reclassification, smooth coneflower should have little changes at individual populations due to drought and temperature changes under predicted climate change.

Our Response: The climate change models we used do not account for impacts to the species' vital rates. However, given that smooth coneflower is tolerant of increased temperatures and drought, we have determined that climate change is not likely a major factor affecting the species' resiliency into the foreseeable future.

Determination of Smooth Coneflower's Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of endangered species or threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

As also described above, the term ''foreseeable future'' extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors. Where we had data over longer time frames, we analyzed those data (*e.g.,* climate data); however, for the factors most influential in affecting the status of the smooth coneflower, such as development and succession due to lack of adequate management, we could only reliably predict the magnitude of the primary threats and the subsequent effects on smooth coneflower over a time frame of 20 to 30 years. Therefore, we consider the foreseeable future to be 20–30 . Threats that are reasonably likely to affect the species in the foreseeable future include habitat loss due to development pressure on private lands and habitat succession due to lack of adequate management (see *Habitat Degradation or Loss Due to Development and Absence of Natural Disturbance,* above), including fire suppression near or on private lands and accidental mowing and herbicide application from roadside maintenance activities. Thus, all populations of smooth coneflower that are not actively managed or formally protected remain at risk of extirpation in the future. The 20–30 year period reflects the range from the time when the species was listed (1992) to the present (30 years), and provides a timeframe of reference observations that enables the Service to predict future management scenarios for the species and the species' response to threats and management actions. This prior experience indicates that a 20 to 30 year timeframe is the expected period over which implementation of management practices (such as prescribed fire) by conservation partners and tracking of the species' response to managed habitat improvement is reliable. Further, this time period coincides with the SLEUTH urban growth models, allowing us to make reliable predictions with respect to the threat of development. For formally protected populations, we expect management of the threat of fire suppression to continue as part of ongoing management well into the future. Therefore, we used the 20- to 30-year timeframe in developing our projections of future conditions for smooth coneflower.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we find that smooth coneflower continues to face threats from habitat succession (resulting from lack of fire or other management), particularly in areas where development is increasing near existing populations, thus making fire management difficult. In addition, development pressure, especially for unprotected populations on private lands, remains a concern. We are concerned about long-term management because several populations do not have management plans or the management plans no longer reflect the best available science. Even populations occurring on protected land adjacent to private lands are becoming increasingly more difficult to manage due to neighbors' concerns about nearby fires and smoke pollution. Even with agreements in place to protect them, populations in roadside

and utility ROWs still face threats from maintenance activities, especially herbicide spraying and mowing. The decline or disappearance of some smooth coneflower populations across the range of the species has been documented in Natural Heritage Program records and is attributed to habitat loss. Habitat loss (Factor A) is considered to be a moderate threat currently and is expected to continue in the foreseeable future.

At the time of listing in 1992, there was concern that smooth coneflower plants would be collected for the horticulture or pharmaceutical trade (Factor B). However, we do not find that collecting is currently a threat to this species or is expected to be in the foreseeable future.

Disease and predation (Factor C) were not identified as a significant threat to smooth coneflower when the species was listed in 1992. Natural herbivory by insects and mammals may occur, but it is a considered a low-magnitude threat because the species has sustained populations and there is no indication that the magnitude of an undetermined natural predation pressure significantly affects smooth coneflower survival. We find that disease and predation are not currently threats to this species, and we do not expect them to be threats in the foreseeable future.

The existing regulatory mechanisms (Factor D) are not adequate to protect smooth coneflower from development and habitat succession. Populations of smooth coneflower on USFS, DOD, and USDOE lands receive some protection by management protocols applicable to those lands. Furthermore, some populations in NC, SC, and VA occur on State-owned lands managed by their respective Natural Heritage Programs or the NCDACS as ''dedicated nature preserves.'' However, while NC, GA, and VA have plant protection laws, they only regulate the collection and trade of listed species and do not prohibit the destruction of populations on private lands or otherwise mandate protection. There is no State law protecting rare plants in SC.

Other natural and manmade factors affecting the continued existence (Factor E) of smooth coneflower identified at the time of listing (1992) include low genetic variability within populations, encroachment by exotic species, herbicide use, and the importance of periodic disturbance (addressed above under Factor A). Since listing, climate change is another factor that has been identified. Of these threats, encroachment by exotic (invasive) species and use of herbicides to manage those exotic species continue to be a threat to smooth coneflower populations. New information since the time of listing indicates that smooth coneflower displays a relatively high level of diversity and that populations may be able to respond to selection pressures and maintain viability due to continued genetic exchange sustained by the outcrossing mating system of the species. Based on the number, distribution, and genetic diversity of the species, we conclude that potential impacts associated with stochastic events are not a threat to smooth coneflower. Despite our uncertainty about the species' vulnerability to climate change, we do not consider climate change to be a threat to smooth coneflower based on the current resiliency of the species and its demonstrated tolerance to periods of drought.

Further, since the species' 1992 listing under the Act, new smooth coneflower occurrences have been discovered throughout the range of the species, especially with the new sites in the coastal plain of GA and SC. Our understanding of the species' distribution has improved as a result of increased survey efforts; the species is now known from 44 populations (up from 21 populations at the time of listing), 16 of which currently have high to medium resiliency. The species' geographic representation is good, given the distribution of highly resilient populations over a four-State area. We believe that this improvement in the species' viability demonstrates that it is not currently in danger of extinction throughout its range despite the persistence of the above-described threats.

In conclusion, based on our assessment of the best available scientific and commercial information, we find that while smooth coneflower populations continue to face threats from habitat loss and invasive species, and existing regulatory mechanisms are currently inadequate to protect some smooth coneflower populations from development and habitat succession, there are currently 16 protected, high resiliency smooth coneflower populations and a total of 44 populations, up from 21 populations at the time of listing. Therefore, the species no longer meets the Act's definition of an endangered species.

We, therefore, proceed with determining whether smooth coneflower meets the Act's definition of a threatened species. The ongoing threats of habitat loss, habitat fragmentation, habitat succession, and encroachment of nonnative and invasive species are of sufficient imminence, scope, or magnitude to affect the resiliency of smooth coneflower populations for the foreseeable future. The species relies on management such as prescribed fire and mechanical clearing to maintain its habitat. However, management plans for most of the areas in which the species is protected are outdated, and it is uncertain how those plans will continue to be implemented. Threatened development near protected sites could impede management of those sites with fire. Adequate management commitments would need to be secured for more populations before the species could be delisted. Thus, after assessing the best available information, we conclude that although smooth coneflower is not currently in danger of extinction, but it is likely to become in danger of extinction within the foreseeable throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Center for Biological Diversity*), vacated the aspect of our Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014) that provided that the Service does not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction in that portion.

Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range. In undertaking this analysis for smooth coneflower, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify

any portions of the range where the species is endangered.

For smooth coneflower, we considered whether the threats are geographically concentrated in any portion of the species' range at a biologically meaningful scale, which may indicate this portion could have a different status. We examined the threats of habitat succession, habitat loss, and invasive species, as well as the cumulative effects of these threats, and considered whether management actions were being implemented. Smooth coneflower populations on private lands throughout the range face the threat of development and are not being managed with prescribed fire. However, while the development threat is concentrated near already urbanizing areas, most coneflower populations near those areas are protected in preserves. The decline or disappearance of some smooth coneflower populations across the range of the species has been documented in Natural Heritage Program records and is attributed to habitat loss, primarily due to lack of proper management. There is no indication that management is more or less likely to be implemented in any particular area within the range; thus, no specific population appears to be more subject to stochastic events than others. Further, encroachment by invasive species, which is most prevalent in disturbed areas, such as highway ROWs or utility corridors, occurs throughout the smooth coneflower's range. Accordingly, we found no concentration of threats in any portion of the smooth coneflower's range at a biologically meaningful scale. Thus, there are no portions of the species' range where the species has a different status from its rangewide status. Therefore, it is unnecessary for us to determine whether any portion of the species' range is significant. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that smooth coneflower meets the Act's definition of a threatened species. Therefore, we are reclassifying smooth coneflower from an endangered species to a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. The Act encourages cooperation with the States and requires that recovery actions be implemented for all listed species. The protections required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. As discussed earlier in this document, section 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystem.

Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan identifies site-specific management actions that set a trigger for review of the five factors that control whether a species may be downlisted or delisted, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. All planning documents can be found on our website (*https://www.fws.gov/program/endangered-species*).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands (like TNC preserves and county-owned nature preserves). To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands where appropriate. Funding for recovery actions could become available from a variety of sources, including Federal budgets, State programs, and cost share grants from non-Federal landowners, the academic community, and nongovernmental organizations. We invite you to submit any new information on this species whenever it becomes available (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) requires Federal agencies to evaluate their actions with respect to any species that is listed as an endangered or threatened species. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species. If a Federal action may affect a listed species, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require consultation as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the USFS; issuance of section 404 Clean Water Act (33 U.S.C. 1251 *et seq.*) permits by the USACE; and construction and maintenance of roads or highways by the Federal Highway Administration.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a final listing on proposed and ongoing activities within the range of a listed species. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

II. Final Rule Issued Under Section 4(d) of the Act

The Act allows the Secretary to promulgate protective regulations for threatened species pursuant to section 4(d). Because we are reclassifying this species as a threatened species, the prohibitions in section 9 would not apply directly. We are, therefore, enacting a set of regulations to provide for the conservation of the species in accordance with section 4(d) of Act,

which also authorizes us to apply any of the prohibitions in section 9 to a threatened species. The rule includes a description of the kinds of activities that would or would not constitute a violation.

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as she deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to [her] with regard to the permitted activities for those species. [She] may, for example, permit taking, but not importation of such species, or [she] may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Provisions of the 4(d) Rule

Exercising the Secretary's authority under section 4(d) of the Act, we have developed a rule that is designed to address the smooth coneflower's specific threats and conservation needs. Although the statute does not require the Service to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of smooth coneflower.

As discussed above under Summary of Biological Condition and Threats, we have concluded that smooth coneflower is likely to become in danger of extinction within the foreseeable future primarily due to the present or threatened destruction, modification, or curtailment of its habitat or range (specifically due to fire suppression and subsequent ecological succession and development, and encroachment from invasive species). Specifically, a number of activities have the potential to affect smooth coneflower, including land clearing for development, fire suppression, and herbicide application to highway and utility ROWs. Extending the Act's section 9 prohibitions for plants, including making it unlawful to remove, damage, or destroy smooth coneflowers, will provide for conservation of the species by helping to preserve remaining populations, slowing their rate of potential decline, and decreasing synergistic, negative effects from other stressors. Prohibiting import and export, transportation, and commerce of smooth coneflower limits unauthorized propagation and distribution, which prevents potential hybridization with other species of *Echinacea* and subsequent inbreeding depression. As a whole, the 4(d) rule helps in the efforts to recover the species.

The provisions of this 4(d) rule promote conservation of smooth coneflower by encouraging management of the landscape in ways that meet both land management considerations and the conservation needs of smooth coneflower, specifically by providing exceptions for State agency conservation actions, scientific permits for research, and use of cultivated-origin seeds for education. The provisions of this rule are one of many tools that we will use to promote the conservation of smooth coneflower.

This 4(d) rule provides for the conservation of smooth coneflower by extending the prohibitions of section 9(a)(2), prohibiting the following activities, except as otherwise authorized or permitted: Import or export; removing and reducing to possession smooth coneflower from areas under Federal jurisdiction; maliciously damaging or destroying the species on any area under Federal jurisdiction; removing, cutting, digging up, or damaging or destroying the species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law; delivering, receiving, carrying, transporting, or shipping the species in interstate or foreign commerce in the course of a commercial activity; and selling or offering for sale the species in interstate or foreign commerce.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened plants under certain circumstances. Regulations governing permits are codified at 50 CFR 17.72. With regard to threatened plants, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for botanical or horticultural exhibition, for educational purposes, or for other activities consistent with the purposes and policy of the Act. Additional statutory exemptions from the prohibitions are found in sections 9 and 10 of the Act.

We recognize the special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist us in implementing all aspects of the Act. In this regard, section 6 of the Act provides that we shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, as set forth at 50 CFR 17.71(b), any employee or agent of the Service or of a State conservation agency that is operating a conservation program pursuant to the terms of a cooperative agreement with the Service in accordance with section 6(c) of the

Act, who is designated by that agency for such purposes, will be allowed, when acting in the course of official duties, to remove and reduce to possession from areas under Federal jurisdiction smooth coneflowers that are covered by an approved cooperative agreement to carry out conservation programs. In addition, in accordance with 50 CFR 17.61(c)(2) through (4), any employee or agent of the Service, any other Federal land management agency, or a State conservation agency, who is designated by that agency for such purposes, will be able to, when acting in the course of official duties, remove and reduce to possession smooth coneflower from areas under Federal jurisdiction without a permit to care for a damaged or diseased specimen, or to salvage or dispose of a dead specimen.

We also recognize the beneficial and educational aspects of activities with seeds of cultivated plants, which generally enhance the propagation of the species. We intend to monitor the interstate and foreign commerce and the import and export of these specimens in a manner that will not inhibit such activities, providing the activities do not represent a threat to the survival of the species in the wild. In this regard, we have created an exception from the prohibitions for seeds of cultivated specimens, provided that a statement that the seeds are of ''cultivated origin'' accompanies the seeds or their container (*e.g.,* the seeds could be moved across State lines or between territories for purposes of seed banking or use for outplanting without additional regulations).

Nothing in this 4(d) rule changes in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or our ability to enter into partnerships for the management and protection of smooth coneflower. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between us and other Federal agencies, where appropriate.

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act, need not be prepared in connection with determining and implementing a species' listing status under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that there are no Tribal interests affected by this rule.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov.*

Authors

The primary authors of this rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Raleigh Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.12, in paragraph (h), by revising the entry for ''*Echinacea laevigata*'' under FLOWERING PLANTS in the List of Endangered and Threatened Plants to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
FLOWERING PLANTS				
*	*	*	*	*
Echinacea laevigata	Smooth coneflower	Wherever found	T	57 FR 46340, 10/8/1992; 87 FR [insert **Federal Register** page where the document begins], 7/6/2022; 50 CFR 17.73(f).[4d]
*	*	*	*	*

■ 3. Amend § 17.73 by adding paragraphs (c) through (f) to read as follows:

§ 17.73 Special rules—flowering plants.

* * * * *

(c)–(e) [Reserved]

(f) *Echinacea laevigata* (smooth coneflower)—(1) *Prohibitions.* The following prohibitions that apply to endangered plants also apply to *Echinacea laevigata.* Except as provided under paragraph (f)(2) of this section, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.61(b) for endangered plants.

(ii) Remove and reduce to possession from areas under Federal jurisdiction, as set forth at § 17.61(c)(1) for endangered plants.

(iii) Maliciously damage or destroy the species on any areas under Federal jurisdiction, or remove, cut, dig up, or damage or destroy the species on any other area in knowing violation of any State law or regulation or in the course of any violation of a State criminal trespass law, as set forth at section 9(a)(2)(B) of the Act.

(iv) Engage in interstate or foreign commerce in the course of commercial activity, as set forth at § 17.61(d) for endangered plants.

(v) Sell or offer for sale, as set forth at § 17.61(e) for endangered plants.

(2) *Exceptions from prohibitions.* In regard to *Echinacea laevigata,* you may:

(i) Conduct activities, including activities prohibited under paragraph (f)(1) of this section, if they are authorized by a permit issued in accordance with the provisions set forth at § 17.72.

(ii) Conduct activities authorized by a permit issued under § 17.62 prior to August 5, 2022 for the duration of the permit.

(iii) Remove and reduce to possession from areas under Federal jurisdiction, as set forth at § 17.61(c)(2) through (4) for endangered plants and § 17.71(b).

(iv) Engage in any act prohibited under paragraph (f)(1) of this section with seeds of cultivated specimens, provided that a statement that the seeds are of ''cultivated origin'' accompanies the seeds or their container.

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–14291 Filed 7–5–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2020–0078; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BE82

Endangered and Threatened Wildlife and Plants; Endangered Species Status for the Canoe Creek Clubshell and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine that the Canoe Creek clubshell (*Pleurobema athearni*), a freshwater mussel species endemic to a single watershed in north-central Alabama, is an endangered species under the Endangered Species Act of 1973 (Act), as amended. We also designate critical habitat for the species under the Act. In total, approximately 58.5 river kilometers (36.3 river miles) in St. Clair and Etowah Counties, Alabama, fall within the boundaries of the critical habitat designation. This rule extends the Act's protections to the species and its designated critical habitat.

DATES: This rule is effective August 5, 2022.

ADDRESSES: This final rule is available on the internet at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2020–0078. Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *https://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0078.

The coordinates or plot points from which the maps are generated are included in the decision file for this critical habitat designation and are available at *https://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0078 and on the Service's website at *https://www.fws.gov/office/alabama-ecological-services.* Any additional tools or supporting information that we developed for the critical habitat designation will also be available at the Service's website set out above and may also be included in the preamble and at *https://www.regulations.gov,* or both.

FOR FURTHER INFORMATION CONTACT: William J. Pearson, Field Supervisor, U.S. Fish and Wildlife Service, Alabama Ecological Services Field Office, 1208 Main Street, Daphne, AL 36526; telephone 251–441–5181. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become endangered in the foreseeable future throughout all or a significant portion of its range). We have determined that the Canoe Creek clubshell meets the definition of an endangered species; therefore, we are listing it as such. To the maximum extent prudent and determinable, we must designate critical habitat for any species that we determine to be an endangered or threatened species under the Act. Listing a species and designation of critical habitat can be completed only by issuing a rule.

What this document does. This rule lists the Canoe Creek clubshell (*Pleurobema athearni*) as an endangered species and designates critical habitat for this species under the Endangered Species Act. We are designating critical habitat in 2 units totaling approximately 58.5 river kilometers (km) (36.3 river miles (mi)) in St. Clair and Etowah Counties, Alabama.

The basis for our action. Under section 4(a)(1) of the Act, we may determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that habitat degradation through changes in water quality and quantity (Factor A), increased sedimentation (Factor A), and climate events (Factor E) are the primary threats to the species.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

Economic analysis. In accordance with section 4(b)(2) of the Act, we prepared an economic analysis of the impacts of designating critical habitat. We made the draft economic analysis

available for public comments on November 3, 2020 (85 FR 69540).

Peer review and public comment. We sought the expert opinions of eight appropriate specialists with expertise in biology, habitat, and threats to the species regarding the species status assessment report. We did not receive any responses to our peer review requests. We also considered all comments and information we received from the public during the comment period for the proposed listing and critical habitat for the Canoe Creek clubshell.

Previous Federal Actions

On November 3, 2020, we published in the **Federal Register** a proposed rule (85 FR 69540) to list the Canoe Creek clubshell as an endangered species and to designate critical habitat for the species under the Act (16 U.S.C. 1531 *et seq.*). Please refer to that proposed ruled for a detailed description of other previous Federal actions concerning the Canoe Creek clubshell prior to the proposal's publication.

Summary of Changes From the Proposed Rule

In preparing this final rule, we reviewed and fully considered comments from the public on our November 3, 2020, proposed rule regarding Canoe Creek clubshell (85 FR 69540). This final rule incorporates minor, non-substantive changes to the critical habitat unit descriptions (see Critical Habitat Designation) based on the comments we received. However, the information we received during the comment period for the proposed rule did not change our determination that the Canoe Creek clubshell is an endangered species.

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Canoe Creek clubshell. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species. The SSA report and other materials relating to this rule can be found at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2020–0078.

Summary of Comments and Recommendations

In the November 3, 2020, proposed rule, we requested that interested parties submit written comments by January 4, 2021. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposed rule. A newspaper notice inviting general public comment was published in the The St. Clair Times legal notice section on November 12, 2020. Although we invited requests for a public hearing in the rule, we did not receive any requests for a public hearing. All substantive information provided during the comment period has either been incorporated directly into this final determination, in the final economic analysis, or is addressed below.

Public Comments

We received 60 public comments in response to the proposed rule. We reviewed all comments we received during the public comment period for substantive issues and new information regarding the proposed rule. No new information concerning the proposed listing and designation of critical habitat for the Canoe Creek clubshell was received. Fifty-eight commenters were supportive of the proposal to list the Canoe Creek clubshell as endangered, to designate critical habitat, or both. Two commenters provided information about forestry practices but offered neither support nor opposition to the proposed rule. We did not receive any comments in opposition of the proposed rule. Below, we provide a summary of public comments we received; however, comments outside the scope of the proposed rule and those without supporting information did not warrant an explicit response and, thus, are not presented here. Identical or similar comments have been consolidated and a single response provided.

(1) Comment: One commenter indicated that the Service should consider forestry best management practices (BMPs) as part of the overall conservation benefit for the species and account for these beneficial actions in any threat analysis as done in past rules. A related comment recommended that the Service expressly recognize silviculture conducted in accordance with State-approved BMPs as a category of activities not expected to negatively impact the species' conservation and recovery efforts in the final rule's preamble and that these BMPs can ameliorate threats. Similarly, another commenter recommended the Service include a discussion of not only the ability of forest management to retain adequate conditions but also to improve forest conditions, which may redound to the benefit of species.

Our Response: We have considered the conservation benefits of implementing BMPs in our analyses. For example, in the SSA report, we explain that forestry BMPs will likely reduce sediments originating from forestry activities. We recognize that silvicultural operations (forestry activities) are widely implemented in accordance with State-approved best management practices (BMPs), and the adherence to these BMPs broadly protects water quality particularly related to sedimentation to an extent that does not impair the species' conservation. Consistent with how we have addressed this issue in other relevant rules, we identified normal silvicultural practices that are carried out in accordance with BMPs as an example of an action that is unlikely to result in a violation of section 9 and the use of BMPs as an example of an activity that could ameliorate threats to physical and biological features essential to the conservation of the Canoe Creek clubshell. However, given the species' low abundance and lack of successful reproduction and recruitment, the potential protection of water quality provided by BMPs do not appear to offset factors of decline. Therefore, we did not include a discussion of the ability of forest management to improve forest conditions to an extent that they may benefit the Canoe Creek clubshell.

(2) Comment: One commenter recommended that the description of designated critical habitat be clarified to state that critical habitat is limited to the bankfull width of the designated streams.

Our Response: We have clarified in this final rule that the boundaries of critical habitat extend laterally to the bankfull width. The critical habitat proposed for designation was not intended to include adjacent terrestrial components.

(3) Comment: One commenter recommended the Service note in the final rule its willingness to work collaboratively with forest owners adjacent to designated critical habitat to develop streamlined agreements, similar to Safe Harbor Agreements, that provided regulatory assurances to landowners and recognize that forest management conducted with approved BMPs will not be subject to enforcement under the prohibition on take in section 9 of the ESA.

Our Response: It is our mission to collaborate with public and private partners to conserve, protect, and enhance fish and wildlife and the habitats on which they depend. Tools are available through Section 10 of the

Act for private landowners to coordinate with the Service to facilitate conservation of listed species and receive regulatory assurances and certainty for their actions. A discussion of these conservation tools is outside the scope of this rulemaking, but they will be identified and discussed in forthcoming recovery documents. We agree that when used and properly implemented, BMPs can offer a substantial improvement to water quality compared to forestry operations where BMPs are not properly implemented. Normal silvicultural practices that are carried out in accordance with BMPs as an action that can maintain favorable habitat conditions for the Canoe Creek clubshell. In addition, we recognize that silvicultural operations are widely implemented in accordance with State-approved best management practices (BMPs; as reviewed by Cristan *et al.* 2018, entire), and the adherence to these BMPs broadly protects water quality, particularly related to sedimentation (as reviewed by Cristan *et al.* 2016, entire; Warrington *et al.* 2017, entire; and Schilling *et al.* 2021, entire), to an extent that does not impair the species' conservation. However, if adverse effects to listed species or critical habitat are likely or if take is reasonably certain to occur, formal consultation under section 7 with an accompanying biological opinion or a take permit under section 10 of the Act would be necessary to avoid violating section 9 of the Act.

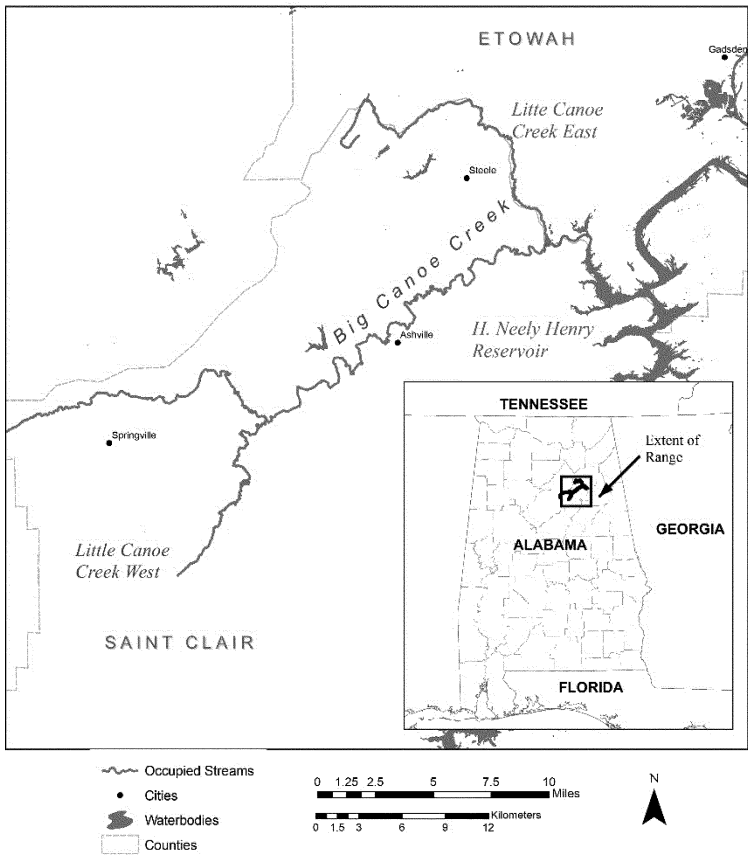
I. Final Listing Determination

Background

The Canoe Creek clubshell is a narrow endemic mussel that is only known from the Big Canoe Creek watershed in St. Clair and Etowah counties, Alabama. The species' current distribution is similar to its historical distribution, which has likely always been narrow. However, the current range of the species is disjunct; the eastern and western portions of its range are separated by a stretch of river that exceeds the dispersal distance of the species' host fish (the clubshell's primary mode of dispersal in the larval stage) and contains an inhabitable portion. As a result, we believe there is no genetic exchange occurring between the western and eastern portions of the species' range and we characterize these portions as subpopulations.

Please refer to our November 3, 2020, proposed rule (85 FR 69540) and the species status assessment report (Service 2020, entire) for a summary of species background information.

Canoe Creek Clubshell (*Pleurobema athearni*)
Range Map
St. Clair and Etowah Counties, Alabama



Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an ''endangered species'' or a ''threatened species.'' The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an

''endangered species'' or a ''threatened species'' because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the species should be proposed for listing as an endangered or threatened species under the Act. It does, however, provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS–R4–ES–2020–0078 on *https://www.regulations.gov.*

To assess the Canoe Creek clubshell's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (*e.g.,* wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (*e.g.,* droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (*e.g.,* climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

Individual, Subpopulation, and Species Needs

Juvenile and adult Canoe Creek clubshells need stable instream substrates, including, but not limited to, coarse sand and gravel for settlement and sheltering. Clean, flowing water is needed to keep these substrates free from excess sedimentation that may reduce the amount of available habitat for sheltering, hinder a mussel's ability to feed, and, in severe instances, cause smothering and death (see *Risk Factors for the Canoe Creek Clubshell,* below, for information on impacts of sedimentation). Clean, flowing water is also needed to attract host fish and disperse juveniles throughout stream reaches. In addition, freshwater mussels are sensitive to changes in water quality parameters such as temperature, dissolved oxygen, ammonia, and

pollutants. Therefore, while the precise tolerance thresholds for these water quality parameters are unknown for the Canoe Creek clubshell, we know the species requires water of sufficient quality to sustain its natural physiological processes for normal behavior, growth, and survival at all life stages (see *Risk Factors for the Canoe Creek Clubshell,* below, for more information on water quality impairments). Food and nutrients are needed for individuals at all life stages for survival and growth. Lastly, the presence of host fish is needed for successful reproduction and dispersal. Host fish used by the Canoe Creek clubshell include the tricolor shiner (*Cyprinella trichroistia*), Alabama shiner (*C. callistia*), and striped shiner (*Luxilus chrysocephalus*), among others.

To be healthy at the subpopulation and species levels, the Canoe Creek clubshell needs individuals to be present in sufficient numbers throughout the subpopulations; reproduction, which is evidenced by the presence of multiple age classes within a subpopulation; and connectivity among mussel beds (local aggregations) within a subpopulation and between subpopulations. Mussel abundance facilitates reproduction. Mussels do not actively seek mates; males release sperm into the water column, where it drifts until a female takes it in (Moles and Layzer 2008, p. 212). Therefore, successful reproduction and subpopulation growth requires a sufficient number of females to be downstream of a sufficient number of males.

There must also be multiple mussel beds of sufficient density such that local stochastic events do not eliminate most or all the beds. Connectivity among beds within each subpopulation is also needed to allow mussel beds within a stream reach to be recolonized by one another and recover from stochastic events. A nonlinear distribution of beds over a sufficiently large area helps buffer against stochastic events that may impact portions of a clubshell subpopulation. Similarly, having multiple subpopulations that are connected to one another protects the species from catastrophic events, such as spills, because subpopulations can recolonize one another following events that impact the entirety or portions of one subpopulation.

Risk Factors for the Canoe Creek Clubshell

We identified several factors that are influencing the viability of the Canoe Creek clubshell. The primary factors include sedimentation, water quality, and climate events. For a complete discussion on the factors influencing the Canoe Creek clubshell, including the impacts of connectivity and conservation efforts, see the species status assessment report (Service 2020, pp. 30–53).

Sedimentation

Under a natural flow regime, sediments are washed through river and stream systems, and the overall amount of sediment in the substrate remains relatively stable over time. However, some past and ongoing activities or practices can result in elevated levels of sediment in the substrate. This excessive stream sedimentation (or siltation) can be caused by soil erosion associated with upland activities (*e.g.,* agriculture, poor forest management practices, unpaved roads, road construction, development, unstable streambanks, and urbanization) and stream channel destabilization associated with other activities (*e.g.,* dredging, poorly installed culverts, pipeline crossings, or other instream structures) (Brim Box and Mossa 1999, p. 102; Wynn *et al.* 2016, pp. 36–52). In severe cases, stream bottoms can become ''embedded,'' whereby substrate features including larger cobbles, gravel, and boulders are surrounded by, or buried in, sediment, which eliminates interstitial spaces (small openings between rocks and gravels).

The negative effects of increased sedimentation on mussels are relatively well-understood (Brim Box and Mossa 1999, entire; Gascho Landis *et al.* 2013, entire; Poole and Downing 2004, pp. 118–124). First, the river processes and sediment dynamics caused by increased sedimentation degrade and reduce the amount of habitat available to mussels. Juvenile mussels burrow into interstitial spaces in the substrate. Therefore, juveniles are particularly susceptible to excess sedimentation that removes those spaces, and they are unable to find adequate habitat to survive and become adults (Brim Box and Mossa 1999, p. 100). Second, sedimentation interferes with juvenile and adult physiological processes and behaviors. Mussels can die from being physically buried and smothered by excessive sediment. However, the primary impacts of excess sedimentation on individuals are sublethal; sedimentation can reduce a mussel's ability to feed (Brim Box and Mossa 1999, p. 101) and reproduce (by reducing the success of glochidial attachment and metamorphosis; Beussink 2007, pp. 19–20).

The primary activities causing sedimentation that have occurred, and continue to occur, in the Big Canoe Creek watershed include urbanization and development, agricultural practices, and forest management (Wynn *et al.* 2016, pp. 9–10, 50–51). Approximately 59 percent of the Big Canoe Creek watershed is in evergreen or mixed deciduous forest, and forestry activities are common in central Big Canoe Creek and Little Canoe Creek West. Agriculture is also common, with pasture and small farms comprising 18 percent, and cultivated crops comprising 2.3 percent, of land use in the watershed. Urban development comprises 6 percent of the watershed's land use and is concentrated near the cities of Ashville and Springville near the western clubshell subpopulation, and Steele near the eastern subpopulation (Wynn *et al.* 2016, p. 9).

A rapid habitat assessment survey that included an evaluation of sedimentation deposition was completed at multiple sites in the Big Canoe Creek watershed from 2008–2013 (Wynn *et al.* 2016, pp. 37–39). Overall habitat quality varied from poor to optimal throughout Big Canoe Creek's nine subwatersheds, but six subwatersheds were reported impaired by sedimentation (Wynn *et al.* 2016, p. 51).

Water Quality

Water quality in freshwater systems can be impaired through contamination or alteration of water chemistry. Chemical contaminants are ubiquitous throughout the environment and are a major reason for the current declining status of freshwater mussel species nationwide (Augspurger *et al.* 2007, p. 2025). Chemicals such as ammonia enter the environment through both point and nonpoint discharges, including spills, industrial sources, municipal effluents, and agricultural runoff. These sources contribute organic compounds, heavy metals, pesticides, herbicides, and a wide variety of newly emerging contaminants to the aquatic environment.

Alteration of water chemistry parameters is another type of impairment. Reduced dissolved oxygen levels and increased water temperatures are of particular concern. Runoff and wastewater can wash nutrients (*e.g.,* nitrogen and phosphorus) into the water column, which can stimulate excessive plant growth (Carpenter *et al.* 1998, p. 561). The decomposition of this plant material can lead to reduced dissolved oxygen levels and eutrophication. Increased temperatures from climate changes (Alder and Hostetler 2013, U.S. Geological Survey (USGS) National Climate Change Viewer) and low flow events during periods of drought can

also reduce dissolved oxygen levels (Haag and Warren 2008, p. 1176).

The effects of water quality impairments on freshwater mussels is well studied (Naimo 1995, entire; Havlik and Marking 1987, entire; Milam *et al.* 2005, entire; Markich 2017, entire). Contaminants, reduced dissolved oxygen levels, and increased temperatures are primary types of impairments that affect mussel survival, reproduction, and fitness. Freshwater mussels in their early life stages are among the most sensitive organisms to contaminants, but all life stages are vulnerable and can suffer from both acute and chronic effects (Augspurger *et al.* 2003, p. 2569). Depending on the type and concentration, contaminants can cause mortality of or sublethal effects (*e.g.,* reduced filtration efficiency, growth, and reproduction) on mussels at all life stages.

In addition to contaminants, alterations in water chemistry, especially reduced dissolved oxygen levels and increased temperatures, can have negative impacts on mussels. Although juveniles tend to be more vulnerable, reduced dissolved oxygen levels can have lethal and sublethal impacts on mussels in all life stages. Mussels require oxygen for metabolism and when levels are low, normal functions and behaviors (*e.g.,* ventilation, filtration, oxygen consumption, feeding, growth, and reproduction) are impaired. Below a certain level, mortality can occur. Lastly, increased water temperatures can impact mussel health. Young juveniles (less than 3 weeks old) are particularly sensitive, with upper and lower thermal limits 2 to 3 degrees Celsius (°C) higher or lower than juveniles 1 to 2 years older (Martin 2016, pp. 14–17). While drastic increases in temperatures beyond thermal tolerances can cause mortality, the most common negative effects of temperatures on mussels is caused by relatively minor increases that exacerbate impacts caused by other issues, such as contamination. For example, temperature increases impair physiological functions like immune response, filtration and excretion rates, oxygen consumption, and growth (Pandolfo *et al.* 2012, p. 73). Temperature increases have been linked to increased respiration rates and have also been linked to increased toxicity of some metals, like copper (Rao and Khan 2000, pp. 176–177).

In the Big Canoe Creek watershed, water quality impairments have historically impacted the Canoe Creek clubshell and continue to do so. Rapid habitat assessments conducted from 2008–2013 found 24 of 34 sites to have suboptimal, marginal, or poor habitat and sedimentation and elevated nutrient levels were documented throughout the watershed. For further discussion on water quality impairments within the range of the Canoe Creek clubshell, see the species status assessment report (Service 2020, pp. 35–43). Historically, point source discharges and pesticide and herbicide applications were not well regulated. The Clean Water Act (CWA; 33 U.S.C. 1251 *et seq.*) is the primary Federal law in the United States governing water pollution. A primary role of the CWA is to regulate the point source discharge of pollutants to surface waters through a permit process pursuant to the National Pollutant Discharge Elimination System (NPDES). The NPDES permit process may be delegated by the Environmental Protection Agency (EPA) to the States. In Alabama, this authority has been delegated to the Alabama Department of Environmental Management. Currently, Alabama Department of Environmental Management requires that discharges not exceed state water quality standards or criteria. However, it has been found that organisms commonly used in toxicity testing for determining water quality criteria may be less sensitive to tested toxicants than some freshwater mussels (Wang *et al.* 2007). Because there is no information on the Canoe Creek clubshell's sensitivity to common pollutants, we are not sure whether Federal and State water quality parameters are protective for this species.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; 7 U.S.C. 136 *et seq.*) is intended to protect against unreasonable human health or environmental effects. While pesticides are usually tested on standard biological media (*e.g.,* honey bees (*Apis sp.*), daphnia (*Daphnia magna*), bluegill sunfish (*Lepomis macrochirus*), rainbow trout (*Oncorhynchus mykiss*), mice (*Mus musculus*)), often endangered and threatened species are more susceptible to pollutants than test organisms commonly used in bioassays. While State and Federal regulations have become more stringent and toxicity and environmental consequences of contaminants are better understood, the use of many pesticides and herbicides are more commonplace. Runoff and discharges are also concerns now and into the future with the ongoing urbanization of the area.

Climate Events

Climate events such as droughts and floods can have significant impacts on freshwater systems and their fundamental ecological processes (Poff *et al.* 2002, pp. ii–v). Drought can cause dewatering of freshwater habitats and low flows, which exacerbate water quality impairments (*e.g.,* dissolved oxygen, temperature, contaminants). Streams with smaller drainage areas are especially vulnerable to drought because they are more likely to experience extensive dewatering than larger streams that maintain substantial flow (Haag and Warren 2008, pp. 1172–1173). Floods can cause excessive erosion, destabilize banks and bed materials, and lead to increases in sedimentation and suspended solids. Climate change can affect the frequency and duration of drought and floods, as well as alter normal temperature regimes. Higher water temperatures, which are common during the low flow periods of droughts, decrease mussel survival (Gough *et al.* 2012, p. 2363).

Severe drought and major floods can have significant impacts on mussel communities (Haag and Warren 2008, p. 1165; Hastie *et al.* 2001, p. 107; Hastie *et al.* 2003, pp. 40–45). Reduced flows from drought can isolate or eliminate areas of suitable habitat for mussels in all life stages and render individuals exposed and vulnerable to drying and predation (Golladay *et al.* 2004, pp. 503–504). Drought can also degrade water quality (*e.g.,* decreased dissolved oxygen levels and increased temperatures), which can reduce mussel survival, reproduction, and fitness (Golladay *et al.* 2004, p. 501; Haag and Warren 2008, pp. 1174–1176) (see discussion above under ''Water Quality''). If severe or frequent, droughts can cause substantial declines in mussel abundance. Flooding can also affect mussels by dislodging individuals and depositing them in unsuitable habitat, which can affect their ability to survive and reproduce (Hastie *et al.* 2001, pp. 108, 114). Higher turbidity and reduced visibility during high flows reduce the chances of successful fertilization of the female and impede the host fish's ability to find and take up conglutinates.

The stream segments within Big Canoe Creek where clubshells occur have relatively small drainage sizes, which render them particularly vulnerable to drought. Combined with other stressors such as water quality degradation that occur within the watershed, severe droughts can have significant impacts on the species (Haag and Warren 2008, p. 1175). No studies have been conducted specifically on the impacts of drought events to Canoe Creek clubshells within Big Canoe Creek. However, neighboring streams of similar size and condition experienced drastic declines in the density and

abundance of the warrior pigtoe (*Pleurobema rubellum,* a mussel species similar to the clubshell). Following a severe drought event in 2000, warrior pigtoe abundance declined by 65 to 83 percent (Haag and Warren 2008, p. 1165), and multiple sites were extirpated. We presume that Big Canoe Creek faced similar conditions following this and other severe drought events because of its geographic proximity and similar size and condition. Additionally, we presume the Canoe Creek clubshell's response to the drought event was comparable to that of the warrior pigtoe given its similar life-history characteristics and physiological and habitat needs.

While the impacts on mussels following the drought in 2000 were well documented (Golladay *et al.* 2004, entire; Haag and Warren 2008, entire), drought events have been occurring in the area and affecting mussel communities for decades. The severity and frequency of droughts is closely monitored and recorded at the local and State levels by multiple initiatives (NDMC 2019; USGS 2019). The National Oceanic and Atmospheric Administration's (NOAA) National Integrated Drought Information System (NIDIS) program keeps one of the most extensive records (beginning in 1895) of drought in Alabama. The program uses the Palmer Drought Severity Index (PDSI), which is a measurement of dryness based on evapotranspiration (NOAA 2020). These data indicate that over the past 100 years (1918–2018), approximately 6 percent of years experienced severe drought.

While severe droughts are natural events that these streams have always experienced, this part of Alabama has undergone more frequent severe drought events over the last 20 years; the number of severe drought years has increased to approximately 11 percent (NOAA 2020, unpaginated). Water flow gauge data at a Big Canoe Creek gauging site reported low flows that correlate to the severe and exceptional droughts in the Big Canoe Creek watershed during 2000, 2007, and 2008 (USGS 2019). The severe drought events that occurred in relatively short succession during a prolonged dry period likely caused severe impacts to the survival, reproduction, and abundance of Canoe Creek clubshells. Although we do not have specific data on the Canoe Creek clubshell in response to these drought events, the decline of other freshwater mussel species was documented in a nearby watershed. The dark pigtoe (*Pleurobema furvum*), a freshwater mussel with similar life history characteristics of the Canoe Creek clubshell, was extirpated at sites with low densities following the 2000 severe drought event (Haag and Warran 2008, pp. 1173).

Cumulative Effects

It is likely that individual stressors identified are synergistic and have cumulative impacts on the species. For instance, an increase in drought frequency would amplify water quality issues predicted to occur with increases in developed land use. Decreased stream flows would be even less able to accommodate increasing levels of non-point source pollution associated with and expected from increased human populations within the range of the Canoe Creek clubshell. Further, increasing water temperatures from drought events have been and will continue to exacerbate water quality issues such as decreases in dissolved oxygen in Big Canoe Creek (see ''Climate Events,'' above).

Species Condition

The Canoe Creek clubshell's ability to withstand, or be resilient to, stochastic events and disturbances such as drought and fluctuations in reproductive rates is extremely limited. The species has likely always been a rare, narrow endemic of the Big Canoe Creek watershed; however, past and ongoing stressors, including decreased water quality from drought events, development, and agriculture, among other sources, have greatly reduced the resiliency of the species. At present, the clubshell has extremely low abundance, shows no signs of successful reproduction, and has poor connectivity within and among subpopulations.

During comprehensive mussel surveys conducted in 2017 and 2018 in the Big Canoe Creek watershed, only 25 Canoe Creek clubshells were found (Fobian *et al.* 2017, entire; Fobian 2018, entire). In the western subpopulation, 9 individuals were found in 2 of the 40 sites that were surveyed. In the eastern subpopulation, 16 individuals were found at only 1 of the 8 sites that were surveyed. In the 25 years prior to these surveys, fewer than 15 live individuals were found (Fobian *et al.* 2017, pp. 9–10). Further, the age structure of the individuals located consisted of aged adults and the surveys found no evidence of successful recruitment (*i.e.,* sub adults (Fobian *et al.* 2017, pp. 9–10)).

In addition to a low abundance, the clubshell is experiencing recruitment failure; juveniles are not surviving to reproductive ages and joining the adult population (Strayer and Malcom 2012, pp. 1783–1785). This is evidenced by the species' heavily skewed age class distribution. Of the 25 individuals found in recent surveys, all were aging adults (Fobian *et al.* 2017, entire; Fobian 2018, entire). This skewed age class distribution is indicative of a species that is not successfully reproducing and is in decline.

Lastly, the resiliency of each subpopulation is limited by their disjunct distribution. The stretch of unsuitable habitat separating the subpopulations prevents individuals from dispersing from one subpopulation to another. This isolation renders the subpopulations vulnerable to extirpation because individuals are unable to recolonize portions of the range following stochastic disturbances that eliminate entire mussel beds or a subpopulation.

The Canoe Creek clubshell's ability to withstand catastrophic events (redundancy) is also limited, primarily because of its narrow range. Severe droughts resulting in decreased water quality and direct mortality were likely the primary causes of the species' recent decline. Compared to a more wide-ranging species whose risk is spread over multiple populations across its range, the entirety of the clubshell's range is impacted by a severe drought event. However, the impacts of other potential catastrophic events, such as contaminant spills, may be restricted to a portion of the clubshell's range, especially because the species' subpopulations are not directly downstream from one another.

The ability of the Canoe Creek clubshell to adapt to changing environmental conditions (representation) over time is also likely limited. There are no studies that have explicitly explored the species' adaptive capacity or the fundamental components—phenotypic plasticity, dispersal ability, and genetic diversity—by which it is characterized. The clubshell is a narrow endemic, inhabiting a single watershed, and we do not observe any ecological, behavioral, or other form of diversity that may indicate adaptive capacity across its range; thus, we presume the species currently has limited ability to adapt to changing environmental conditions.

Future Condition

As part of the SSA, we also developed three future condition scenarios to capture the range of uncertainties regarding future threats and the projected responses by the Canoe Creek clubshell. Our scenarios assumed a moderate or enhanced probability of severe drought, and either propagation

or no propagation of the species. Because we determined that the current condition of the Canoe Creek clubshell was consistent with an endangered species (see Determination of Canoe Creek Clubshell's Status, below), we are not presenting the results of the future scenarios in this rule. Please refer to the SSA report (Service 2020) for the full analysis of future scenarios.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. To assess the current and future condition of the species, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Conservation Efforts and Regulatory Mechanisms

State Protections

The Canoe Creek clubshell is currently ranked as a priority 1 (highest conservation concern) species of greatest conservation need in Alabama (Shelton-Nix 2017, p. 51; ANHP 2017, p. 41), but is not currently listed as State threatened or endangered (ADCNR 2015, p. 23, ANHP 2017, p. 41). However, all mussel species not listed as a protected species under the Invertebrate Species Regulation are partially protected by other regulations of the Alabama Game, Fish, and Fur Bearing Animals Regulations. Regulation 220–2-.104 prohibits the commercial harvest of all but the 11 mussel species for which commercial harvest is legal (ADCNR 2015, p. 438). The Canoe Creek clubshell is not one of the 11 mussel species for which commercial harvest is legal.

Conservation Actions

The Service and numerous partners are working to provide technical guidance and offering conservation tools to meet both species and habitat needs in aquatic systems of Alabama. The Big Canoe Creek watershed has been designated as a Strategic Habitat Unit by the Alabama Rivers and Streams Network (a group of non-profit organizations, private companies, State and Federal agencies and concerned citizens that recognize the importance of clean water and working together to maintain healthy water supplies and investigate water quality, habitat conditions, and biological quality in rivers and streams and make these findings to the public) for the purpose of facilitating and coordinating watershed management and restoration efforts as well as focus funding to address habitat and water quality issues (Wynn *et al.* 2016, p. 11, Wynn *et al.* 2018, entire). In 2016, the Geological Survey of Alabama completed a watershed assessment of the Big Canoe Creek system for the recovery and restoration of imperiled aquatic species (Wynn *et al.* 2016, entire). This assessment is being used by multiple Federal, State, and non-government organizations to contribute to restoration projects that will improve habitat and water quality for at risk and listed species like the Canoe Creek clubshell. An example of organizations working together under Alabama Rivers and Streams Network is the removal of the Goodwin's Mill Dam in 2013 on Big Canoe Creek, which restored connectivity to a portion of the range of the Canoe Creek clubshell within Little Canoe Creek (west). Multiple agencies and groups came together for this removal including: the Service's Partners for Fish and Wildlife Program, Ecological Services, and Fisheries programs, Alabama Department of Conservation and Natural Resources (ADCNR), Geological Survey of Alabama, Alabama Department of Environmental Management, Alabama Power Company, The Nature Conservancy, Coosa River Keeper, and Friends of Big Canoe Creek.

The Nature Conservancy is very active in Alabama and has listed Big Canoe Creek as a priority watershed for focused conservation efforts. The Nature Conservancy has been awarded a National Fish and Wildlife Foundation grant to create a watershed coordinator position for the Big Canoe Creek watershed that will work with landowners on headwater protection through land acquisition and easements; protect water quality by restoring and bolstering riparian buffers on public and private lands; install on the ground restoration projects that stabilize eroding streambanks and increase overall water quality and instream habitat on public and private lands; and promote public access and recreational use of the river through conservation and protection of the water resource. The Nature Conservancy has also received funding from Natural Resources Conservation Service's Regional Conservation Partnership Program to restore degrading streambanks in several watersheds in Alabama, including the Big Canoe Creek watershed. These efforts are in their early stages and have not yet resulted in improvements to the status of the Canoe Creek clubshell.

The Friends of Big Canoe Creek is a non-governmental organization formed in 2008 for purpose of preserving and protecting the Big Canoe Creek watershed through education and participation of on the ground conservation efforts that was instrumental in advocating for and nominating land along the creek for inclusion into Forever Wild, a State program that buys land to protect and preserve it. As of 2018, a 382-acre tract of land was established as the Big Canoe Creek Nature Preserve with about a mile of creek frontage near Springville in St. Clair County. The preserve will be retained by the Alabama Land Trust and maintained by the City of Springville. While the Canoe Creek clubshell is not known to occupy the Big Canoe Creek Nature preserve, it is expected that the species will benefit from the habitat protections the preserve provides.

In 2021, the Alabama Aquatic Biodiversity Center (a program of the ADCNR) submitted a final report detailing aspects of the species' reproductive periodicity, fish host relationships, and propagation methods. The Alabama Aquatic Biodiversity Center has been successful in propagating individuals of the species and has begun releasing them into the Big Canoe Creek watershed. In March 2020, approximately 1,500 individuals of the Canoe Creek clubshell were stocked into Big Canoe Creek. Annual monitoring to evaluate growth and survival is planned, and additional propagation and stocking efforts will continue in upcoming years.

In summary, the Canoe Creek clubshell is currently comprised of a critically low number of older adults that are failing to recruit young. The severity and frequency of drought events in the past two decades, combined with other ongoing habitat-related stressors such as sedimentation and water quality degradation and the mussel's naturally inefficient reproductive strategy, likely caused the decline of the species to its current vulnerable condition. The Canoe Creek clubshell's vulnerability to ongoing

stressors is heightened to such a degree that it is currently on the brink of extinction in the wild as a result of its narrow range and critically low numbers.

Determination of the Canoe Creek Clubshell's Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of ''endangered species'' or ''threatened species.'' The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened species'' because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Canoe Creek Clubshell's Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we find that past and ongoing stressors including decreased water quality from drought, development, and agriculture, among other sources (Factor A), have reduced the resiliency of the Canoe Creek clubshell to such a degree that the species is particularly vulnerable to extinction. The Canoe Creek clubshell has likely always been a rare, narrow endemic within the Big Canoe Creek, and the species has some natural ability to withstand stochastic demographic fluctuations and catastrophic events such as a severe drought, which are characteristic of the environment in which it evolved. However, the frequency of severe drought events in the past two decades, combined with other ongoing habitat-related stressors and the mussel's naturally inefficient reproductive strategy, likely caused the decline of the species to its current vulnerable condition from which it is likely unable to recover naturally. The species' declining trend and tenuous status is evidenced by the results of recent comprehensive surveys in both the western and eastern subpopulations that reveal the species is comprised of a limited number of older adults that are failing to recruit young. We anticipate these threats will continue to act on the species in the future. The Canoe Creek clubshell's vulnerability to ongoing stressors is heightened as a result of its narrow range and critically low numbers such that it is currently in danger of extinction throughout its range. Thus, after assessing the best available information, we conclude that the Canoe Creek clubshell is in danger of extinction throughout all of its range.

Canoe Creek Clubshell's Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. We have determined the Canoe Creek clubshell is in danger of extinction throughout all of its range and, accordingly, did not undertake an analysis to determine whether there is a significant portion of its range that may have a different status. Because we have determined the Canoe Creek clubshell warrants listing as endangered throughout all of its range, our determination does not conflict with the decision in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020), because that decision related to the SPR analyses for a species that warrants listing as threatened, not endangered, throughout all of its range.

Determination of Status

Our review of the best available scientific and commercial information indicates that the Canoe Creek clubshell meets the Act's definition of an endangered species. Therefore, we are listing the Canoe Creek clubshell as an endangered species in accordance with sections 3(6) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning consists of preparing draft and final recovery plans, beginning with the development of a recovery outline and making it available to the public subsequent to a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies, to the maximum extent practicable, recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or removal from protected status (''delisting''), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*https://ecos.fws.gov/ecp/species/4693*), or from our Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of

native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

Following publication of this final rule, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Alabama would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Canoe Creek clubshell. Information on our grant programs that are available to aid species recovery can be found at: *https://www.fws.gov/service/financial-assistance.*

Please let us know if you are interested in participating in recovery efforts for the Canoe Creek clubshell. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must consult with the Service.

Federal agency actions within the species' habitat that may require consultation, as described in the preceding paragraph include management and any other landscape-altering activities. These actions include, but are not limited to, work authorized by the U.S. Army Corps of Engineers that administers the issuance of section 404 Clean Water Act permits that regulate fill of wetlands and the Federal Highway Administration that regulates the construction and maintenance of roads or highways. Additional actions that may require consultation are those conducted by the U.S. Fish and Wildlife Service under the Partners for Fish and Wildlife Program. This program provides technical and financial assistance to private landowners and Tribes who are willing to help meet habitat needs of Federal trust species. The Farm Service Agency administers the Conservation Reserve Program, which includes providing incentives for farmers and private landowners to use their environmentally sensitive agricultural land for conservation benefit. The Natural Resources Conservation Service works with private landowners under multiple Farm Bill programs, all aimed at the conservation of water and soil.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) endangered fish or wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any species listed as an endangered species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22. With regard to endangered wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a listing on proposed and ongoing activities within the range of the listed species. Based on the best available information, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

(1) Normal agricultural and silvicultural practices, including herbicide and pesticide use, that are carried out in accordance with any existing regulations, permit and label requirements, and best management practices.

(2) Normal residential development and landscape activities that are carried out in accordance with any existing regulations, permit requirements, and best management practices.

(3) Normal recreational hunting, fishing, or boating activities that are carried out in accordance with all existing hunting, fishing, and boating regulations, and following reasonable practices and standards.

Based on the best available information, the following activities, which are activities that the Service finds could potentially harm the Canoe Creek clubshell and result in ''take'' of the species, may potentially result in a violation of section 9 of the Act if they are not authorized in accordance with applicable law; this list is not comprehensive:

(1) Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of the Canoe Creek clubshell, including import or export across State lines and international boundaries, except for properly documented antique specimens of the taxon at least 100 years old, as defined by section 10(h)(1) of the Act.

(2) Unauthorized modification of the channel, substrate, temperature, or water flow of any stream or water body in which the Canoe Creek clubshell is known to occur.

(3) Unauthorized discharge of chemicals or fill material into any waters in which the Canoe Creek clubshell is known to occur.

(4) Introduction of nonnative species that compete with or prey upon the Canoe Creek clubshell, such as the zebra mussel (*Dreissena polymorpha*) and Asian clam (*Corbicula fluminea*).

(5) Pesticide applications in violation of label restrictions.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Alabama Ecological Services

Field Office (see **FOR FURTHER INFORMATION CONTACT**).

II. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Designation also does not allow the government or public to access private lands, nor does designation require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features that occur in specific occupied areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. The implementing regulations at 50 CFR 424.12(b)(2) further delineate unoccupied critical habitat by setting out three specific parameters: (1) when designating critical habitat, the Secretary will first evaluate areas occupied by the species; (2) the Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species; and (3) for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are

occupied by the species and important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species. In considering whether features are essential to the conservation of the species, the Service may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

Canoe Creek clubshells live in freshwater rivers and streams. Clubshells, like many other freshwater mussels, live in aggregations called mussel beds, which can be patchily distributed throughout an occupied river or stream reach, but together comprise a mussel population. Mussel beds are connected to one another when host fish infested by mussel larvae in one bed disperse the larvae to another bed. While adults are mostly sedentary, larval dispersal among beds causes mussel density and abundance to vary dynamically throughout an occupied reach over time. Connectivity among beds and populations is essential for maintaining resilient populations because it allows for recolonization of areas following stochastic events. Populations that do not occupy a long enough reach or have too few or sparsely distributed beds are vulnerable to extirpation.

The primary requirements for individual Canoe Creek clubshells include the following: stable instream substrate for attaching and sheltering; clean, flowing water to keep substrates free from excess sedimentation and to facilitate host fish interactions and feeding; appropriate water quality and temperatures to meet physiological needs for survival, growth, and reproduction; food and nutrients to survive and grow; and host fish for reproduction and dispersal (see *Individual, Subpopulation, and Species Needs,* above, for more discussion of these needs).

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of the Canoe Creek clubshell from studies of the species' habitat, ecology, and life history as described below. Additional information can be found in the SSA report (Service 2020, entire; available on *https://www.regulations.gov* under Docket No. FWS–R4–ES–2020–0078). We have determined that the following physical or biological features are essential to the conservation of the Canoe Creek clubshell:

(1) Suitable substrates and connected instream habitats, characterized by a geomorphically stable stream channel (a channel that maintains its lateral dimensions, longitudinal profile, and spatial pattern over time without aggrading or degrading bed elevation) and connected instream habitats (*e.g.,* stable riffle-run-pool habitats that provide flow refuges consisting of silt-free gravel and coarse sand substrates).

(2) A hydrologic flow regime (*i.e.,* the magnitude, frequency, duration, and seasonality of discharge over time) necessary to maintain benthic habitats where the species is found; to maintain connectivity of streams with the floodplain; and to provide for normal behavior, growth, and survival of all life stages of Canoe Creek clubshell mussels and their fish hosts.

(3) Water quality (including, but not limited to, temperature, conductivity, hardness, turbidity, ammonia, heavy metals, oxygen content, and other chemical characteristics) necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages of Canoe Creek clubshell mussels and their fish hosts.

(4) Sediment quality (including, but not limited to, coarse sand and/or gravel substrates with low to moderate amounts of fine sediment, low amounts of attached filamentous algae, and other physical and chemical characteristics) necessary for normal behavior, growth, and viability of all life stages of Canoe Creek clubshell mussels and their fish hosts.

(5) The presence and abundance of known fish hosts, which may include the tricolor shiner (*Cyprinella trichroistia*), Alabama shiner (*C. callistia*), and striped shiner (*Luxilus chrysocephalus*), necessary for

recruitment of the Canoe Creek clubshell mussel.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. The features essential to the conservation of the Canoe Creek clubshell may require special management considerations or protections to ensure that conditions are improved. Examples of these threats include excessive amounts of fine sediment deposited in the channel, changes in water quality (impairment), activities that cause a destabilization of the stream channel and/or its banks, loss of riparian cover, and altered hydrology from inundation, channelization, withdrawals, or flow loss/scour resulting from other human-induced perturbations.

Management activities that could ameliorate these threats include, but are not limited to: Use of best management practices designed to reduce sedimentation, erosion, and bank-side destruction; protection of riparian corridors and retention of sufficient canopy cover along banks; exclusion of livestock and nuisance wildlife (feral hogs, exotic ungulates); moderation of surface and ground water withdrawals to maintain natural flow regimes; increased use of stormwater management and reduction of stormwater flows into the systems; use of highest water quality standards for wastewater and other return flows; and reduction of other watershed and floodplain disturbances that release sediments, pollutants, or nutrients into the water.

In summary, we find that the areas we are designating as critical habitat contain the physical and biological features that are essential to the conservation of the species and that may require special management considerations or protection. Special management considerations or protection may be required of the Federal action agency to eliminate, or to reduce to negligible levels, the threats affecting the physical and biological features of each unit.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. We are not designating any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that meet the definition of critical habitat.

To inform our designation, we reviewed observations of one or more live individuals, or recent dead shell material, from 1999 to the present because Canoe Creek clubshells may be difficult to detect and some sites have not been visited multiple times. Recently dead shell material at a site indicates the species is likely present in that area, given their average life span of 25 to 35 years. We confirmed that these areas continued to be occupied in 2017 and 2018 from surveys (Fobian *et al.* 2017, pp 26–29; Fobian 2018 pers. comm.; Fobian 2019, unpaginated). Therefore, we consider portions of the Big Canoe Creek mainstem and portions of Little Canoe Creek in its eastern and western reaches as occupied by the Canoe Creek clubshell at the time of listing.

The Canoe Creek clubshell has likely always been a narrow endemic within its single watershed. Therefore, the species' redundancy and representation is limited, but likely similar to that which it was historically. However, the species has an extremely limited ability to withstand stochastic events and disturbances because of its now critically low numbers. Conserving the species will therefore require increasing the species' abundance throughout its range and successful recruitment. Although conservation of the Canoe Creek clubshell will require improving the species' resiliency, we concluded that the occupied areas designated as critical habitat are sufficient to ensure the conservation of the species because these areas represent the maximum extent of the historical range that is capable or likely to become capable of supporting the Canoe Creek clubshell. Inundation of the lower reaches of the Big Canoe Creek watershed after the completion of Neely Henry Dam removed the physical and biological features necessary for the species for food, shelter, and reproduction in the intervening stream reaches between the occupied reaches of habitat. Based on the information available, the extent of designated CH is the best estimate of the extent of habitat that is essential to the conservation of the species.

Sources of data for this critical habitat designation include multiple databases maintained by the Service, museums, universities, nongovernmental organizations, and State agencies; scientific and agency reports; peer-reviewed journal articles; and numerous survey reports on streams throughout the species' range.

In summary, for areas within the geographic area occupied by the species at the time of listing, we delineated critical habitat unit boundaries as follows: We evaluated habitat suitability of stream segments within the geographic area occupied at the time of listing and retained those segments that contain some or all of the physical and biological features to support life-history functions essential for conservation of the species. Host fish species (minnows in the genus *Cyprinella* and *Luxilus*) are distributed throughout the occupied reaches and provide additional support that these areas are also occupied by the Canoe Creek clubshell. Then, we assessed those occupied stream segments retained through the above analysis and refined the starting and ending points by evaluating the presence or absence of appropriate physical and biological features. We selected upstream and downstream cutoff points to reference existing easily recognizable landmarks, including stream confluences, highway crossings, and the Federal Energy Regulatory Commission boundary of H. Neely Henry Reservoir. Unless otherwise specified, any stream beds located directly beneath bridge crossings or other landmark features used to describe critical habitat spatially, such as stream confluences, are considered to be wholly included within the critical habitat unit. Critical habitat stream segments were then mapped using ArcGIS Pro version 2.3.3 (ESRI, Inc.), a Geographic Information Systems program.

When determining critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the Canoe Creek clubshell. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this final rule have been excluded by text in the rule and are not designated as critical habitat. With the publication of

this final rule, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We designate as critical habitat streams that are occupied at the time of listing (*i.e.,* currently occupied) and contain one or more of the physical or biological features that are essential to support life-history processes of the species. Both designated units contain all of the identified physical or biological features and support multiple life-history processes and therefore meet the definition of critical habitat.

The final critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *https://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0078 and on our internet site at *https://www.fws.gov/office/alabama-ecological-services.*

Critical Habitat Designation

We are designating approximately 58.5 river kilometers (km) (36.3 river miles (mi)) in two units as critical habitat for the Canoe Creek clubshell. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for the Canoe Creek clubshell. The two units we designate as critical habitat are: (1) Little Canoe Creek East and (2) Big Canoe Creek/Little Canoe Creek West. Table 1 shows the critical habitat units and the approximate size of each unit. In Alabama, all waters are held within the public trust. The Service consulted with the State to confirm the status of ownership of the river bottoms in these river segments. However, this information was not available at the time of publication of this final rule.

TABLE 1—CRITICAL HABITAT UNITS FOR THE CANOE CREEK CLUBSHELL

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Adjacent land ownership by type	Size of unit in kilometers (miles)	Occupied?
1. Little Canoe Creek East	Private, County	9.7 (6.0)	Yes.
2. Big Canoe Creek/Little Canoe Creek West	Private	48.8 (30.3)	Yes.
Total		58.5 (36.3)	Yes.

Note: Sizes may not sum due to rounding.

We present brief descriptions of both units, and reasons why they meet the definition of critical habitat for the Canoe Creek clubshell, below.

Unit 1: Little Canoe Creek East

Unit 1 consists of 9.7 river km (6.0 river mi) of Little Canoe Creek East, due east of the Town of Steele, in St. Clair and Etowah Counties, Alabama. The unit consists of the Little Canoe Creek mainstem to the bankfull width from the intersection with the Federal Energy Regulatory Commission boundary of H. Neely Henry Reservoir (at elevation 155 meters (m) (509 feet (ft)) above mean sea level and approximately 4.4 river km (2.7 river mi) upstream of its confluence with Big Canoe Creek), upstream 9.7 river km (6.0 river mi) to the U.S. Highway 11 bridge crossing.

This unit is currently occupied by the Canoe Creek clubshell. The majority of the adjacent land surrounding this unit is privately owned. A small amount of the adjacent land is publicly owned in the form of bridge crossings and easements, and portions of the eastern bank of Little Canoe Creek between U.S. Highway 11 to Interstate 59, in Etowah County, Alabama. Approximately 2.4 river km (1.5 river mi) of Little Canoe Creek borders property to the east owned by Etowah County, Alabama.

Unit 1 contains all physical or biological features essential to the conservation of the species. The channel within Unit 1 is relatively stable and provides the necessary riffle-run-pool sequences required by the Canoe Creek clubshell. A continued hydrologic flow regime with adequate water quality and limited fine sediments are present within this unit, providing habitat features that support the Canoe Creek clubshell. The unit also contains fish hosts for the clubshell. The physical and biological features in this unit may require special management considerations or protections to ensure that conditions do not further degrade. Examples of threats within this unit include excessive amounts of fine sediment deposited in the channel, changes in water quality (impairment), activities that cause a destabilization of the stream channel and/or its banks, loss of riparian cover, and altered hydrology from either inundation, channelization, withdrawals, or flow loss/scour resulting from other human-induced perturbations (see Special Management Considerations or Protection, above).

Unit 2: Big Canoe Creek/Little Canoe Creek West

Unit 2 consists of 48.8 river km (30.3 river mi) of Big Canoe Creek and its tributary Little Canoe Creek West, which are located geographically between the cities of Springville and Ashville, St. Clair County, Alabama. The unit consists of the main channel of Big Canoe Creek to the bankfull width from the Double Bridge Road bridge crossing near Ashville, Alabama, upstream 32.2 river km (20.0 river mi) to the Washington Valley Rd (St. Clair County Road 23) bridge crossing near Springville, Alabama; and Little Canoe Creek West from its confluence with Big Canoe Creek, upstream 16.6 river km (10.3 river mi) to the confluence of Stovall Branch. This unit is currently occupied by the Canoe Creek clubshell. The majority of this unit is adjacent to private land, except for any small amount of adjacent land that is publicly owned in the form of bridge crossings and easements.

Unit 2 contains all physical or biological features essential to the conservation of the species. The channel within Unit 2 is relatively stable and provides the necessary riffle-run-pool sequences required by the Canoe Creek clubshell. A continued hydrologic flow regime with adequate water quality and

limited fine sediments is present within this unit, providing habitat features that support the Canoe Creek clubshell. A diverse fish fauna, including fish hosts for the clubshell, are known from this unit. The physical and biological features in this unit may require special management considerations or protections to ensure that conditions do not degrade. Examples of threats within this unit include excessive amounts of fine sediment deposited in the channel, changes in water quality (impairment), activities that cause a destabilization of the stream channel and/or its banks, loss of riparian cover, and altered hydrology from either inundation, channelization, withdrawals, or flow loss/scour resulting from other human-induced perturbations (see Special Management Considerations or Protection, above).

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species.

We published a final rule revising the definition of ''destruction or adverse modification'' on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must consult with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

Compliance with the requirements of section 7(a)(2), is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate formal consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law) and, subsequent to the previous consultation: (1) if the amount or extent of taking specified in the incidental take statement is exceeded; (2) if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion; or (4) if a new species is listed or critical habitat designated that may be affected by the identified action.

In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinitiate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the ''Adverse Modification'' Standard

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate section 7(a)(2) of the Act by destroying or adversely modifying such habitat, or that may be affected by such designation.

Activities that the Service may, during a consultation under section 7(a)(2) of the Act, consider likely to destroy or adversely modify critical habitat include, but are not limited to:

(1) Actions that would alter the geomorphology of stream and river habitats. Such activities could include, but are not limited to, instream excavation or dredging, impoundment, channelization, sand and gravel mining, clearing riparian vegetation, and discharge of fill materials. These activities could cause aggradation or degradation of the channel bed elevation or significant bank erosion and result in entrainment or burial of this mussel, and could cause other direct or cumulative adverse effects to this species and its life cycles.

(2) Actions that would significantly alter the existing flow regime where this species occurs. Such activities could include, but are not limited to, impoundment, urban development, water diversion, and water withdrawal. These activities could eliminate or reduce the habitat necessary for growth and reproduction of this mussel and its fish hosts.

(3) Actions that would significantly alter water chemistry or water quality (for example, temperature, pH, contaminants, and excess nutrients). Such activities could include, but are not limited to, hydropower discharges, or the release of chemicals, biological pollutants, or heated effluents into surface water or connected groundwater at a point source or by dispersed release (nonpoint source). These activities could alter water conditions that are beyond the tolerances of this mussel, its fish hosts, or both, and result in direct or cumulative adverse effects to the species throughout its life cycle.

(4) Actions that would significantly alter stream bed material composition and quality by increasing sediment deposition or filamentous algal growth. Such activities could include, but are not limited to, construction projects, gravel and sand mining, oil and gas development, coal mining, livestock grazing and other agricultural practices, irresponsible timber harvest, and other watershed and floodplain disturbances that release sediments or nutrients into the water. These activities could eliminate or reduce habitats necessary for the growth and reproduction of this mussel, its fish hosts, or both, by causing excessive sedimentation and burial of the species or its habitat, or nutrification leading to excessive filamentous algal growth. Excessive filamentous algal growth can cause reduced nighttime dissolved oxygen levels through respiration, and prevent juvenile mussels from settling into stream sediments.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DoD), or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation. There are no DoD lands within the final critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if we determine that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless we determine, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

On December 18, 2020, we published a final rule in the **Federal Register** (85 FR 82376) revising portions of our regulations pertaining to exclusions of critical habitat. These final regulations became effective on January 19, 2021 and apply to critical habitat rules for which a proposed rule was published after January 19, 2021. Consequently, these new regulations do not apply to this final rule.

Under section 4(b)(2) of the Act, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise discretion to exclude the area only if such exclusion would not result in the extinction of the species. We describe below the process that we undertook for taking into consideration each category of impacts and our analyses of the relevant impacts.

In this final rule, we have not considered any areas for exclusion from critical habitat.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas designated. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.''

The ''without critical habitat'' scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (*e.g.,* under the Federal listing as well as other Federal, State, and local regulations). The baseline, therefore, represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.,* conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat when conducting a discretionary 4(b)(2) exclusion analysis.

For this particular designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the Canoe Creek clubshell, which was revised based on comments received during the comment period (IEc 2021, entire). We began by conducting a screening analysis of the designation of critical habitat in order to focus our analysis on the key factors that are likely to result in incremental economic impacts. The purpose of the screening analysis is to filter out particular geographic areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts.

In particular, the screening analysis considers baseline costs (*i.e.,* absent critical habitat designation) and includes probable economic impacts where land and water use may be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species. Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. If there are any unoccupied units in the critical habitat designation, the screening analysis assesses whether any additional management or conservation efforts may incur incremental economic impacts. This screening analysis, combined with the information contained in our IEM, constitutes what we consider our economic analysis of the critical habitat designation for the Canoe Creek clubshell and is summarized in the narrative below.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities.

As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from the designation of critical habitat for the Canoe Creek clubshell, first we identified, in the IEM dated November 27, 2019, probable incremental economic impacts associated with the following categories of activities: (1) Agriculture, (2) poultry farming, (3) grazing, (4) development, (5) recreation, (6) restoration activities, (7) flood control, (8) transportation, and (9) utilities. We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. In areas where the Canoe Creek clubshell is present, Federal agencies would be required to consult with the Service under section 7 of the Act on activities they fund, permit, or implement that may affect the species. When this rule becomes effective (see **DATES**, above), consultations to avoid the destruction or adverse modification of Canoe Creek clubshell critical habitat would be incorporated into the existing consultation process.

In our IEM, we attempted to clarify the distinction between the effects that will result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for the Canoe Creek clubshell's critical habitat. Because the designation of critical habitat for the Canoe Creek clubshell is finalized concurrently with the listing, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the species being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would result in sufficient harm or harassment to constitute jeopardy to the Canoe Creek clubshell would also likely adversely affect the essential physical or biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this designation of critical habitat.

The evaluation of incremental costs of designating critical habitat for the Canoe Creek clubshell indicates costs are relatively low. The critical habitat designation for the Canoe Creek clubshell totals approximately 58.5 river kilometers (36.3 river miles) of river up to the bankfull width adjacent to private property across two currently occupied units in the Big Canoe Creek watershed. Numerous other listed species co-occur with the Canoe Creek clubshell in these areas (*e.g.* Georgia pigtoe, finelined pocketbook (*Hamiota altilis*), and triangular kidneyshell (*Ptychobranchus greenii*)). As a result, all activities with a Federal nexus occurring in these areas are already subject to section 7 consultation requirements regardless of a critical habitat designation for the Canoe Creek clubshell. Based on historical consultation rates for co-occurring species, we anticipate approximately five or fewer section 7 consultation actions per year in the critical habitat areas for the Canoe Creek clubshell.

In addition, any actions that may affect the Canoe Creek clubshell or its habitat in these areas would also affect designated critical habitat, and it is unlikely that any additional conservation efforts would be recommended to address the adverse modification standard over and above those recommended as necessary to avoid jeopardizing the continued existence of the species. Therefore, when section 7 consultations occur, the only costs expected are those associated with the additional administrative effort needed to consider adverse modification during the consultation process. While this additional analysis would require time and resources by both the Federal action agency and the Service, we believe that in most circumstances, these costs would be predominantly administrative in nature and would not be significant.

Further, we do not expect the designation of critical habitat for the Canoe Creek clubshell to trigger additional requirements under State or local regulations or have perceptional effects on markets. We also do not predict the designation would result in additional section 7 efforts needed to conserve the species. Thus, the annual administrative burden is unlikely to reach $100 million.

In conclusion, based on our estimate of the number of consultations and their costs, which would likely be limited to those associated with administrative efforts, we estimate that the annual costs to the Service and Action agencies from designating critical habitat for the Canoe Creek clubshell would be approximately $18,300. Therefore, the designation is unlikely to meet the threshold of $100 million in a single year for an economically significant rule, with regard to costs, under E.O. 12866.

Consideration of National Security Impacts

Section 4(a)(3)(B)(i) of the Act may not cover all DoD lands or areas that pose potential national-security concerns (*e.g.,* a DoD installation that is in the process of revising its INRMP for a newly listed species or a species previously not covered). If a particular area is not covered under section 4(a)(3)(B)(i), national-security or homeland-security concerns are not a factor in the process of determining

what areas meet the definition of ''critical habitat.'' Nevertheless, when designating critical habitat under section 4(b)(2), the Service must consider impacts on national security, including homeland security, on lands or areas not covered by section 4(a)(3)(B)(i). Accordingly, we will always consider for exclusion from the designation areas for which DoD, Department of Homeland Security (DHS), or another Federal agency has requested exclusion based on an assertion of national-security or homeland-security concerns.

We cannot, however, automatically exclude requested areas. When DoD, DHS, or another Federal agency requests exclusion from critical habitat on the basis of national-security or homeland-security impacts, it must provide a reasonably specific justification of an incremental impact on national security that would result from the designation of that specific area as critical habitat. That justification could include demonstration of probable impacts, such as impacts to ongoing border-security patrols and surveillance activities, or a delay in training or facility construction, as a result of compliance with section 7(a)(2) of the Act. If the agency requesting the exclusion does not provide us with a reasonably specific justification, we will contact the agency to recommend that it provide a specific justification or clarification of its concerns relative to the probable incremental impact that could result from the designation. If the agency provides a reasonably specific justification, we will defer to the expert judgment of DoD, DHS, or another Federal agency as to: (1) Whether activities on its lands or waters, or its activities on other lands or waters, have national-security or homeland-security implications; (2) the importance of those implications; and (3) the degree to which the cited implications would be adversely affected in the absence of an exclusion. In that circumstance, in conducting a discretionary section 4(b)(2) exclusion analysis, we will give great weight to national-security and homeland-security concerns in analyzing the benefits of exclusion.

In preparing this rule, we have determined that the lands within the designation of critical habitat for the Canoe Creek clubshell are not owned, managed, or used by the DoD or DHS, and, therefore, we anticipate no impact on national security or homeland security. Consequently, the Secretary is not exercising her discretion to exclude any areas from the final designation based on impacts on national security.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security discussed above. We consider a number of factors, including whether there are permitted conservation plans (such as HCPs, safe harbor agreements (SHAs), or candidate conservation agreements with assurances (CCAAs)) covering the species in the area, or whether there are non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at the existence of Tribal conservation plans and partnerships and consider the government-to-government relationship of the United States with Tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this final rule, we have determined that there are currently no HCPs or other management plans for the Canoe Creek clubshell, and the designation does not include any Tribal lands or trust resources. Therefore, we anticipate no impact on Tribal lands, partnerships, or HCPs from this critical habitat designation and thus, as described above, we are not excluding any particular areas on the basis of the presence of conservation agreements or impacts to trust resources.

Summary of Exclusions Considered Under 4(b)(2) of the Act

During the development of this final rule, we considered any additional information we received through the public comment period to determine whether any specific areas should be excluded from the final critical habitat designation under authority of the Act's section 4(b)(2) and our implementing regulations at 50 CFR 424.19. We are not excluding any areas from the critical habitat designation under section 4(b)(2) of the Act based on economic impacts, national security impacts, or other relevant impacts, such as partnerships, management, or protection afforded by cooperative management efforts.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual

sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be directly regulated by this designation. There is no requirement under the RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities will be directly regulated by this rulemaking, the Service certifies that this final critical habitat designation will not have a significant economic impact on a substantial number of small entities.

During the development of this final rule, we reviewed and evaluated all information submitted during the comment period on the November 3, 2020, proposed rule (85 FR 69540) that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. Based on this information, we affirm our certification that this critical habitat designation will not have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. OMB has provided guidance for implementing this Executive Order that outlines nine outcomes that may constitute ''a significant adverse effect'' when compared to not taking the regulatory action under consideration. The economic analysis finds that none of these criteria are relevant to this analysis. Thus, based on information in the economic analysis, energy-related impacts associated with Canoe Creek clubshell conservation activities within critical habitat are not expected. As such, the designation of critical habitat is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or Tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments because the units do not occur within the jurisdiction of small governments. Therefore, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the Canoe Creek clubshell in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify

critical habitat. A takings implications assessment has been completed and concludes that this designation of critical habitat for the Canoe Creek clubshell does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of the critical habitat designation with, appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the rule does not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this rule identifies the physical or biological features essential to the conservation of the species. The designated areas of critical habitat are presented on maps, and the rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), *cert. denied,* 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that no Tribal lands fall within the boundaries of the critical habitat for the Canoe Creek clubshell, so no Tribal lands will be affected by the designation.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2020–0078 and upon request from the Alabama Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rule are the staff members of the U.S. Fish and Wildlife Service Species Assessment Team and Alabama Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11, in paragraph (h), by adding an entry for ''Clubshell, Canoe Creek'' to the List of Endangered and Threatened Wildlife in alphabetical order under CLAMS to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
CLAMS				
*	*	*	*	*
Clubshell, Canoe Creek	*Pleurobema athearni*	Wherever found	E	87 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS], July 6, 2022; 50 CFR 17.95(f).[CH]
*	*	*	*	*

■ 3. Amend § 17.95, in paragraph (f), by adding an entry for ''Canoe Creek Clubshell (*Pleurobema athearni*)'' before the entry for ''Appalachian Elktoe (*Alasmidonta raveneliana*)'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(f) *Clams and Snails.*

Canoe Creek Clubshell (*Pleurobema athearni*)

(1) Critical habitat units are depicted for St. Clair and Etowah Counties, Alabama, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of the Canoe Creek clubshell consist of the following components:

(i) Suitable substrates and connected instream habitats, characterized by a geomorphically stable stream channel (a channel that maintains its lateral dimensions, longitudinal profile, and spatial pattern over time without aggrading or degrading bed elevation) and connected instream habitats (such as stable riffle-run-pool habitats that provide flow refuges consisting of silt-free gravel and coarse sand substrates).

(ii) A hydrologic flow regime (*i.e.,* the magnitude, frequency, duration, and seasonality of discharge over time) necessary to maintain benthic habitats where the species is found; to maintain connectivity of streams with the floodplain; and to provide for normal behavior, growth, and survival of all life stages of Canoe Creek clubshell mussels and their fish hosts.

(iii) Water quality (including, but not limited to, temperature, conductivity, hardness, turbidity, ammonia, heavy metals, oxygen content, and other chemical characteristics) necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages of Canoe Creek clubshell mussels and their fish hosts.

(iv) Sediment quality (including, but not limited to, coarse sand and/or gravel substrates with low to moderate amounts of fine sediment, low amounts of attached filamentous algae, and other physical and chemical characteristics) necessary for normal behavior, growth, and viability of all life stages of Canoe Creek clubshell mussels and their fish hosts.

(v) The presence and abundance of fish hosts, which may include the tricolor shiner (*Cyprinella trichroistia*), Alabama shiner (*C. callistia*), and striped shiner (*Luxilus chrysocephalus*), necessary for recruitment of the Canoe Creek clubshell mussel.

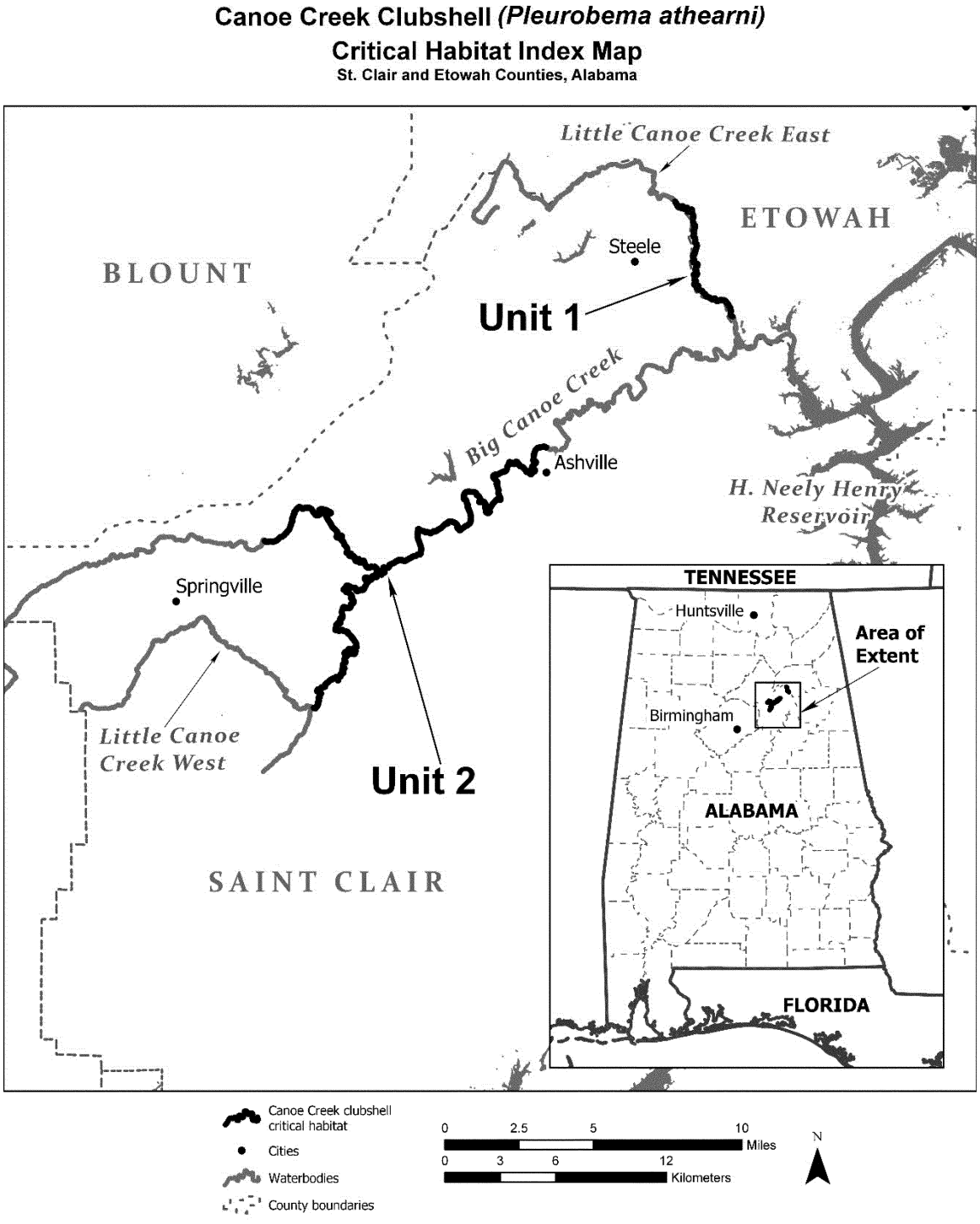
(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of the final rule.

(4) Data layers defining map units were created from the National Hydrography High Resolution Dataset, and critical habit units were mapped using North American Datum (NAD) 1983 Universal Transverse Mercator (UTM) Zone 16N coordinates. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's internet site at *https://www.fws.gov/daphne,* at *https://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0078, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Index map follows:

BILLING CODE 4333–15–P

Figure 1 to Canoe Creek Clubshell (*Pleurobema athearni*) paragraph (5)

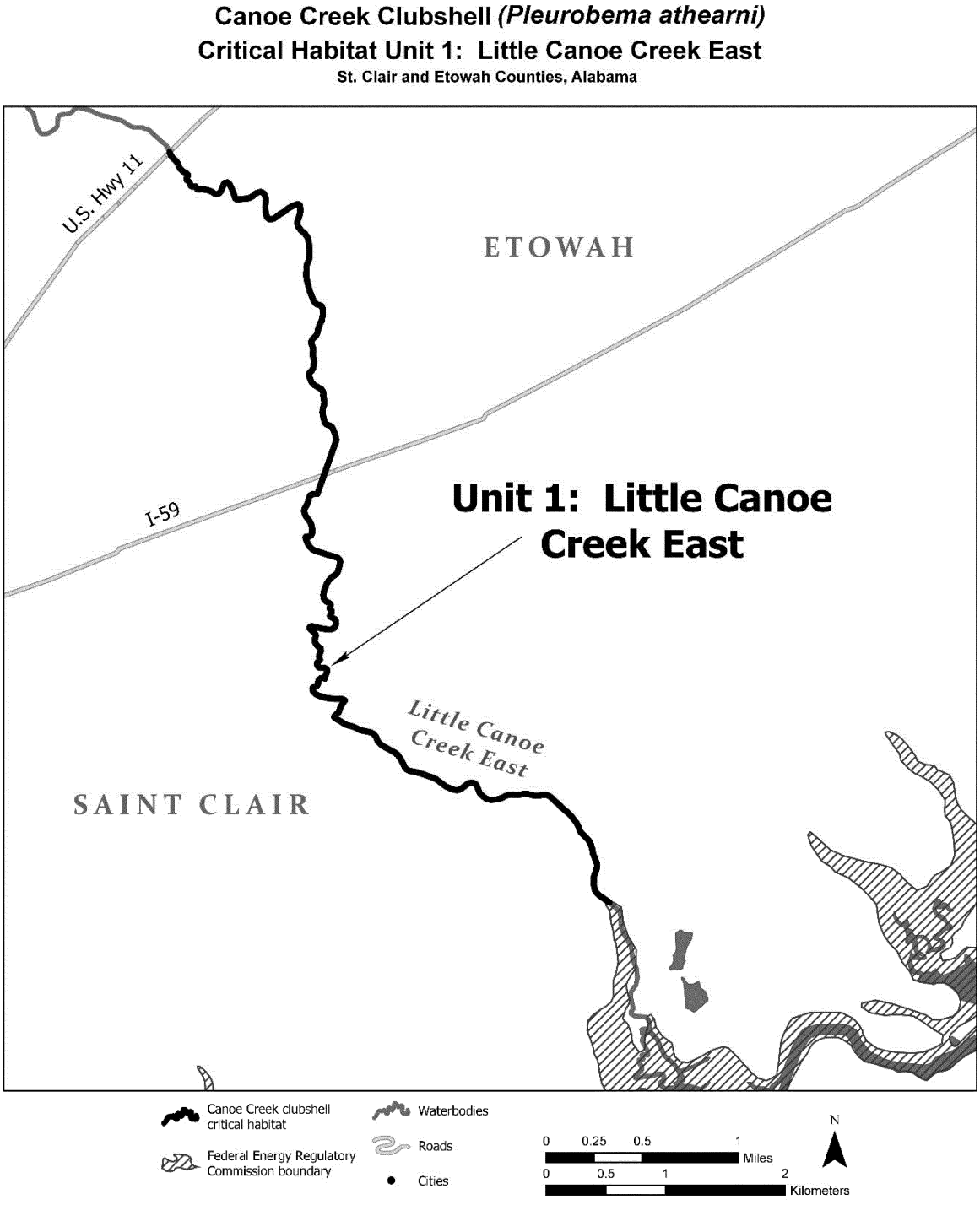


(6) Unit 1: Little Canoe Creek East, St. Clair and Etowah Counties, Alabama.

(i) Unit 1 consists of 9.7 river km (6.0 river mi) of Little Canoe Creek East, due east of the Town of Steele, in St. Clair and Etowah Counties, Alabama.

(ii) Map of Unit 1 follows:

Figure 2 to Canoe Creek Clubshell (*Pleurobema athearni*) paragraph (6)(ii)

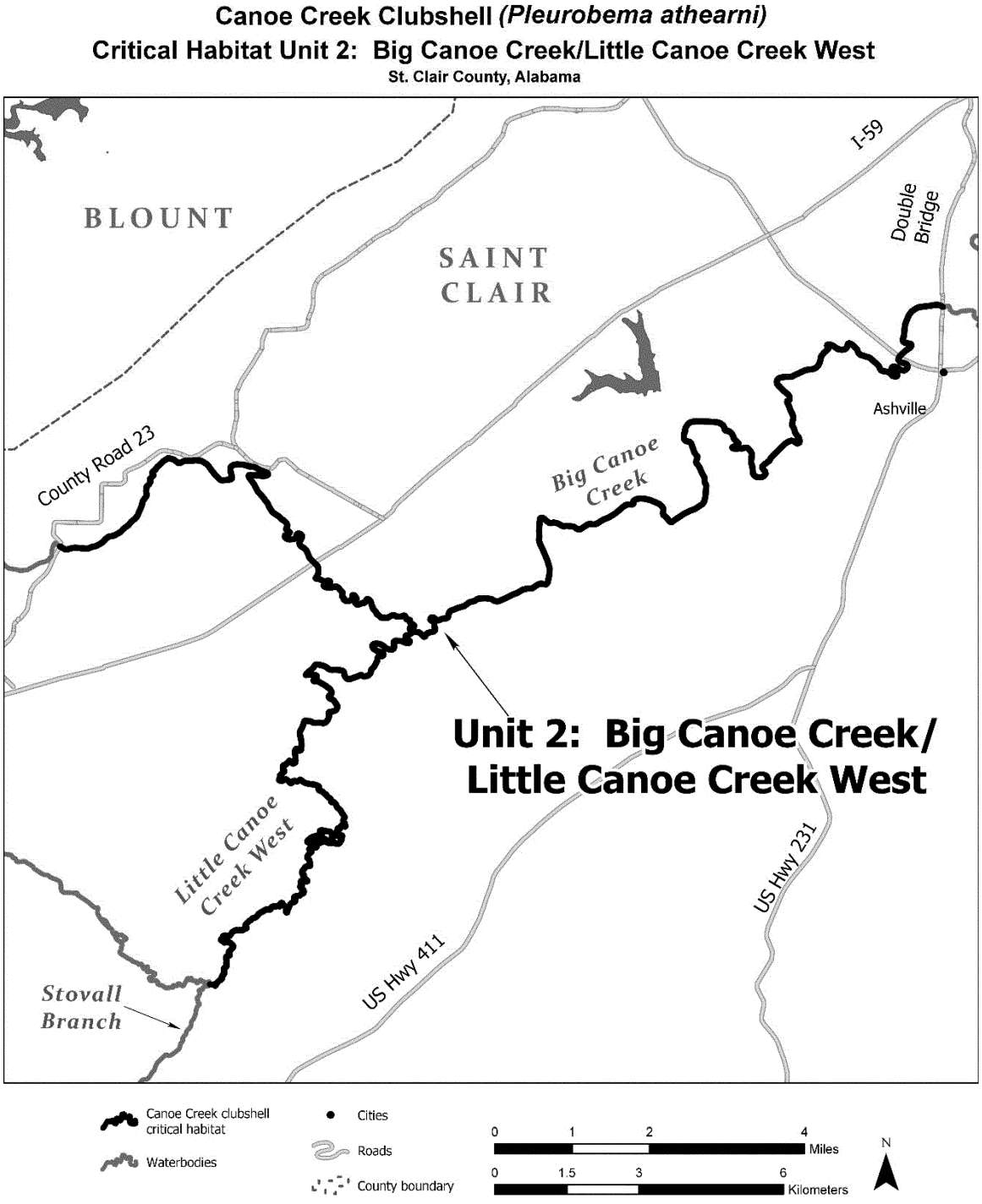


(7) Unit 2: Big Canoe Creek/Little Canoe Creek West, St. Clair County, Alabama.

(i) Unit 2 consists of 48.8 river km (30.3 river mi) of Big Canoe Creek and its tributary Little Canoe Creek West.

(ii) Map of Unit 2 follows:

Figure 3 to Canoe Creek Clubshell (*Pleurobema athearni*) paragraph (7)(ii)



* * * * *

Martha Williams

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–14312 Filed 7–5–22; 8:45 am]

BILLING CODE 4333–15–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

RIN 0648–BL05

Fisheries of the Northeastern United States; Atlantic Mackerel; 2022 Interim Action Extension

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

ACTION: Temporary rule; interim measures extended.

SUMMARY: This temporary rule extends the interim specifications for the 2022 fishing year to address new assessment information regarding the status of the Atlantic mackerel stock. This action continues to reduce potential Atlantic mackerel overfishing based on new 2021 assessment findings while a revised rebuilding plan is being developed.

DATES: The expiration date of the temporary rule published January 12, 2022 (87 FR 1700), is extended to Friday, January 13, 2023.

ADDRESSES: The supporting documents for the action are available upon request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 N State Street, Dover, DE 19901. These documents are also accessible via the internet at *https://www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Aly Pitts, Fishery Management Specialist, (978) 281–9352.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council (Council) manages the Atlantic mackerel fishery under the Mackerel, Squid, and Butterfish (MSB) Fishery Management Plan (FMP). Section 305(c) of the Magnuson-Stevens Act allows the Secretary to implement interim measures to reduce or address overfishing. In situations such as this, in which the Mid-Atlantic Council is finalizing a new rebuilding plan, section 304(e)(6) allows the Council to request the Secretary to implement interim measures to reduce overfishing, even if such measures are not sufficient themselves to stop overfishing, until such measures can be replaced by the rebuilding plan. As further described below, NMFS implements this action to extend the interim rule that adjusts the domestic annual harvest (DAH, or commercial quota) from the previously implemented amount of 17,312 metric tons (mt) to 4,963 mt in order to minimize overfishing while the Council's revised rebuilding plan can be implemented (87 FR 1700; January 12, 2022). The initial interim rule for this action included additional background on specifications and the details of how the Council derived its recommended specifications for Atlantic mackerel. Those details are not repeated here. For additional information, please refer to the initial interim rule for this action.

Interim Atlantic Mackerel Specifications for 2022

Based on the recommendations of the Scientific and Statistical Committee (SSC), the MSB Monitoring Committee, and the Council, this action sets the 2022 Atlantic mackerel specifications, specifically the DAH to 4,963 mt. These specifications also maintain the 129-mt river herring and shad catch cap for 2022. There is an Atlantic mackerel stock assessment update scheduled for 2022 that will inform future specifications.

The initial temporary rule has an effective period limited by the Magnuson-Stevens Act to 180 days, with a potential extension of an additional 186 days. The Council has approved a revised rebuilding plan, which it intends to be implemented by January 1, 2023. However, the expected rulemaking implementing the rebuilding plan will not be in place before the expiration of the initial interim rule, on July 11, 2022. Therefore, we are extending the interim measures for 186 days to ensure the revised 2022 specifications remain in place for the full 2022 fishing year.

Justification for Extended Interim Measures

Section 305(c) of the Magnuson-Stevens Act (16 U.S.C. 1855(c) authorizes the Secretary of Commerce to implement interim measures to address overfishing. This action meets the 305(c) requirements for interim measures because it is necessary to minimize overfishing on the Atlantic mackerel stock that remains overfished while the Council develops a new rebuilding program for the stock.

While some changes resulting from the 2021 stock assessment were expected, the magnitude of the shift in the perception of stock status necessitating changes to the catch limits was not, and could not have been, foreseen. The assessment results only recently became available, after the Council took final action on, and we implemented, the 2022 specifications. Based on this new information, and only two years after the implementation of the original rebuilding program for mackerel, the Council needed to develop a new rebuilding plan to incorporate the most recent scientific information. However, given that the new information only recently became available, the Council could not complete an action to develop a new rebuilding plan and adjust specifications in time for the 2022 fishing year. Because of unforeseen specification adjustments necessary to address the recent stock assessment, the Council requested that NMFS take action to reduce potential additional Atlantic mackerel harvest in 2022 via a reduction in the commercial quota while the Council developed a new Atlantic mackerel rebuilding plan for 2023. If this temporary rule is not implemented by July 11, 2022, the 2022 specifications will revert to those previously implemented based on information that does not include the most recent 2021 assessment results. Delayed implementation of these measures increases the risk and magnitude of overfishing for 2022 by allowing the original 17,312 mt commercial catch rather than 4,963 mt, implemented by the initial interim rule.

Extending these interim measures minimizes overfishing in the Atlantic mackerel fishery and additional negative impacts to the already overfished fishery resource, as well as ensures mackerel specifications are based on the best scientific information available. Therefore, avoiding the serious conservation and management problem of subjecting the overfished Atlantic mackerel stock to continued overfishing conditions due to previously unforeseen circumstances justifies these interim measures, and outweighs the benefit of advance notice and comment.

Renewal of Interim Regulations

The Magnuson-Stevens Act limits NMFS' authority to implement interim measures for an initial period of 180 days, with a potential extension up to an additional 186 days, if warranted. The public had an opportunity to comment on the specification measures in this temporary rule upon issuance of the initial interim rule, and we did not receive any comments in response to the public notice on the initial interim rule. In accordance with Magnuson-Stevens Act section 305(c)(3)(B), NMFS is extending the interim measures for one additional period of not more than 186 days to maintain the interim measures until permanent rulemaking can be implemented.

Classification

NMFS issues this action pursuant to section 305(c) of the Magnuson-Stevens Act. This action is required by 50 CFR part 648, which was issued pursuant to section 304(b).

The Assistant Administrator for Fisheries, NOAA, finds that it would be unnecessary and contrary to the public interest to provide for prior notice and an opportunity for public comment, pursuant to 5 U.S.C. 553(b)(B). We implemented an interim rule on January 7, 2022, effective through July 11, 2022, that set Atlantic mackerel commercial harvest levels for 2022 that would maintain total catch similar to 2021 levels. This action would extend the interim measures to reduce catch rates to ensure 2022 catch does not exceed harvest levels to minimize overfishing. This rule would maintain the commercial DAH of 4,963 mt to maintain total 2022 harvest levels and incorporate new estimates of Canadian landings and U.S. recreational harvest. Harvest levels have been well below the DAH in recent years, and based on recent fishery operations and trends, this action is not expected to substantially change overall effort or harvest levels.

This action is being implemented pursuant to section 305(c) of the Magnuson-Stevens Act in order to minimize overfishing while the Council responds to the new, updated information. These provisions of the Magnuson-Stevens Act anticipate that interim provisions like these can be extended by publication in the **Federal Register** if the public had been provided an opportunity to comment on the original measures. A delay would be contrary to the public interest for the Atlantic mackerel fishery. Implementing a reduced DAH for fishing year 2022 was anticipated and discussed during development and implementation of the original specifications action (86 FR 38586, June 22, 2021), as well as at the August and October 2021 Council meetings. Fishery stakeholders are anticipating action to reduce mackerel harvest for the entirety of 2022, and they were provided the opportunity to comment on this in response to the public notice for the original interim rule.

Where the public has had an opportunity to review the development of the Council action to reduce Atlantic mackerel catch for 2022 based on the best available science (the purpose of this action), as well as the original interim rule, the value of a delay in its effectiveness would be outweighed by the need to implement this adjustment as quickly as possible. Failure to implement this action as quickly as possible for the remainder of the 2022 fishing year could result in 2022 catch that could have potential negative biological impacts, as well as the potential to hinder the efficacy of the Council's new rebuilding plan, which presumed the interim measures would apply to the entirety of 2022. Given the high-volume nature of the fishery and the reduced DAH, there is a risk that the fishery will exceed the DAH if there is a lapse of the interim rule. A delay would be contrary to the public interest while we take action to implement the Council's new rebuilding plan for this species. For the same reasons, the Assistant Administrator finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay of effectiveness period for this. This rule should be effective as close to and not after, July 11, 2022, as possible, to fully realize the intended benefits to this high-volume fishery.

This action is being taken pursuant to the 305(c) emergency action and interim measures provision of the Magnuson-Stevens Act and is exempt from Office of Management and Budget (OMB) review.

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

This rule does not duplicate, conflict, or overlap with any existing Federal rules.

This action would not establish any new reporting or recordkeeping requirements.

This interim rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

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

Dated: June 28, 2022.

Samuel D. Rauch, III,

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

[FR Doc. 2022–14181 Filed 7–5–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 128
Wednesday, July 6, 2022

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

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 121, 125, and 128

RIN 3245–AH69

Veteran-Owned Small Business and Service-Disabled, Veteran-Owned Small Business—Certification

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The Small Business Administration (SBA) is proposing to amend its regulations to implement a statutory requirement to certify Veteran-Owned Small Business Concerns and Service-Disabled Veteran-Owned Small Business Concerns participating in the Veterans Certification Program.

DATES: Comments must be received on or before August 5, 2022.

ADDRESSES: You may submit comments, identified by RIN 3245–AH69, by any of the following methods:

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

2. *For Mail, Paper, Disk, or CD/ROM Submissions:* Timothy Green, U.S. Small Business Administration, Office of Veterans Business Development, 409 Third Street SW, 5th Floor, Washington, DC 20416.

3. *Hand Delivery/Courier:* Timothy Green, U.S. Small Business Administration, Office of Veterans Business Development, 409 Third Street SW, 5th Floor, Washington, DC 20416.

Instructions: SBA will post all comments on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* please submit the information to Timothy Green, U.S. Small Business Administration, Office of Veterans Business Development, 409 Third Street SW, 5th Floor, Washington, DC 20416, or send an email to *Timothy.green@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination on whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Timothy Green, U.S. Small Business Administration, Office of Veterans Business Development, 409 Third Street SW, 5th Floor, Washington, DC 20416; (202) 205–6777; *Timothy.green@sba.gov.* This phone number may also be reached by individuals who are deaf or hard of hearing, or who have speech disabilities, through the Federal Communications Commission's TTY-Based Telecommunications Relay Service teletype service at 711.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Small Business Administration (SBA) is seeking input and comments on a proposed rule to establish a certification program for Veteran-Owned Small Businesses (VO SBC) and Service-Disabled Veteran-Owned Small Businesses (SDVO SBC). SBA is planning to amend its regulations to implement section 862 of the National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283, 128 Stat. 3292 (January 1, 2021) (NDAA 2021).

The Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business Programs, set forth in 38 U.S.C. 8127, authorize Federal contracting officers to restrict competition to eligible VO SBCs and SDVO SBCs for Department of Veterans Affairs (VA) contracts. To be eligible for VA contracts, VO SBCs and SDVO SBCs must be verified by VA's Center for Verification and Evaluation (CVE) in accordance with 38 U.S.C. 8127. There is currently no Government-wide SDVO SBC certification program, and firms seeking to be awarded SDVO SBC sole source or set-aside contracts with Federal agencies other than the VA, only need to self-certify their status as set forth in section 36 of the Small Business Act, 15 U.S.C. 657f.

NDAA 2021 amended the VO SBC/SDVO SBC requirements to transfer the responsibility for certification of VO SBCs and SDVO SBCs to SBA as of January 1, 2023 (Transfer Date) and created a certification requirement at SBA for SDVO SBCs seeking sole source and set-aside contracts across the Federal Government. Section 862 also created a one-year grace period after the Transfer Date for businesses currently self-certifying to file an application for SDVO SBC certification with SBA. Self-certified SDVO SBCs that submit an application within the one-year grace period will maintain eligibility until SBA makes a final eligibility decision. With the exception of this grace period, once this rulemaking is finalized, VO SBCs and SDVO SBCs that are not certified by SBA's Veterans Certification Program (Vets Program) will not be eligible to receive sole source or set-aside VO SBC or SDVO SBC awards across the Federal Government.

Firms verified by VA's CVE prior to the Transfer Date will be deemed eligible by SBA during the time that remains in the firm's three-year term of eligibility. To remain certified by SBA after the Transfer Date, those verified firms will be required to meet all conditions of eligibility as described in SBA's revised regulations. With this rulemaking, SBA is also proposing to grant reciprocity to participants in SBA's 8(a) Business Development and Women-Owned Small Business (WOSB) programs that are owned and controlled by one or more veterans, or in the case of an SDVO SBC, service-disabled veterans. Both the 8(a) and WOSB programs require applicants to demonstrate ownership and control to be eligible for certification. The ownership and control requirements for those programs are basically the same as those set forth in this proposed rule for VO SBCs and SDVO SBCs, and the rulemaking would provide an expedited application and review process for 8(a)/WOSB-certified firms seeking VO SBC/SDVO SBC certification. In such cases, SBA would confirm the identified individual's eligibility as a veteran or service-disabled veteran before granting certification. SBA believes reciprocity between SBA's certification programs would create program administration efficiencies as well as reduced processing time for applicants.

SBA proposes to implement the Veterans Certification Program in a new 13 CFR part 128. As proposed, 13 CFR part 128 would be organized into the following subparts: Subpart A—Provisions of General Applicability, Subpart B—Eligibility Requirements for the Veterans Certification Program, Subpart C—Certification of VO SBC or SDVO SBC Status, Subpart D—Federal

Contract Assistance, Subpart E—Protests Concerning VO SBC and SDVO SBCs, Subpart F—Penalties and Retention of Records, and Subpart G—Surplus Personal Property for Veteran-Owned Small Business Programs. SBA's proposed rule is an effort to create a seamless transfer of the VO SBC/SDVO SBC verification function from VA to SBA. To accomplish this task, SBA consolidated existing regulations for the SDVO SBC program at 13 CFR part 125 with VA's CVE verification guidelines at 38 CFR part 74. To further ensure continuity for Vets Program participants during and after the transfer, SBA generally adopted VA's application guidelines, rules on continuing eligibility, program examinations, and program exit procedures at 38 CFR part 74 with few exceptions.

Concurrently, SBA proposes to amend 13 CFR part 125 to remove SDVO SBC regulations in subparts A through F, consisting of §§ 125.11 through 125.100, and include them in 13 CFR part 128. SBA also proposes to amend references to part 125 in SBA's size regulations at 13 CFR part 121.

II. Section-by-Section Analysis

For ease of review, SBA organized proposed part 128's ''Section-by-Section Analysis'' into subparts and sections. Each section has a citation, heading, and the section's source citation. The source citations correspond to either 13 CFR part 125 or 38 CFR part 74. Sections with no corresponding regulation are marked ''New.''

Subpart A—Provisions of General Applicability

Section 128.100 What is the purpose of this part? (New)

Proposed § 128.100 would add a general purpose section for the Veterans Certification Program with statutory authority for contractual assistance to VO SBCs and SDVO SBCs. There was no equivalent section in previous SDVO regulations at part 125 and SBA is proposing this amendment to match the general applicability subparts found in SBA's other certification programs.

Section 128.101 What type of assistance is available under this part? (New)

Given the unique nature of VA's contractual assistance program, SBA believes it is important to distinguish the differences in contractual assistance available between VO SBC/SDVO SBC contracts at VA and SDVO SBC contracts across the rest of the Federal Government. Accordingly, this proposed amendment adds the two types of assistance available to participants in the Veterans Certification Program. There was no equivalent section in previous SDVO SBC regulations in part 125.

Section 128.102 What definitions are important in the Veterans Certification Program? (Former § 125.11 and 38 CFR 74.1)

Section 128.102 as proposed, consolidates the definitions sections of 13 CFR 125.11 and 38 CFR 74.1. In general, § 128.102 would adopt VA's existing definitions which applied to the verification process, remove duplicate definitions between VA and SBA regulations, remove VA definitions that referenced SBA's definitions at § 125.11, and eliminate definitions that are no longer applicable to the SBA's new certification program. Section 125.11 currently includes a definition of VO SBC and SDVO SBC. SBA is proposing to move these definitions into the eligibility section at § 128.200 in subpart B.

Subpart B—Eligibility Requirements for the Veterans Certification Program

Section 128.200 What are the requirements a concern must meet to qualify as a VO SBC or SDVO SBC? (New)

As proposed, this section would reflect the separate and distinct eligibility requirements for certification as a VO SBC or SDVO SBC. Proposed § 128.200 would incorporate the definitions of VO SBC and SDVO SBC previously included as definitions in § 125.11. Proposed § 128.200 would also expand how SBA currently defines a VO SBC/SDVO SBC. Previously, only VO SBC/SDVO SBCs that were small in their primary North American Industry Classification System (NAICS) code were considered eligible. This proposed amendment would allow an entity to apply for certification if the concern, with its affiliates, meets the size standard corresponding to any NAICS code under which it currently conducts business activities. Given that ''currently conducts business activities'' is not defined in regulations, SBA is seeking comment on how best to define this term for the purposes of certification. For set aside or sole source VO or SDVO contracts, certified firms would still be required to be small within the size standard corresponding to the NAICS code assigned to the contract. This proposed amendment is also reflected in the definitions section at § 128.102 and application procedures at § 128.303.

Pursuant to NDAA 2021, the proposed section would add paragraph (c)(1) to require participants to certify with SBA and paragraph (c)(2) to clarify that certification is only required for sole source and set-aside awards. Firms that do not apply for certification in the Vets Program may continue to self-certify their status, receive contract awards outside the Vets Program through open competition or other types of set-asides, and count toward an agency's goals. For example, a self-certified SDVO SBC may be awarded a small business set-aside and the agency may count the award as both a small business and SDVO SBC toward the agency's goals. For those purposes only, contracting officers would be able to accept self-certifications without requiring them to verify any documentation.

Section 128.201 What other eligibility requirements apply for individuals or businesses? (Former 38 CFR 74.2(b) Through (f))

Section 128.201 as proposed, would add conditions of eligibility for certification which are incorporated from additional eligibility requirements for verification by CVE at § 74.2(b) through (f). This rulemaking proposes to eliminate consideration of whether an individual who is currently incarcerated, or on parole or probation owns or controls an applicant concern in determining whether the applicant possesses good character and qualifies as a VO SBC or SDVO SBC. SBA believes that its role should be limited to determining whether an applicant is owned and controlled by one or more veterans or service-disabled veterans. Whether an individual involved with the applicant is currently incarcerated, or on parole or probation is a responsibility issue, and whether a concern possesses the responsibility to perform a contract is a contract specific issue, not an underlying eligibility issue. SBA views the issues as to whether the concern has the necessary integrity to perform a contract in the same way as it does questions relating to whether the concern has the necessary financial wherewithal, capacity or tenacity, and perseverance to perform a contract. All are responsibility issues determined by a contracting officer relating to a specific contract. SBA's certification as to whether an applicant is owned and controlled by one or more veterans or service-disabled veterans should be limited to consideration of an individual's status as a veteran or service-disabled veteran, the ownership and control of the applicant, and ensuring that the applicant qualifies as

small under the size standard corresponding to any work that it currently performs and would continue to seek to perform through the VO or SDVO small business programs. Thus, as proposed, the good character review would be limited to ensuring that an applicant or principal was not debarred or suspended. SBA also considered retaining a modified good character requirement that could render an applicant ineligible if there were outstanding issues relating to moral turpitude or business integrity, but again concluded that that would also be more appropriately considered by a contracting officer as an issue of responsibility. SBA specifically requests comments on this issue.

The regulations at 38 CFR 74.2(a) currently include ownership and control as a condition of eligibility. As proposed, § 128.200 already requires ownership and control as an eligibility requirement, so it was not included in this section. While drafting this proposed section, SBA considered adopting additional eligibility requirements found in other SBA programs such as 8(a) additional eligibility requirements in § 124.108. However, for continuity purposes, SBA is proposing to adopt the additional eligibility requirements directly from 38 CFR part 74.

Section 128.202 Who does SBA consider to own a Veteran-Owned or Service-Disabled Veteran-Owned SBC? (Former § 125.12)

While SBA's existing ownership requirements at § 125.12 apply to both VO SBC and SDVO SBCs, § 125.12 refers only to service-disabled veterans. This section as proposed, would add a reference to veterans in the following section: § 128.202(a) through (g), which correspond to current regulations at § 125.12(a) through (g).

Proposed § 128.202(f) would incorporate 38 CFR 74.3(b) requiring participants to notify SBA of any change of ownership. In § 125.12(f), SBA addresses change of ownership but does not require notification to the agency. Proposed § 128.202(f) would require participants to notify SBA of a change of ownership and attest to continued eligibility in accordance with proposed § 128.307. There are no other proposed amendments to SBA's existing ownership regulations at § 125.12. SBA is also requesting comment on this section as proposed, including any suggested amendments to VO/SDVO ownership; for example, whether the proposed regulations at § 128.202 should more closely match the WOSB/Economically Disadvantaged WOSB (EDWOSB) ownership regulations found at 13 CFR 127.201.

Section 128.203 Who does SBA consider to control a Veteran-Owned or Service-Disabled Veteran-Owned SBC? (Former § 125.13)

Proposed § 128.203 would include SBA's existing control requirements at § 125.13 and revise the section to add reference to veterans. SBA previously administered only the SDVO SBC self-certification program and § 125.13 did not specifically reference VOSB requirements. To be verified by VA and subsequently certified by SBA on the Transfer Date, VO SBCs are required to meet the same control requirements as SDVO SBCs per 38 CFR 74.4. There are no other proposed amendments to SBA's existing control regulations at § 125.133. As proposed, SBA control regulations do not address franchise, license, or distributor agreements. SBA is seeking comment as to whether these types of agreements should be addressed within proposed § 128.203. For example, should SBA take a similar approach to the agency's loan assistance regulations in § 121.301(f)(5)?

Current SBA regulations at § 125.13(i), (k), and (l) list several ''rebuttable presumptions'' of control by a non-veteran. As proposed, SBA is adopting those existing regulations in full but is soliciting comment as to whether those rebuttable presumptions should be viewed merely as factors of control by non-veterans rather than conditions of ineligibility that an applicant must rebut. Additionally, SBA is requesting comment on whether any of the rebuttable presumptions as proposed should be amended. SBA is also requesting comment on this section as proposed including any suggested amendments to VO SBC/SDVO SBC control. For example, whether the proposed regulations at § 128.203 should more closely match the WOSB/EDWOSB control regulations found at 13 CFR 127.202.

Section 128.204 What size standards apply to VO SBC and SDVO SBCs? (Former § 125.14)

Proposed § 128.204 would include SBA's existing size requirements at § 125.14 and revise the section to incorporate VO SBCs. SBA previously administered only the SDVO SBC self-certification program, so § 125.14 did not specifically reference VO SBC requirements. To be verified by VA and subsequently certified by SBA on the Transfer Date, VO SBCs are required to meet the same size requirements as SDVO SBCs. As such, this section would also be amended to reflect the VO SBCs.

Subpart C—Certification of VO SBC or SDVO SBC Status

Subpart C as proposed, would adopt VA's existing application and oversight guidelines at 38 CFR 74.10 through 74.22 and incorporate these sections into SBA certification for VO SBC and SDVO SBCs. References to VA's application, the CVE program, the term ''verification,'' the Vendor Information Pages (VIP) database, and VA forms would be removed throughout proposed §§ 128.300 through 128.310 and replaced where relevant with SBA, certification, and references to SBA's database and online application system.

VA's Records Management section (38 CFR 74.25 through 74.29) would not be incorporated into subpart C, as these provisions are no longer applicable to this program. SBA will seek Office of Management and Budget (OMB) approval for the information collection required for this program. SBA does not anticipate collecting additional information that was not previously collected by VA.

Section 128.300 How is a concern certified as a VO SBC or SDVO SBC? (Former § 74.2)

Proposed § 128.300 would include VA's eligibility requirements at 38 CFR 74.2(a), with proposed revisions to remove references to VA and to reflect SBA's certification program. SBA's proposed rule would also grant certification based on an applicant's participation in SBA's 8(a) Business Development and WOSB/EDWOSB programs. SBA anticipates that many participants may seek multiple certifications and believes reciprocity between SBA's certification programs will create program administration efficiencies as well as reduce the processing time for applicants. In granting certification for these programs, SBA reviews ownership and control of the applicant to determine eligibility. The ownership and control requirements that apply to disadvantaged individuals for 8(a) certification and those applying to women for WOSB/EDWOSB certification are basically the same as those applying to veterans and service-disabled veterans for the Veterans Certification Program. An applicant would be required to certify that there are no material changes in its ownership or control since its 8(a) or WOSB certification, and SBA would then accept its previous determinations that the identified individual owned and controlled the VO SBC/SDVO SBC

applicant. In such cases, SBA would confirm the identified individual's eligibility as a veteran or service-disabled veteran.

There is likelihood that 8(a) or WOSB firms granted reciprocity will have remaining ''time in program'' on their existing certifications that would not align with the proposed three-year eligibility period for this Vets Program. In these instances, SBA would align recertification based on the firm's existing certification eligibility period. As an example, a WOSB firm certified in 2022 would be required to reapply for WOSB certification at the end of their three-year eligibility period in 2025. If granted reciprocity into the proposed Vets Program in 2023, that firm would have two remaining years of eligibility. In 2025, the firm would apply for recertification to WOSB and then if eligible, would be granted a three-year eligibility period for both programs. That firm would then be required to update their status in the Veterans Certification Program to reflect recertification by WOSB. SBA is seeking comment on this approach to recertification and whether SBA should amend 8(a) regulations at part 124 and WOSB/EDWOSB regulations at 13 CFR part 127 to reflect reciprocity between programs.

Section 128.301 Where must an application be filed? (Former § 74.10)

Proposed § 128.301 would include VA's requirements at 38 CFR 74.10 for application to CVE, propose revisions to remove references to VA, and reflect that an applicant must apply to SBA for certification after the rule is effective. At the time of this proposed rule, SBA has not announced its application platform or certification database for the Vets Program. Accordingly, the proposed amendments have general references to this technology. When finalized, the rule will include instructions to apply online and access the certification database.

Section 128.302 How does SBA process applications for certification? (Former § 74.11)

Proposed § 128.302 would include VA's guidelines for application processing by CVE at 38 CFR 74.11, propose revisions to remove references to VA, and reflect SBA's certification program. As proposed, this section would remove specific processing guidelines in § 128.302(a) as SBA has not established the policies and procedures for application processing at this time. SBA also proposes to add an additional sentence at the end of § 128.302(e) to establish SBA's authority to decertify a firm in the event that the firm failed to inform SBA of any changed circumstance in accordance with § 128.306. The regulation at 38 CFR 74.11(e)(1), which requires participants to notify VA of bankruptcy details within 30 days, would be incorporated into §§ 128.302(e) and 128.307 to require participants to notify SBA in the event of a bankruptcy filing.

Section 128.303 What must a concern submit to apply for VO SBC or SDVO SBC certification? (Former § 74.12)

Proposed § 128.303 would amend VA's documentation requirements at 38 CFR 74.12 for application to CVE. This amendment would include general requirements for submission to SBA rather than list each document individually as with the current VA regulation. As proposed, this section would grant certification based on participants in SBA's 8(a) Business Development and WOSB/EDWOSB programs that are owned and controlled by one or more veterans, or in the case of SDVO SBCs, service-disabled veterans. The proposed amendment would demonstrate how applicants may submit documentation as evidence of program eligibility. Proposed § 128.303 would add paragraphs (d) and (e) to require a concern to provide a full explanation in the case of an applicant that was previously decertified, previously denied certification, or failed to notify SBA of a material change affecting its eligibility. SBA is seeking comment whether an explanation in these circumstances should be required as part of an application and if so, should SBA establish a time limit for reapplication in which an explanation would be required (*e.g.,* A firm that reapplies within three years of denial would be required to provide an explanation of that denial. If that firm reapplies after a period of three years, it would not be required to submit an explanation with the application).

In terms of demonstrating that an applicant qualifies as a small business, the proposed rule would provide that an applicant must demonstrate that it qualifies as small under the size standard corresponding to any NAICS code under which it currently conducts business activities. SBA believes that this standard makes more sense than requiring an applicant to qualify as small under the size standard corresponding to its primary industry classification. In order to be eligible for a specific SDVO or VO small business contract, a firm must qualify as small under the size standard corresponding to the NAICS code assigned to that contract. Whether a firm qualifies as small under its primary industry classification is not relevant to that determination (unless the size standard for the firm's primary industry classification is the same as that for the NAICS code assigned to the contract, but even then, the only relevant size standard is that corresponding to the NAICS code assigned to the contract). SBA believes that a firm that does not qualify as small under its primary industry classification should not be precluded from seeking and being awarded SDVO or VO small business contracts if it qualifies as small for those contracts. SBA believes that the certification process should ensure that an applicant is owned and controlled by one or more veterans or service-disabled veterans and that it could qualify as a small business for a VO or SDVO set-aside contract. As such, SBA believes that requiring an applicant to demonstrate that it qualifies as small for any industry under which it currently conducts business is more appropriate than requiring it to demonstrate that it qualifies as small under its primary industry classification.

Section 128.304 Can an applicant appeal SBA's initial decision to deny an application? (Former § 74.13)

Proposed § 128.304 would include VA's regulation at 38 CFR 74.13 for a denied application with CVE and proposed revisions would remove references to VA and reflect SBA's certification program. In addition, this section would add a sentence at the beginning of § 128.304(a) which would clearly establish that there is no reconsideration process for initial applications once they have been denied. SBA believes that the appeals process with SBA's Office of Hearings and Appeals (OHA) as outlined in 13 CFR part 134 serves as an adequate substitute for the process of reconsideration. Given that this proposed rule would eliminate reconsideration upon initial application, SBA proposes to shorten the reapplication period after denial from 6 months to 90 calendar days. SBA seeks comment on the proposed elimination of the reconsideration process. If, on appeal, OHA overturns SBA's initial decision to deny an applicant, should SBA consider a reconsideration process where the remanded application is then denied for reasons other than those identified in the initial application? Should SBA allow a reconsideration of all denials prior to OHA appeal? SBA also requests comment specifically on denial decisions based solely on eligibility as a veteran or service-disabled veteran. Current VA

regulations do not allow for reconsideration of these types of denials. Should SBA allow for reconsideration in these limited circumstances?

This section as proposed would not incorporate 38 CFR 74.13(b) through (f): paragraph (b) reconsideration of veteran eligibility criteria, paragraph (c) reconsideration, paragraph (d) is no longer applicable as it references an SBA determination on size, paragraph (e) is a duplicate of paragraph (b), and paragraph (f) is a second reference to the reconsideration process.

Section 128.305 Can an applicant or participant reapply for certification? (Former § 74.14)

As proposed, § 128.305 would include VA's 38 CFR 74.14 reapplication requirements, proposed revisions would remove references to VA and to reflect SBA's certification program. SBA's proposed rule would adopt the VA requirement that the applicant must wait for a period of 90 calendar days after a denial decision before a new application will be processed by SBA. As proposed participants may reapply for certification within 120 calendar days of the end of their eligibility period and the subsequent eligibility period would be based on the date of the new determination letter. SBA is requesting comment on this proposed procedure for recertification. Specifically, should SBA reduce the window for applicants to reapply prior to the end of eligibility period and if an applicant successfully reapplies to the Vets Program, should the eligibility period be based on the original date that eligibility was set to expire as opposed to the date of the determination letter?

Section 128.306 What length of time may a business participate in the Veterans Certification Program? (Former § 74.15)

Proposed § 128.306 would include VA's 38 CFR 74.15 program eligibility term and continuing obligation requirements, including a provision specifying that a business concern would receive an eligibility term of three years from the date of SBA's approval letter establishing its VO SBC or SDVO SBC certified status. Proposed revisions would remove references to VA and reflect SBA's certification program. SBA does not believe that yearly recertification is necessary, but requests comments as to whether recertification every three years is the appropriate term of certification. Paragraphs (e) and (f) of this section would include the consequences of a program examination referenced in paragraph (d). For organizational purposes, SBA would redesignate paragraphs (e) and (f) as paragraphs (d)(1) and (2), respectively. SBA's proposed rule would adopt VA's eligibility period of three years. SBA is soliciting comment on whether that period is appropriate for the proposed SBA Vets Program.

Section 128.307 What are a participant's ongoing obligations to SBA? (Former § 74.3(b))

Proposed § 128.307 would include 38 CFR 74.3(b) that requires participants to notify CVE of any change of ownership; proposed revisions would remove references to VA and to reflect SBA's certification program. This section as proposed does not require prior SBA approval of a material change. SBA is soliciting comment as to whether this section should require SBA approval prior to a material change that could affect eligibility. Sections 36 and 36A of the Small Business Act (15 U.S.C. 657f and 657f–1) ''require the periodic recertification'' of a firm's status as an eligible VO SBC or SDVO SBC. As noted above in § 128.306, SBA is proposing that a VO SBC or SDVO SBC certification generally last three years. SBA has interpreted the ''periodic recertification'' requirement set forth in the Small Business Act to require recertification every three years. This proposed rule would not require participants to recertify on an annual basis as an ongoing obligation. SBA requests comments as to whether three years is the appropriate length of time to require recertification. SBA wants to ensure that it meets its statutory mandate, but at the same time does not want to impose any unnecessary burdens on VO SBCs and SDVO SBCs.

Section 128.308 What is a certification examination and what will SBA examine? (Former § 74.20)

Proposed § 128.308 would include VA's 38 CFR 74.2(a) verification exam requirements, with revisions that would remove references to VA and to reflect SBA's certification program.

Section 128.309 What are the ways a business may exit certification status? (Former § 74.21)

Proposed § 128.309 would include VA's 38 CFR 74.21 guidelines on exiting the CVE program, with revisions that would remove references to VA and reflect SBA's certification program. The proposed section would also include paragraph (d)(10) which adds failure to recertify as good cause to remove a firm from the Vets Program.

Section 128.310 What are the procedures for decertification? (Former § 74.22)

Proposed § 128.310 would include VA's 38 CFR 74.22 guidelines on canceling program participation by the agency; proposed revisions would remove references to VA and to reflect SBA's certification program.

Subpart D—Federal Contract Assistance

Section 128.400 What are VO and SDVO contracts? (Former § 125.17)

As proposed, § 128.400(a) would amend the text in § 125.17 to reflect VA's authority to award set-aside and sole source to VO SBCs and SDVO SBCs. The amendment references the VA Acquisition Regulation (VAAR) at chapter 8 of title 48, Code of Federal Regulations. An additional amendment at § 128.400(b) as proposed, would distinguish VA contracts from SDVO SBC contracts with the rest of the Federal Government.

Section 128.401 What requirements must an SDVO SBC meet to submit an offer on a contract? (Former § 125.18)

As proposed, § 128.401 would amend the current regulation at § 125.18(a) to require certification to be eligible for a VO or SDVO SBC set-aside or sole source contract. The proposed rule would add § 128.401(a)(2)(i) and (ii) to allow an uncertified VO SBC or SDVO SBC to submit an offer while their application is pending with SBA. SBA intends to prioritize those applications where the contracting officer has identified the applicant as the apparent successful offeror. This proposed rule would also amend former paragraph (b) at § 125.18 to add eligibility for VO SBC joint ventures (JV) in the Vets Program and reference § 128.402, a new stand-alone section to address JV requirement for VOVO SBCs and SDVO SBCs. The remaining paragraphs in § 125.18 would add references to VO SBCs.

Section 128.402 May a joint venture submit an offer on a VO SBC or SDVO SBC requirement? (Former § 125.18(b))

As stated above, SBA is proposing a stand-alone § 128.402 that would address JV requirements for VOVO SBCs and SDVO SBCs. Section 128.402(a) as proposed, generally would state conditions upon which a JV may be certified by SBA and as set forth in 48 CFR part 819, includes the requirement that all joint ventures must be certified to be awarded a VO SBC or SDVO SBC contract with VA. SBA does not intend to require SDVO SBC JVs to certify for contracts with the rest of the Federal Government.

The proposed rule would also add paragraph (b)(11) in § 128.402 to provide that a VO SBC or SDVO SBC participant cannot be a joint venture partner on more than one joint venture that submits an offer for a specific VO SBC or SDVO SBC contract. Although the proposed rule would apply this requirement to all contracts, procuring agencies and small businesses have raised concerns to SBA in the context of multiple award contracts where it is possible that one firm could be a member of several joint ventures that receive contracts. In such a situation, several agencies were troubled that orders under the Multiple Award Contract may not be fairly competed if one firm was part of two or more quotes. They believed that one firm having access to pricing information for several quotes could skew the pricing received for the order.

Sections 128.403 Through 128.408 (Former §§ 125.21 Through 125.26)

Generally, §§ 128.403 (former § 125.21) ''requirements not available to VO or SDVO contracts,'' 128.405 (former § 125.23) ''sole source contracts to VO and SDVO SBCs,'' and 128.406 (former § 125.24) ''VO or SDVO contracts at or below the simplified acquisition threshold'' would be amended to distinguish VA procurements from all other procurements. As previously stated, VAAR specifically governs requirements exclusive to VA prime and subcontracting actions at chapter 8 of title 48, Code of Federal Regulations, and supplements the Federal Acquisition Regulation (FAR), which contains guidance applicable to most Federal agencies.

As proposed, § 128.404(d) would add a requirement that prohibits agencies from requiring one or more certifications in addition to its VO SBC/SDVO SBC certification. This amendment is already included in SBA's regulations at § 125.2(e)(6)(i) but had not been added to the SDVO SBC program.

No amendments are proposed were made to existing regulations in either § 128.407 or § 128.408 currently at § 125.25 or § 125.526.

Subpart E—Protests Concerning VO SBCs and SDVO SBCs

Section 128.500 What are the requirements for filing a VO SBC and SDVO SBC status protest? (New)

As proposed, § 128.500 would serve as the sole section addressing status protests for VO SBCs and SDVO SBCs. Currently, SBA's Director of Government Contracting processes all status protests of self-certified SDVO SBCs for non-VA contracts in accordance with 13 CFR part 125 and SBA's OHA hears all challenges to a VO SBC or SDVO SBC's inclusion in the VA database in accordance with 38 U.S.C. 8127(f)(6)(B)(i). NDAA 2021 transfers the entirety of 38 U.S.C. 8127(f) to 15 U.S.C. 657f and authorizes OHA to review all status protests of VO SBCs and SDVO SBCs, regardless of the procurement agency. Accordingly, proposed part 128 would not include §§ 125.27 through 125.31 on SDVO SBC status protests. Proposed § 128.500 would add paragraph (a) to reflect revised status protest procedures described above with a reference to part 134. Paragraph (b) as proposed would distinguish separate procedures for size and status protests. Amendments to part 134 are not included in this proposed rule and will be amended separately to reference SBA's Veterans Certification Program.

Subpart F—Penalties and Retention of Records

The proposed rule would adopt SBA's existing regulations at 13 CFR 125.32 and 33 (former §§ 125.32 and 125.33) and revise the sections to add reference to VO SBCs. SBA previously administered only the SDVO SBC self-certification program, so §§ 125.32 and 125.33 did not specifically reference VO SBC requirements.

Subpart G—Surplus Personal Property for Veteran-Owned Small Business Programs

Section 128.700 How does a small business concern owned and controlled by veterans obtain Federal surplus personal property? (Former § 125.100)

The Veterans Small Business Enhancement Act provides that VO SBCs should be considered for surplus personal property distributions. Those firms seeking to participate in the program are required to be verified by VA's CVE as a condition of eligibility. Section 128.700(a)(1) would amend this regulation to reflect the transfer of certification to SBA as mandated by NDAA 2021.

Part 121

This proposed rule would amend references to the current SDVO SBC program in part 121. These amendments would correspond to the newly-created part 128.

SBA has not proposed amendments to part 124, 127, or 134 with this rulemaking. However, SBA is seeking comment whether the final rule should include amendments to these parts to reflect the proposed Vets Program. For example, part 124 may need to be amended to reflect reciprocity with the proposed Vets Program; part 127 grants reciprocity to firms verified by CVE and would be amended to reference this Vets Program; and part 134 would need to be amended to remove references to CVE and update procedures for denial, cancellation, and inclusion in the SBA database.

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

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this proposed rule is a significant regulatory action for the purposes of Executive Order 12866. Accordingly, the next section contains SBA's Regulatory Impact Analysis.

Regulatory Impact Analysis

1. Is there a need for the regulatory action?

This rulemaking is necessary to satisfy statutory requirements to implement section 862 of the National Defense Authorization Act for Fiscal Year 2021 amendments to the Small Business Act which requires SBA to certify VO SBCs and SDVO SBCs.

2. What is the baseline, and the incremental benefits and costs of this regulatory action?

OMB directs agencies to establish an appropriate baseline to evaluate any benefits, costs, or transfer impacts of regulatory actions and alternative approaches considered. The baseline should represent the agency's best assessment of what the world would look like absent the regulatory action. For a regulatory action that modifies or replaces an existing regulation, a baseline assuming no change to the regulation generally provides an appropriate benchmark for evaluating benefits, costs, or transfer impacts of proposed regulatory changes and their alternatives.

Baseline

Section 862 of NDAA 2021 amended sections 36 and 36A of the Small Business Act to require SBA to certify the status of VO SBCs and SDVO SBCs seeking sole source and set-aside contracts across the Federal Government. This regulation would replace VA's existing regulations governing the verification of VO SBCs

and SDVO SBCs for sole source or set-aside contracts awarded by VA. Prior to NDAA 2021, SDVO SBC firms seeking to contract with Federal agencies other than VA only needed to self-certify their status. SDVO SBC firms currently self-certifying must apply within a one-year grace period after the Transfer Date.

SBA's proposed regulations will not add any additional burden to current participants in VA's VIP Verification Program. The VIP Verification Program has a three-year term of eligibility and to enter the program, applicants submit an online application with documents supporting the application. To remain in the program, VA requires participants to notify the agency of a change in circumstances such as a change in ownership or control of the firm. VA also requires participants to undergo a program examination to verify the accuracy of any statement or information provided as part of the verification application process. At the end of the three-year term of eligibility, a participant must reapply to the program using the same procedures as the initial application.

With the proposed regulations, SBA would institute the same process of initial application, program examination, and reapplication at the end of the applicant's three-year term of eligibility. Firms verified by VA prior to the Transfer Date would be deemed eligible by SBA for the time that remains in the firm's three-year term of eligibility. To remain certified by SBA after the Transfer Date, those verified firms would be required to meet all conditions of eligibility as described in the proposed regulation such as certification examinations and reapplication at the end of the firm's term of eligibility. Current participants in the VIP Verification Program would have no additional cost burden associated with the SBA's proposed regulations implementing the Veterans Certification Program. VA existing regulations for VO SBCs and SDVO SBCs that contract solely with the VA serve as an appropriate benchmark for this regulatory impact analysis. Accordingly, this analysis will focus on the benefits and costs to those previously self-certified SDVO SBCs that would be required to certify with SBA.

Benefit

The benefit of the proposed regulation is a reduction in the ambiguity and uncertainty for contracting officers in the process of making Federal contract awards to eligible SDVO firms that were previously only required to self-certify. Under the existing system for agencies outside of VA, the burden of SDVO SBC eligibility compliance is placed upon the awarding contracting officer. Contracting officers must review the documentation of the apparent successful offeror on a SDVO SBC contract. Under this proposed rule, the burden is placed upon SBA. All a contracting officer needs to do is to confirm that the firm is in fact a certified SDVO SBC in SBA's certification database and a responsible contractor. A contracting officer would not have to look at any documentation provided by a firm or prepare any internal memorandum memorializing any review. This will encourage more contracting officers to set aside opportunities for SDVO SBC Vets Program participants as the validation process will be controlled by SBA in the System for Award Management (SAM), the Dynamic Small Business Search (DSBS) database, and SBA's certification database. The reduced responsibility to verify eligibility at contract award may also result in a minor cost savings to the contracting agencies.

Cost

While current participants in the Vet VIP Verification Program would have no additional costs associated with the proposed regulations, SBA anticipates costs associated with self-certified SDVO SBCs currently seeking contracts with the rest of the Federal Government. Previously, those firms only needed to self-certify their status to pursue SDVO SBC sole source and set-asides. With NDAA 2021, those firms must apply to SBA for certification within a one-year grace period ending on January 1, 2024. Eligible SDVO SBC firms that are certified by SBA after the Transfer Date will then be required to meet all program eligibility requirements going forward to include: notify SBA of a change in circumstances, undergo a program certification examination, and reapply for certification at the end of their eligibility period.

To estimate the number of SDVO SBC applicants within the first year of the certification, SBA reviewed firms actively registered as SDVO SBCs in SAM. SBA believes that the number of firms listed in SAM is the most recent and reliable data to estimate participation and total costs of the Vets Program for the purposes of this regulatory impact study. Registration in SAM is required for all businesses seeking to contract with the Federal Government, registrants may select to represent themselves as SDVO SBCs without going through a certification process, and firms must recertify their registration one-year after initial SAM registration. While it is not anticipated that every firm registered as an SDVO SBC in SAM will apply for certification within the first year of the Vets Program, SAM registrations serve as what SBA would consider the maximum number of firms that would likely seek certification.

Accordingly, SBA estimates that as many as 21,468 self-certified SDVO SBCs could apply for initial certification within the first year of the program. This estimate is based on 32,284 SDVO SBC firms registered in SAM and excludes 10,816 firms registered in SAM but already verified by VA as of December 2021.

SDVO SBCs Registered in SAM	32,284
Less: VA-Verified SDVO SBCs Included in SAM	10,635
Self-Certified SDVO SBCs	21,649
Less: VA-Verified VO SBCs Self-Certified as SDVO SBCs	181
Self-Certified SDVO SBCs Anticipated to Seek SBA Certification	21,468

The following table represents the estimated total number of Program Participant actions during the first five years of the Vets Program.

NUMBER OF PROGRAM PARTICIPANTS

Year	Initial applications	Program examinations	Recertifications	Yearly totals
1	17,174	1,025	2,114	19,288
2	8,500	560	2,006	10,506
3	7,500	420	527	8,027
4	7,500	810	7,715	15,215
5	7,500	635	4,202	11,706
Totals	48,174	3,455	16,565	64,739

For the purposes of this proposed rule, SBA estimated ''time to complete'' for three types of certification actions: initial application, program examination, and reapplication at the end of the eligibility period. For the initial application, SBA estimates that applicants would complete the application process in 1 hour, a program examination in 1 hour, and reapplication in 1 hour. The estimated time to complete would include entering information into SBA's online application platform and submission of supporting documentation to prove eligibility. It also assumes that the information requested by SBA during initial certification is already held by the firms during the ordinary course of business and would require minimum preparation prior to submission. Similarly, participants would be minimally burdened during program examinations and reapplications. During their period of eligibility, participants would be required to review, maintain, and update documentation submitted to SBA during initial certification. In the event of a change in circumstances while in the Program, participants would have previously notified SBA of the change and already uploaded documentation to support eligibility. SBA's proposed rule would not require additional information or documents that the firm would not already have on hand and would not impose additional burden on the participant. SBA is soliciting comment as to whether these times to complete these actions are reasonable.

Hourly cost to the participant is based on estimated manager's salary of $93.44/hour (based on the median hourly wage of $46.72 for construction managers, according to the BLS 2020 Occupational Outlook Handbook, plus 100% for benefits and overhead). Based on an estimate of 1 hour per program action and an hourly cost of $93.44, the five-year total cost burden for the proposed rule would be $3,219,569. SBA estimates that an applicant's cost burden to apply and maintain eligibility for this proposed Program would require 3 total hours at a cost burden of $280.32 per applicant.

COSTS TO PARTICIPANTS

Year	Initial applications	Program examinations	Recertifications	Yearly totals
1	$1,604,776	$95,776	$197,532	$1,898,084
2	794,240	52,326	187,441	1,034,007
3	700,800	39,712	49,243	789,755
4	700,800	75,686	720,923	1,497,410
5	700,800	59,334	392,672	1,152,807
Totals	4,501,416	322,835	1,547,811	6,372,062

SBA believes that participants would not incur any start-up costs, operation or maintenance costs, service costs, or require additional capital as a result of this proposed rule because there should be no cost in setting up or maintaining systems to collect the required information. As stated previously, the information requested should be collected and retained by the applicant in the ordinary course of business. SBA is soliciting comment as to whether this assumption is accurate.

SBA estimates the cost to the government of implementing the certification program to be $30M across fiscal year (FY) 2022 and FY2023 and approximately $20M annually thereafter. SBA worked with VA and OMB to secure a $10M transfer from VA's Supply Fund to cover transition costs, including tech system development. An additional $20M was requested in the President's Budget for FY2023 for year one program operations. SBA and VA anticipate an up to 250% surge in application volume relative to VA's current volume. The increase in volume will be handled primarily by surging contract support. SBA's $20M request includes $2.5M for full time equivalents (FTEs) (current salaries and expenses (S&E) for VA FTEs assigned to the program), $1.35M for information technology (IT) overhead (system maintenance and standard IT services for staff and contractors), and $16M in contract costs (based on FY21 VA contract costs scaled to account for application surge and projected efficiencies). The cost of operating the program may decrease after the initial application surge, but would rise every third year when the 2023 cohort is up for recertification. This cost estimate also eliminates CVE's costs of administering the program. CVE reported a cost of $12,302,497 for 14,762 cases in FY2021. This cost is not directly comparable to SBA's estimate, however, because it excludes items like some support costs, that are included in SBA's cost estimate.

3. What are the alternatives to this rulemaking?

This proposed rule would implement specific statutory provisions in Section 862 of the 2021 NDAA. There are no alternatives that would meet the statutory requirements.

Executive Order 12988

This proposed rule meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil

Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

This proposed rule does not have federalism implications as defined in Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive order. As such it does not warrant the preparation of a federalism assessment.

Executive Order 13175

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

Executive Order 13563

This Executive order directs agencies to, among other things: (a) Afford the public a meaningful opportunity to comment through the internet on proposed regulations, with a comment period that should generally consist of not less than 60 days; (b) provide for an ''open exchange'' of information among government officials, experts, stakeholders, and the public; and (c) seek the views of those who are likely to be affected by the rulemaking, even before issuing a notice of proposed rulemaking. As far as practicable or relevant, SBA considers these requirements in developing this rule, as discussed below.

1. *Did the agency use the best available techniques to quantify anticipated present and future costs when responding to E.O. 12866 (e.g., identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes)?*

To the extent possible the agency utilized the most recent data available in the Federal Procurement Data System-Next Generation, SAM, and VA's VIP database.

2. *Public participation:* Did the agency: (a) Afford the public a meaningful opportunity to comment through the internet on any proposed regulation, with a comment period that should generally consist of not less than 60 days; (b) provide for an ''open exchange'' of information among Government officials, experts, stakeholders, and the public; (c) provide timely online access to the rulemaking docket on *Regulations.gov*; and (d) seek the views of those who are likely to be affected by rulemaking, even before issuing a notice of proposed rulemaking?

The proposed rule will have a 30-day comment period and will be posted on *www.regulations.gov* to allow the public to comment meaningfully on its provisions. SBA believes a 30-day comment period is reasonable and sufficient for this proposed rule for several reasons. First, SBA believes a 30-day comment period is sufficient for this proposed rule because the rule does not propose significant changes to the programs that are not statutorily mandated. In drafting this proposed rule, SBA sought to minimize the impact to the certification process as the certification authority moves to SBA and generally adopted VA's existing program guidelines in 38 CFR part 74. Second, SBA anticipates that this proposed rule will receive a substantial number of comments from the public, even with a 30-day comment period. Third, SBA and VA have taken significant efforts to engage the veteran small business community during preparations for the transfer and have used this engagement as consideration while drafting this proposed rule. Finally, a 30-day comment period is needed due to the time required to promulgate a final rule to be effective on January 1, 2023. SBA intends to use these comments as an integral component in drafting the final rule.

3. *Flexibility:* Did the agency identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public?

This rulemaking is necessary to satisfy statutory requirements to implement section 862 of 2021 NDAA 2021. A description of the need for this regulatory action and the benefits and costs associated with this action, including possible distributional impacts that relate to Executive Order 13563, are included above in the Regulatory Impact Analysis under Executive Order 12866.

Congressional Review Act (5 U.S.C. 801–808)

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a ''major 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. SBA will submit a report containing this rulemaking and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rulemaking has been reviewed and determined by OMB not to be a ''major rule'' under 5 U.S.C. 804(2).

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

In carrying out its statutory mandate to certify VO SBC and SDVO SBC firms, SBA intends to collect information from VO SBC and SDVO SBC applicants or participants through an online application system. This collection of information will require submission or retention of documents that support the applicant's certification and continued eligibility.

SBA intends to implement a certification and information collection platform that replicates the currently approved information collection by VA's CVE (OMB Control Number 2900–0675). In other words, the information collected by SBA will include eligibility documents previously collected by VA. SBA does not anticipate that these changes would impact the content of the information currently collected or add additional burden to what is currently required by VA for verification.

As discussed above, this rule proposes to fully implement the statutory requirement for small business concerns to be certified by SBA in order to be awarded a set-aside or sole source contract under the Veterans Certification Program. As a result of these changes, the rule proposes to eliminate SDVO SBC self-certification and set the standards for certification by SBA. SBA anticipates that these changes would impact firms currently self-certifying; however, this impact would be minimal as this information is already held by applicants during the ordinary course of business and would require minimum preparation prior to submission.

At this time, SBA does not have an OMB-approved method for collection but intends to have approval for the collection of information before the rule is finalized.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, small

nonprofit enterprises, and small local governments. According to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601, when an agency issues a rulemaking, it must prepare a regulatory flexibility analysis to address the impact of the rule on small entities. However, section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. The RFA defines ''small entity'' to include ''small businesses,'' ''small organizations,'' and ''small governmental jurisdictions.'' This proposed rule concerns various aspects of SBA's contracting programs. As such, the rule relates to small business concerns, but would not affect ''small organizations'' or ''small governmental jurisdictions.'' SBA's contracting programs generally apply only to ''business concerns'' as defined by SBA regulations, in other words, to small businesses organized for profit. ''Small organizations'' or ''small governmental jurisdictions'' are non-profits or governmental entities and do not generally qualify as ''business concerns'' within the meaning of SBA's regulations.

As stated in the regulatory impact analysis, this rulemaking will impact approximately 21,468 service-disabled veteran-owned small businesses. If adopted in final form, these businesses will have to apply to SBA for certification. However, SBA has proposed to minimize the impact on VO SBCs and SDVO SBCs by accepting verifications already received from VA's CVE program during the term of the firm's eligibility period, and by providing SDVO SBC firms that self-certify a one-year grace period to apply for certification. The additional costs to VO SBCs and SDVO SBCs for certification should be minimal, because the required documentation already exists and is maintained in the normal course of business: such as articles of incorporation, bylaws, stock ledgers or certificates, tax records, etc. In addition, applicants must already provide this information to VA's CVE for verification. SBA does not anticipate that these changes would impact the content of the information currently collected. Thus, the Administrator certifies that the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

List of Subjects

13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant programs—business, Individuals with disabilities, Loan programs—business, Small businesses.

13 CFR Part 125

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

13 CFR Part 128

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

For the reasons stated in the preamble, SBA proposes to amend 13 CFR chapter I as follows:

PART 121—SMALL BUSINESS SIZE REGULATIONS

■ 1. The authority citation for part 121 is revised to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 636(a)(36), 662, 694a(9), and 9012.

§ 121.103 [Amended]

■ 2. Amend § 121.103 by removing the references to ''§ 125.18(b)(2) and (3)'' in paragraph (h)(1)(ii) and adding in their place a reference to ''§ 128.402(b)(2) and (3)''.

§ 121.404 [Amended]

■ 3. Amend § 121.404 by removing the reference to ''§ 125.18(b)(2) and (3)'' in paragraph (d) and adding in its place a reference to ''§ 128.402(b)(2) and (3)''.

PART 125—GOVERNMENT CONTRACTING PROGRAMS

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

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

Subparts A through F [Removed]

■ 5. Remove subparts A through F, consisting of §§ 125.11 through 125.100.
■ 6. Add part 128 to read as follows:

PART 128—VETERANS CERTIFICATION PROGRAM

Subpart A—Provisions of General Applicability

Sec.

128.100 What is the purpose of this part?
128.101 What type of assistance is available under this part?
128.102 What definitions are important in the Veterans Certification Program?

Subpart B—Eligibility Requirements for the Veterans Certification Program

Sec.

128.200 What are the requirements a concern must meet to qualify as a VO SBC or SDVO SBC?
128.201 What other eligibility requirements apply for individuals or businesses?
128.202 Who does SBA consider to own a VO SBC or SDVO SBC?
128.203 Who does SBA consider to control a VO SBC or SDVO SBC?
128.204 What size standards apply to VO SBCs and SDVO SBCs?

Subpart C—Certification of VO SBC or SDVO SBC Status

Sec.

128.300 How is a concern certified as a VO SBC or SDVO SBC?
128.301 Where must an application be filed?
128.302 How does SBA process applications for certification?
128.303 What must a concern submit to apply for VO SBC or SDVO SBC certification?
128.304 Can an Applicant appeal SBA's initial decision to deny an application?
128.305 Can an Applicant or Participant reapply for certification?
128.306 What length of time may a business participate in SBA's Veterans Certification Program?
128.307 What are a Participant's ongoing obligations to SBA?
128.308 What is a certification examination and what will SBA examine?
128.309 What are the ways a business may exit certification status?
128.310 What are the procedures for decertification?

Subpart D—Federal Contract Assistance

Sec.

128.400 What are VO and SDVO contracts?
128.401 What requirements must a VO SBC or SDVO SBC meet to submit an offer on a contract?
128.402 May a joint venture submit an offer on a VO SBC or SDVO SBC requirement?
128.403 What requirements are not available for VO or SDVO contracts?
128.404 When may a contracting officer set aside a procurement for VO SBCs or SDVO SBCs?
128.405 When may a contracting officer award sole source contracts to VO SBCs and SDVO SBCs?
128.406 Are there VO or SDVO contracting opportunities at or below the simplified acquisition threshold?
128.407 May SBA appeal a contracting officer's decision not to make a procurement available for award as an SDVO contract?
128.408 What is the process for such an appeal?

Subpart E—Protests Concerning VO SBCs and SDVO SBCs

Sec.

128.500 What are the requirements for filing a VO SBC and SDVO SBC status protest?

Subpart F—Penalties and Retention of Records

Sec.
128.600 What are the requirements for representing VO SBC or SDVO SBC status, and what are the penalties for misrepresentation?
128.601 What must a concern do in order to be identified as a SDVO SBC in any Federal procurement databases?

Subpart G—Surplus Personal Property for Veteran-Owned Small Business Programs

Sec.
128.700 How does a small business concern owned and controlled by veterans obtain Federal surplus personal property?

Authority: 15 U.S.C. 632(q), 634(b)(6), 644, 645, 657f, 657f–1.

Subpart A—Provisions of General Applicability

§ 128.100 What is the purpose of this part?

Section 8127 of Title 38 within the U.S. Code (38 U.S.C. 8127) authorizes certain procurement mechanisms to provide Veteran-Owned Small Business Concerns (VO SBC) and Service-Disabled Veteran-Owned Small Business Concerns (SDVO SBC) with contracting assistance opportunities at the Department of Veterans Affairs (VA). Section 36 of the Small Business Act (15 U.S.C. 657f) authorizes certain procurement mechanisms to provide SDVO SBCs with contracting assistance opportunities across the Federal Government. In addition, sections 36 and 36A of the Small Business Act (15 U.S.C. 657f,657f–1) authorize the Small Business Administration (SBA) to certify the status of VO and SDVO SBCs. This part implements these mechanisms and ensures that the program created, referred to as the Veterans Certification Program, is substantially related to this important congressional goal in accordance with applicable law.

§ 128.101 What type of assistance is available under this part?

Contracting officers are authorized to restrict competition or award sole source contracts or orders to eligible Service-Disabled Veteran-Owned Small Businesses. In addition, 48 CFR chapter 8 authorizes VA contracting officers to restrict competition or award sole source contracts or orders to eligible Veteran-Owned and Service-Disabled Veteran-Owned Small Businesses.

§ 128.102 What definitions are important in the Veterans Certification Program?

Applicant means a firm applying for inclusion in the certification database.

Contracting officer has the meaning given such term in section 2101 of the Office of Federal Procurement Policy Act (41 U.S.C. 2101).

Day-to-day operations of a firm means the marketing, production, sales, and administrative functions of the firm.

Eligible individual means a veteran, service-disabled veteran, or surviving spouse, as defined in the United States Code and this part.

ESOP has the meaning given the term ''employee stock ownership plan'' in section 4975(e)(7) of the Internal Revenue Code of 1986 (26 U.S.C. 4975(e)(7)).

Extraordinary circumstances, for purposes of this part, are only the following:

(1) Adding a new equity stakeholder;

(2) Dissolution of the company;

(3) Sale of the company;

(4) The merger of the company; and

(5) Company declaring bankruptcy.

Interested party means the contracting activity's contracting officer, SBA, any concern that submits an offer for a specific sole source or set-aside VO or SDVO contract or order (including Multiple Award Contracts), or any concern that submitted an offer in full and open competition and its opportunity for award will be affected by a reserve of an award given to a VO or SDVO SBC.

Joint venture is an association of two or more business concerns for which purpose they combine their efforts, property, money, skill, or knowledge in accordance with this part. A joint venture must be comprised of at least one service-disabled veteran-owned (or veteran-owned as applicable) small business. For VA contracts, a joint venture must be in the form of a separate legal entity.

Negative control includes, but is not limited to, instances where a minority shareholder has the ability, under the concern's charter, by-laws, or shareholder's agreement, to prevent a quorum or otherwise block action by the board of directors or shareholders.

Non-veteran means any individual who does not claim veteran status, or upon whose status an Applicant or Participant does not rely in qualifying for certification.

Participant means a veteran-owned or service-disabled veteran-owned small business concern that has certified status with SBA.

Permanent caregiver, for purposes of this part, is the spouse, or an individual, 18 years of age or older, who is legally designated, in writing, to undertake responsibility for managing the well-being of the service-disabled veteran with a permanent and severe disability, as determined by the Department of Veterans Affairs' Veterans Benefits Administration, to include housing, health and safety. A permanent caregiver may, but does not need to, reside in the same household as the service-disabled veteran with a permanent and severe disability. In the case of a service-disabled veteran with a permanent and severe disability lacking legal capacity, the permanent caregiver shall be a parent, guardian, or person having legal custody. There may be no more than one permanent caregiver per service-disabled veteran with a permanent and severe disability.

(1) A permanent caregiver may be appointed, in a number of ways, including:

(i) By a court of competent jurisdiction;

(ii) By the Department of Veterans Affairs, National Caregiver Support Program, as the Primary Family Caregiver of a Veteran participating in the Program of Comprehensive Assistance for Family Caregivers (this designation is subject to the Veteran and the caregiver meeting other specific criteria as established by law and the Secretary and may be revoked if the eligibility criteria do not continue to be met); or

(iii) By a legal designation.

(2) Any appointment of a permanent caregiver must in all cases be accompanied by a written determination from the Department of Veterans Affairs that the veteran has a permanent and total service-connected disability as set forth in 38 CFR 3.340 for purposes of receiving disability compensation or a disability pension. The appointment must also delineate why the permanent caregiver is given the appointment, must include the consent of the veteran to the appointment and how the appointment would contribute to managing the veteran's well-being.

Primary industry classification means the six-digit North American Industry Classification System (NAICS) code designation which best describes the primary business activity of the Participant. The NAICS code designations are described in the NAICS Manual published by the U.S. Office of Management and Budget.

Principal place of business means the business location where the individuals who manage the concern's day-to-day day operations spend most working hours and where top management's current business records are kept. If the office from which management is directed and where the current business records are kept are in different locations, SBA will determine the principal place of business for program purposes.

Service-connected has the meaning given that term in 38 U.S.C. 101(16).

Service-disabled veteran is a veteran who possesses either a valid disability rating letter issued by the Department of Veterans Affairs, establishing a service-connected rating between 0 and 100 percent, or a valid disability determination from the Department of Defense or is registered in the Beneficiary Identification and Records Locator Subsystem or successor system, maintained by Department of Veterans Affairs' Veterans Benefits Administration as a service-disabled veteran. Reservists or members of the National Guard disabled from a disease or injury incurred or aggravated in line of duty or while in training status also qualify.

Service-disabled veteran with a permanent and severe disability means a veteran with a service-connected disability that has been determined by the Department of Veterans Affairs, in writing, to have a permanent and total service-connected disability as set forth in 38 CFR 3.340 for purposes of receiving disability compensation or a disability pension.

Small business concern means, at the time of qualification, a concern that, with its affiliates, meets the size standard corresponding to any NAICS code under which it currently conducts business activities, pursuant to part 121 of this chapter. At time of contract offer, a VO or SDVO SBC must be small within the size standard corresponding to the NAICS code assigned to the contract.

Surviving spouse has the meaning given the term in 38 U.S.C. 101(3).

Unconditional ownership means ownership that is not subject to conditions precedent, conditions subsequent, executory agreements, voting trusts, restrictions on or assignments of voting rights, or other arrangements causing or potentially causing ownership benefits to go to another (other than after death or incapacity). The pledge or encumbrance of stock or other ownership interest as collateral, including seller-financed transactions, does not affect the unconditional nature of ownership if the terms follow normal commercial practices and the owner retains control absent violations of the terms.

VA is the U.S. Department of Veterans Affairs.

Veteran has the meaning given the term in 38 U.S.C. 101(2). A Reservist or member of the National Guard called to Federal active duty or disabled from a disease or injury incurred or aggravated in line of duty or while in training status also qualifies as a veteran.

Veterans Affairs Acquisition Regulation (VAAR) is the set of rules that specifically govern requirements exclusive to VA prime and subcontracting actions. The VAAR, 48 CFR chapter 8, supplements the Federal Acquisition Regulation (FAR) in 48 CFR chapter 1, which contains guidance applicable to most Federal agencies.

Subpart B—Eligibility Requirements for the Veterans Certification Program

§ 128.200 What are the requirements a concern must meet to qualify as a VO SBC or SDVO SBC?

(a) *Qualification as a Veteran-Owned Small Business Concern.* To qualify as a VO SBC, a business entity must be:

(1) A small business concern under the size standard corresponding to any NAICS code under which it currently conducts business activities;

(2) Not less than 51 percent of which is owned by one or more veterans or, in the case of any publicly owned business, not less than 51 percent of the stock (not including any stock owned by an ESOP) of which is owned by one or more veterans; and

(3) The management and daily business operations of which are controlled by one or more veterans.

(b) *Qualification as a Service-Disabled Veteran-Owned SBC.* To qualify as an SDVO SBC, a business entity must be:

(1) A small business concern under the size standard corresponding to any NAICS code under which it currently conducts business activities;

(2) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly-owned business, not less than 51 percent of the stock (not including any stock owned by an ESOP) of which is owned by one or more service-disabled veterans; and

(3) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a veteran with a disability that is rated by the Secretary of Veterans Affairs as a permanent and total disability who are unable to manage the daily business operations of such concern, the spouse or permanent caregiver of such veteran.

(c) *Veteran-Owned SBC and Service-Disabled Veteran-Owned SBC certifications.* (1) A concern must be certified as a VO or SDVO SBC pursuant to § 128.300 in order to be awarded a VO or SDVO set-aside or sole source contract.

(2) Other small business concerns that do not seek SDVO set-aside or sole source contracts may continue to self-certify their status, receive prime contract or subcontract awards outside the programs, and count toward an agency's goal for awards.

§ 128.201 What other eligibility requirements apply for individuals or businesses?

(a) *Suspension and debarment.* In order to be eligible for VO or SDVO SBC certification and to remain certified, the concern and any of its owners must not have an active exclusion in the System for Award Management at the time of application or recertification or at any time during the concern's period of eligibility. If, after certifying the Participant's eligibility, SBA discovers that a firm has an active exclusion, SBA will remove the Participant from the certification database immediately, notwithstanding the provisions of § 128.308.

(b) *Good character.* Individuals having an ownership or control interest in certified businesses must have good character. If, after certifying a Participant's eligibility, the person(s) controlling the Participant is found to lack good character, SBA will immediately terminate the Participant's certification, notwithstanding the provisions of § 128.310.

(c) *False statements.* If, during the processing of an application, SBA determines, by a preponderance of the evidence standard, that an Applicant has knowingly submitted false information, regardless of whether correct information would cause SBA to deny the application, and regardless of whether correct information was given to SBA in accompanying documents, SBA will deny the application. If, after certifying the Participant's eligibility, SBA discovers that false statements or information have been submitted by a firm, SBA will remove the Participant from the certification database immediately, notwithstanding the provisions of § 128.310. Whenever SBA determines that the Applicant submitted false information, the matter will be referred to the SBA Office of Inspector General for review. In addition, SBA may request that debarment proceedings be initiated by the agency.

(d) *Financial obligations.* Neither an Applicant firm nor any of its eligible individuals that fail to pay significant financial obligations, including unresolved tax liens and defaults on Federal loans, other government-assisted financing, owed to the Federal Government is eligible for certification. However, a firm will not be ineligible to participate in the Veterans Certification Program if the firm or the affected principals can demonstrate that the financial obligations owed have been settled, discharged, or forgiven by the Federal Government. If after certifying the Participant's eligibility SBA discovers that the Participant no longer

satisfies this requirement, SBA will remove the Participant from the certification database in accordance with § 128.310.

(e) *Protest decisions or other negative findings.* Any firm verified in the certification database that is found to be ineligible by a VO or SDVO status protest decision will be immediately removed from the certification database, notwithstanding the provisions of § 128.310. Any firm certified in the certification database that is found to be ineligible due to an SBA protest decision or other negative finding may be immediately removed from the certification database, notwithstanding the provisions of § 128.310. Until such time as SBA receives official notification that the decision is overturned on appeal or the firm applies for and receives certified status from SBA, the firm will not be eligible to participate in the Veterans Certification Program.

(f) *System for Award Management (SAM) registration.* All Applicants and Participants must be registered in SAM at *https://www.sam.gov,* or successor system, prior to application submission.

§ 128.202 Who does SBA consider to own a VO SBC or SDVO SBC?

Generally, a concern must be at least 51% unconditionally and directly owned by one or more veterans, or in the case of an SDVO SBC, service-disabled veterans. More specifically:

(a) *Ownership must be direct.* Ownership by one or more veterans, or in the case of an SDVO SBC, service-disabled veterans, must be direct ownership. A concern owned principally by another business entity that is in turn owned and controlled by one or more veterans or service-disabled veterans does not meet the requirement in this paragraph (a). Ownership by a trust, such as a living trust, may be treated as the functional equivalent of ownership by veterans or service-disabled veterans where the trust is revocable, and veterans or service-disabled veterans, respectively, are the grantors, trustees, and the current beneficiaries of the trust.

(b) *Ownership of a partnership.* In the case of a concern which is a partnership, at least 51% of aggregate voting interest must be unconditionally owned by one or more veterans, or in the case of an SDVO SBC, service-disabled veterans. The ownership must be reflected in the concern's partnership agreement.

(c) *Ownership of a limited liability company.* In the case of a concern which is a limited liability company, at least 51% of each class of member interest must be unconditionally owned by one or more veterans, or in the case of an SDVO SBC, service-disabled veterans.

(d) *Ownership of a corporation.* In the case of a concern which is a corporation, at least 51% of the aggregate of all stock outstanding and at least 51% of each class of voting stock outstanding must be unconditionally owned by one or more veterans, or in the case of an SDVO SBC, service-disabled veterans. In the case of a publicly-owned business, not less than 51 percent of the stock (not including any stock owned by an ESOP) must be unconditionally owned by one or more veterans.

(e) *Stock options' effect on ownership.* In determining unconditional ownership, SBA will disregard any unexercised stock options or similar agreements held by veterans, or in the case of an SDVO SBC, service-disabled veterans. However, any unexercised stock options or similar agreements (including rights to convert non-voting stock or debentures into voting stock) held by non-veterans or non-service-disabled veterans, in the case of an SDVO SBC, will be treated as exercised, except for any ownership interests which are held by investment companies licensed under 15 U.S.C. 681 *et seq.*

(f) *Change of ownership.* A concern may change its ownership or business structure so long as one or more veterans, or in the case of an SDVO SBC, service-disabled veterans own and control it after the change. A concern must notify SBA of a change of ownership in accordance with § 128.307 and attest to continued eligibility.

(g) *Dividends and distributions.* One or more veterans or, in the case of an SDVO SBC, service-disabled veterans must be entitled to receive:

(1) At least 51 percent of the annual distribution of profits paid to the owners of a corporation, partnership, or limited liability company concern;

(2) 100 percent of the value of each share of stock owned by them in the event that the stock or member interest is sold;

(3) At least 51 percent of the retained earnings of the concern and 100 percent of the unencumbered value of each share of stock or member interest owned in the event of dissolution of the corporation, partnership, or limited liability company; and

(4) An eligible individual's ability to share in the profits of the concern must be commensurate with the extent of his/her ownership interest in that concern.

(h) *Community property.* Ownership will be determined without regard to community property laws.

(i) *Surviving spouse.* (1) A small business concern owned and controlled by one or more service-disabled veterans immediately prior to the death of a service-disabled veteran who was the owner of the concern, the death of whom causes the concern to be less than 51 percent owned by one or more service-disabled veterans, will continue to qualify as a small business concern owned and controlled by service-disabled veterans during the time period specified in paragraph (i)(2) of this section if:

(i) The surviving spouse of the deceased veteran acquires such veteran's ownership interest in such concern;

(ii) Such veteran had a service-connected disability (as defined in 38 U.S.C. 101(16)); and

(iii) For a Participant, immediately prior to the death of such veteran, and during the period described in paragraph (i)(2) of this section, the small business concern is included in the certification database.

(2) The time period described in paragraph (i)(1)(iii) of this section is the time period beginning on the date of the veteran's death and ending on the earlier of—

(i) The date on which the surviving spouse remarries;

(ii) The date on which the surviving spouse relinquishes an ownership interest in the small business concern;

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

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

§ 128.203 Who does SBA consider to control a VO or SDVO SBC?

(a) *General.* To be an eligible VO SBC, the management and daily business operations of the concern must be controlled by one or more veterans. To be an eligible SDVO SBC, the management and daily business operations of the concern must be controlled by one or more service-disabled veterans (or in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran). Control by one or more veterans, or in the case of

an SDVO SBC, service-disabled veterans, means that both the long-term decision-making and the day-to-day management and administration of the business operations must be conducted by one or more veterans or service-disabled veterans (or in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran).

(b) *Managerial position and experience.* A veteran, or in the case of an SDVO SBC, a service-disabled veteran (or in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran) must hold the highest officer position in the concern (usually President or Chief Executive Officer (CEO)) and must have managerial experience of the extent and complexity needed to run the concern. The veteran or service-disabled veteran manager (or in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran) need not have the technical expertise or possess the required license to be found to control the concern if the veteran or service-disabled veteran can demonstrate that he or she has ultimate managerial and supervisory control over those who possess the required licenses or technical expertise.

(c) *Control over a partnership.* In the case of a partnership, one or more veterans, or in the case of an SDVO SBC, service-disabled veterans (or in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran) must serve as general partners, with control over all partnership decisions.

(d) *Control over a limited liability company.* In the case of a limited liability company, one or more veterans, or in the case of an SDVO SBC, service-disabled veterans (or in the case of a veteran with permanent or severe disability, the spouse or permanent caregiver of such veteran) must serve as management members, with control over all decisions of the limited liability company.

(e) *Control over a corporation.* One or more veterans, or in the case of an SDVO SBC, service-disabled veterans (or in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran) must control the Board of Directors of the concern.

(1) SBA will deem veteran or service-disabled veteran individuals to control the Board of Directors where:

(i) A single veteran or service-disabled veteran individual owns 100% of all voting stock of an Applicant or concern;

(ii) A single veteran or service-disabled veteran individual owns at least 51% of all voting stock of an Applicant or concern, the individual is on the Board of Directors and no super majority voting requirements exist for shareholders to approve corporation actions. Where super majority voting requirements are provided for in the concern's articles of incorporation, its by-laws, or by state law, the veteran or service-disabled veteran individual must own at least the percent of the voting stock needed to overcome any such super majority voting requirements; or

(iii) More than one veteran, or in the case of an SDVO SBC, service-disabled veteran shareholder seeks to qualify the concern (*i.e.,* no one individual owns 51%), each such individual is on the Board of Directors, together they own at least 51% of all voting stock of the concern, no super majority voting requirements exist, and the veteran or service-disabled veteran shareholders can demonstrate that they have made enforceable arrangements to permit one of them to vote the stock of all as a block without a shareholder meeting. Where the concern has super majority voting requirements, the veteran or service-disabled veteran shareholders must own at least that percentage of voting stock needed to overcome any such super majority ownership requirements. In the case of super majority ownership requirements where there is more than one eligible individual, the veteran or service-disabled veteran shareholders can demonstrate that they have made enforceable arrangements to permit one of them to vote the stock of all as a block without a shareholder meeting.

(2) Where an Applicant or concern does not meet the requirements set forth in paragraph (e)(1) of this section, the veteran or service-disabled veteran individual(s) upon whom eligibility is based must control the Board of Directors through actual numbers of voting directors or, where permitted by state law, through weighted voting (*e.g.,* in a concern having a two-person Board of Directors where one individual on the Board is a veteran or service-disabled veteran and one is not, the veteran or service-disabled veteran vote must be weighted—worth more than one vote—in order for the concern to be eligible). Where a concern seeks to comply with this paragraph (e)(2):

(i) Provisions for the establishment of a quorum cannot permit non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran Directors to control the Board of Directors, directly or indirectly; and

(ii) Any Executive Committee of Directors must be controlled by veteran or, in the case of an SDVO SBC, service-disabled veteran directors unless the Executive Committee can only make recommendations to and cannot independently exercise the authority of the Board of Directors.

(3) Non-voting, advisory, or honorary Directors may be appointed without affecting veteran or service-disabled veteran individuals' control of the Board of Directors.

(4) Arrangements regarding the structure and voting rights of the Board of Directors must comply with applicable state law.

(f) *Super majority requirements.* One or more veteran or, in the case of an SDVO SBC, service-disabled veterans must meet all super majority voting requirements, regardless of legal structure of the Applicant firm. An Applicant must inform the SBA, when applicable, of any super majority voting requirements provided for in its articles of incorporation, its by-laws, by state law, or otherwise. Similarly, after being certified, a Participant must inform the SBA of changes regarding super majority voting requirements.

(g) *Licenses.* A firm must obtain and keep current any and all required permits, licenses, and charters, required to operate the business.

(h) *Unexercised rights.* A veteran or, in the case of an SDVO SBC, service-disabled veteran owner's unexercised right to cause a change in the control or management of the Applicant concern does not in itself constitute control and management, regardless of how quickly or easily the right could be exercised.

(i) *Control by non-veterans or non-service-disabled veterans.* Non-veteran, or in the case of an SDVO SBC, non-service-disabled veteran individuals or entities may not control the firm. There is a rebuttable presumption that non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran individuals or entities control or have the power to control a firm in any of the following circumstances, which are illustrative only and not inclusive:

(1) The non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran individual or entity who is involved in the management or ownership of the firm is a current or former employer or a principal of a current or former employer of any veteran, in the case of an SDVO SBC, service-disabled veteran individual upon whom the firm's eligibility is based. However, a firm may provide evidence to demonstrate that the relationship does not give the non-veteran or non-service-disabled veteran

actual control over the concern and such relationship is in the best interests of the concern.

(2) One or more non-veterans or, in the case of an SDVO SBC, non-service-disabled veterans receive compensation from the firm in any form as directors, officers, or employees, including dividends, that exceeds the compensation to be received by the highest-ranking officer (usually CEO or President). The highest-ranking officer may elect to take a lower amount than the total compensation and distribution of profits that are received by a non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran only upon demonstrating that it helps the concern.

(3) In circumstances where the concern is co-located with another firm in the same or similar line of business, and that firm or an owner, director, officer, or manager, or a direct relative of an owner, director, officer, or manager of that firm owns an equity interest in the concern.

(4) In circumstances where the concern shares employees, resources, equipment, or any type of services, whether by oral or written agreement with another firm in the same or similar line of business, and that firm or an owner, director, officer, or manager, or a direct relative of an owner, director, officer, or manager of that firm owns an equity interest in the concern.

(5) A non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran individual or entity, having an equity interest in the concern, provides critical financial or bonding support.

(6) In circumstances where a critical license is held by a non-veteran or, in the case of an SDVO SBC, non-service-disabled individual, or other entity, the non-veteran or non-service-disabled individual or entity may be found to control the firm. A critical license is considered any license that would normally be required of firms operating in the same field or industry, regardless of whether a specific license is required on a specific contract.

(7) Business relationships exist with non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran individuals or entities which cause such dependence that the Applicant or concern cannot exercise independent business judgment without great economic risk.

(j) *Critical financing.* A non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran individual or entity may be found to control the concern through loan arrangements with the concern or the veteran(s)/service-disabled veteran(s). Providing a loan or a loan guaranty on commercially reasonable terms does not, by itself, give a non-veteran or non-service-disabled veteran individual or entity the power to control a firm, but when taken into consideration with other factors may be used to find that a non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran firm or individual controls the concern.

(k) *Normal business hours.* There is a rebuttable presumption that a veteran or, in the case of an SDVO SBC, service-disabled veteran does not control the firm when the veteran or, in the case of an SDVO SBC, service-disabled veteran is not able to work for the firm during the normal working hours that businesses in that industry normally work. This may include, but is not limited to, other full-time or part-time employment, being a full-time or part-time student, or any other activity or obligation that prevents the veteran or, in the case of an SDVO SBC, service-disabled veteran from actively working for the firm during normal business operating hours.

(l) *Close proximity.* There is rebuttable presumption that a veteran or, in the case of an SDVO SBC, service-disabled veteran does not control the firm if that individual is not located within a reasonable commute to firm's headquarters and/or job-sites locations, regardless of the firm's industry. The veteran or, in the case of an SDVO SBC, service-disabled veteran's ability to answer emails, communicate by telephone, or to communicate at a distance by other technological means, while delegating the responsibility of managing the concern to others is not by itself a reasonable rebuttal.

(m) *Exception for ''extraordinary circumstances.''* SBA will not find that a lack of control exists where a veteran or, in the case of an SDVO SBC, service-disabled veteran does not have the unilateral power and authority to make decisions in ''extraordinary circumstances.'' The only circumstances in which the exception in this paragraph (m) applies are those articulated in the definition of the term in § 128.102.

(n) *Exception for active duty.* Notwithstanding the provisions of this section requiring a veteran or, in the case of an SDVO SBC, service-disabled veteran to control the daily business operations and long-term strategic planning of a concern, where a veteran or, in the case of an SDVO SBC, service-disabled veteran individual upon whom eligibility is based is a reserve component member in the United States military who has been called to active duty, the concern may elect to designate in writing one or more individuals to control the concern on behalf of the veteran or, in the case of an SDVO SBC, service-disabled veteran during the period of active duty. The concern will not be considered ineligible based on the absence of the veteran or service-disabled veteran during the period of active duty. The concern must keep records evidencing the active duty and the written designation of control and provide those documents to SBA.

§ 128.204 What size standards apply to VO SBCs and SDVO SBCs?

(a) At time of contract offer, a VO or SDVO SBC must be small within the size standard corresponding to the NAICS code assigned to the contract.

(b) If the contracting officer is unable to verify that the VO or SDVO SBC is small, the concern shall be referred to the responsible SBA Government Contracting Area Director for a formal size determination in accordance with part 121 of this chapter.

Subpart C—Certification of VO SBC or SDVO SBC Status

§ 128.300 How is a concern certified as a VO SBC or SDVO SBC?

(a) A small business concern must be unconditionally owned and controlled by one or more eligible veterans, in the case of an SDVO SBC, service-disabled veterans or surviving spouses, have completed the online application forms, submitted required supplemental documentation to SBA, and have been examined by SBA.

(b) A certified Participant in SBA's 8(a) Business Development (BD) Program that is owned and controlled by one or more veterans, or in the case of SDVO SBC, service-disabled veterans. The eligible individual(s) for both designations must be the same individual(s) to receive expedited review.

(c) A certified Participant in SBA's Women Owned Small Business (WOSB) or Economically Disadvantaged WOSB (EDWOSB) Program that is owned and controlled by one or more veterans, or in the case of SDVO SBC, service-disabled veterans. The eligible individual(s) for both designations must be the same individual(s) to receive expedited review.

§ 128.301 Where must an application be filed?

An application for certification must be electronically filed in the database located on SBA's web portal. Guidelines and forms are located on the web portal. Upon receipt of the Applicant's electronic submission, an acknowledgment message will be dispatched to the concern containing

estimated processing time and other information.

§ 128.302 How does SBA process applications for certification?

(a) SBA's Director of Government Contracting (D/GC) or designee is authorized to approve or deny applications for certification. SBA will receive, review, and examine all certification applications.

(b) SBA, in its sole discretion, may request clarification of information relating to eligibility at any time in the eligibility determination process. SBA will take into account any clarifications made by an Applicant in response to a request for such SBA.

(c) SBA, in its sole discretion, may request additional documentation at any time in the eligibility determination process. Failure to adequately respond to the documentation request shall constitute grounds for a denial or administrative removal.

(d) An Applicant's eligibility will be based on the totality of circumstances existing on the date of application, except where clarification is made pursuant to paragraph (b) of this section, additional documentation is submitted pursuant to paragraph (c) of this section, as provided in paragraph (e) of this section or in the case of amended documentation submitted pursuant to § 128.304(a). The Applicant bears the burden to establish its status as a VO SBC or SDVO SBC.

(e) Changed circumstances for an Applicant occurring subsequent to its application and which affect eligibility will be considered and may constitute grounds for denial of the application. The Applicant must inform SBA of any changed circumstances that could affect its eligibility for the program (*e.g.,* ownership, control changes, or bankruptcy filing) during its application review and may withdraw their application at that time. The D/GC may propose decertification for any VO SBC or SDVO SBC that failed to inform SBA of any changed circumstances that affected its eligibility for the program during the processing of the application.

(f) The decision of the D/GC to approve or deny an application will be in writing. A decision to deny certification status will state the specific reasons for denial and will inform the Applicant of any appeal rights.

(g) If the D/GC approves the application, the date of the approval letter is the date of Participant certification for purposes of determining the Participant's certification term of eligibility. For approvals contingent on reciprocity due to participation in SBA's other certification programs (*e.g.,* WOSB or 8(a)), the approval letter will contain a date for the Vets Program certification which aligns with the remaining time in the other program(s) in which the Applicant is participating.

(h) The decision may be sent by mail, commercial carrier, or other electronic means. It is the responsibility of the Applicant to ensure all contact information is current in the Applicant's profile.

§ 128.303 What must a concern submit to apply for VO SBC or SDVO SBC certification?

(a) To be certified by SBA as a VO or SDVO SBC, a concern must provide documents and information demonstrating that it is owned and controlled by one or more veterans or, in the case of an SDVO SBC, service-disabled veterans and qualifies as a small business concern as defined in part 121 of this chapter under the size standard corresponding to any NAICS code under which it currently conducts business activities. SBA maintains a list of the minimum required documents that can be found on SBA's website. A concern may submit additional documents and information to support its eligibility. The required documents must be provided to SBA during the application process electronically. This may include, but is not limited to, corporate records, business and personal financial records, including copies of Federal personal and business tax returns as filed with the Internal Revenue Service, and individual and business banking information. From the time the Applicant submits the application, the Applicant must also retain on file, at the principal place of business, a complete copy of all supplemental documentation required by, and provided to, SBA for use in certification examinations.

(b) A small business concern that is certified by the 8(a) BD Program and the individual(s) on whom 8(a) BD Program eligibility is based is one or more veterans, or service-disabled veterans in the case of an SDVO SBC, may use documentation of its most recent annual review, or documentation of its 8(a) acceptance if it has not yet had an annual review, in support of its application for certification. An Applicant must certify that there are no material changes in its ownership or control since its 8(a) certification or annual review and demonstrate that the individuals who own and control it are veterans or, in the case of an SDVO SBC, service-disabled veterans.

(c) A small business concern that is certified by the WOSB/EDWOSB Program and the individual(s) on whom WOSB/EDWOSB Program eligibility is based is one or more veterans, or service-disabled veterans in the case of an SDVO SBC, may use documentation of its most recent annual recertification, or documentation of its acceptance in support of its application for certification. An Applicant must certify that there are no material changes in its ownership or control since its WOSB certification or recertification and demonstrate that the individuals who own and control it are veterans or, in the case of an SDVO SBC, service-disabled veterans.

(d) If a concern was decertified or previously denied certification within the past 3 years, it must include with its application for certification a full explanation of why it was decertified or denied certification, and what, if any, changes have been made. If SBA is not satisfied with the explanation provided, SBA will decline to certify the concern.

(e) If the concern was decertified for failure to notify SBA of a material change affecting its eligibility pursuant to § 128.307, it must include with its application for certification a full explanation of why it failed to notify SBA of the material change. If SBA is not satisfied with the explanation provided, SBA will decline to certify the concern.

§ 128.304 Can an Applicant appeal SBA's initial decision to deny an application?

(a) An Applicant may appeal SBA's decision to deny an application by filing an appeal with the SBA's Office of Hearings and Appeals (OHA) after the Applicant receives the denial in accordance with part 134 of this chapter. The filing party bears the risk that the delivery method chosen will not result in timely receipt by OHA.

(b) The decision may be sent by mail, commercial carrier, or other electronic means.

§ 128.305 Can an Applicant or Participant reapply for certification?

(a) Once an application, an appeal of a denial of an application, or an appeal of a certified status decertification has been denied, or a certified status decertification which was not appealed has been issued, the Applicant or Participant shall be required to wait for a period of 90 calendar days before a new application will be processed by SBA.

(b) Participants may recertify within 120 calendar days prior to the termination of their eligibility period. If a Participant is found to be ineligible, the Participant will forfeit any time remaining on their eligibility period and will be immediately removed from the

certification database. An Applicant removed pursuant to this section may appeal the decision to OHA in accordance with § 128.304. The date of a new determination letter certifying an Applicant will be the beginning of the next 3-year eligibility period.

§ 128.306 What length of time may a business participate in SBA's Veterans Certification Program?

(a) A Participant receives an eligibility term of 3 years from the date of SBA's approval letter establishing certified status. There is no limitation on the number of times a business may recertify to continue eligibility past an initial 3-year term.

(b) The Participant must maintain its eligibility during its tenure and must inform SBA of any changes that may affect its eligibility within 30 calendar days in accordance with § 128.307.

(c) The eligibility term may be shortened by removal pursuant to § 128.201, recertification pursuant to § 128.305(b), failure to maintain certification pursuant to § 138.307, voluntary withdrawal by the Participant pursuant to § 128.309, decertification pursuant to § 128.310, or an adverse status protest pursuant to part 134 of this chapter.

(d) SBA may initiate a certification examination whenever it receives credible information concerning a Participant's eligibility as a VO or SDVO SBC. Upon its completion of the examination, SBA will issue a written decision regarding the continued eligibility status of the questioned Participant.

(1) If SBA finds that the Participant does not qualify as a VO or SDVO SBC, the procedures at § 128.310 will apply, except as provided in § 128.201.

(2) If SBA finds that the Participant continues to qualify as a VO or SDVO SBC, the original eligibility period remains in effect.

§ 128.307 What are a Participant's ongoing obligations to SBA?

Once certified, a VO SBC or SDVO SBC must notify SBA of any material changes that could affect its eligibility within 30 calendar days of any such change and attest to continued eligibility. Material changes include, but are not limited to, a change in the ownership, business structure, management, or bankruptcy. The notification must be in writing and must be uploaded into the concern's profile with SBA. The method for notifying SBA can be found on SBA's web page. A concern's failure to notify SBA of such a material change may result in a certification examination as described in § 128.308, and/or decertification and removal from the certification database for the program (or any successor system) as a designated certified VO SBC or SDVO SBC. In addition, SBA may seek the imposition of penalties under § 128.600.

§ 128.308 What is a certification examination and what will SBA examine?

(a) *General.* A certification examination is an investigation by SBA officials, which verifies the accuracy of any statement or information provided by a certified Participant. Thus, examiners may verify that the Participant currently meets the eligibility requirements of this part, and that it met such requirements at the time of its application or its most recent size recertification. An examination may be conducted on a random, unannounced basis, or upon receipt of specific and credible information alleging that a Participant no longer meets eligibility requirements in this part.

(b) *Scope of examination.* SBA may conduct the examination at one or all of the Participant's offices or work sites. SBA will determine the location(s) of the examination. SBA may review any information related to the concern's eligibility requirements under this part including, but not limited to, documentation related to the legal structure, ownership, and control. Examiners may review any or all of the organizing documents, financial documents, and publicly available information as well as any information identified in § 128.303.

§ 128.309 What are the ways a business may exit certification status?

A Participant may:

(a) Voluntarily decertify its status by submitting a written request to SBA requesting that the concern be removed from public listing in the certification database; or

(b) Delete its record entirely from the certification database; or

(c) SBA may remove a Participant immediately pursuant to § 128.201; or

(d) SBA may remove a Participant from public listing in the certification database for good cause upon formal notice to the Participant in accordance with § 128.310. Examples of good cause include, but are not limited to, the following:

(1) Submission of false information in the Participant's application.

(2) Failure by the Participant to maintain its eligibility for program participation.

(3) Failure by the Participant for any reason, including the death of an individual upon whom eligibility was based, to maintain ownership, management, and control by veterans, service-disabled veterans, or surviving spouses.

(4) Failure by the concern to disclose to SBA the extent to which non-veteran or, in the case of an SDVO SBC, non-service-disabled veteran persons or firms participate in the management of the Participant.

(5) Failure to make required submissions or responses to SBA or its agents, including a failure to make available financial statements, requested tax returns, reports, information requested by SBA or SBA's Office of Inspector General, or other requested information or data within 30 calendar days of the date of request.

(6) Cessation of the Participant's business operations.

(7) Failure by the concern to provide SBA notification within 30 calendar days of any change in ownership.

(8) Failure to inform SBA of any such changed circumstances, as outlined in § 128.307.

(9) Failure by the concern to obtain and keep current any and all required permits, licenses, and charters, including suspension or revocation of any professional license required to operate the business.

(10) SBA will decertify a concern found to be ineligible during a status protest.

(e) The examples of good cause listed in paragraph (d) of this section are intended to be illustrative only. Other grounds for decertifying a Participant include any other cause of so serious or compelling a nature that it affects the present responsibility of the Participant.

§ 128.310 What are the procedures for decertification?

(a) *General.* When SBA believes that a Participant's certified status should be cancelled prior to the expiration of its eligibility term, SBA will notify the Participant in writing. The Notice of Proposed Decertification Letter will set forth the specific facts and reasons for SBA's findings and will notify the Participant that it has 30 calendar days from the date SBA sent the notice to submit a written response to SBA explaining why the proposed ground(s) should not justify decertification.

(b) *Recommendation and decision.* Following the 30-day response period, the D/GC will consider any information submitted by the Participant. Upon determining that decertification is not warranted, the D/GC will notify the Participant in writing. If decertification appears warranted, the D/GC will determine whether to cancel the Participant's certified status.

(c) *Notice requirements.* Upon deciding that decertification is warranted, the D/GC will issue a Notice of Certified Status Decertification. The Notice will set forth the specific facts and reasons for the decision and will advise the concern that it may re-apply after it has met all eligibility criteria in this part and completed the waiting period as set forth in § 128.305(a).

(d) *Effect of decertification.* After the effective date of decertification, a Participant is no longer eligible to appear as ''certified'' in the certification database. However, such concern is obligated to perform previously awarded contracts to the completion of their existing term of performance.

(e) *Appeals.* A Participant may file an appeal with OHA concerning the Notice of Certified Status Decertification decision in accordance with part 134 of this chapter. The decision on the appeal shall be final.

Subpart D—Federal Contract Assistance

§ 128.400 What are VO and SDVO contracts?

(a) For VA procurements, the VAAR specifically governs requirements exclusive to VA prime and subcontracting actions. The VAAR, 48 CFR chapter 8, supplements the Federal Acquisition Regulation (FAR), which contains guidance applicable to most Federal agencies.

(b) For all other SDVO contracts, including Multiple Award Contracts (*see* § 125.1 of this chapter), such are available to an SDVO SBC through any of the following procurement methods:

(1) Sole source awards to an SDVO SBC;

(2) Set-aside awards, including partial set-asides, based on competition restricted to SDVO SBCs;

(3) Awards based on a reserve for SDVO SBCs in a solicitation for a Multiple Award Contract (*see* § 125.1 of this chapter); or

(4) Orders set aside for SDVO SBCs against a Multiple Award Contract, which had been awarded in full and open competition.

§ 128.401 What requirements must a VO SBC or SDVO SBC meet to submit an offer on a contract?

(a) *General.* (1) In order for a concern to submit an offer and be eligible for the award of a VO or SDVO set-aside or sole source contract, the concern must qualify as a small business concern under the size standard corresponding to the NAICS code(s) assigned to the contract and be a certified VO SBC or SDVO SBC, or represent that it has submitted a complete application for VO SBC or SDVO SBC certification to SBA and has not received a negative eligibility determination regarding that application.

(2) If a concern is not certified by SBA at the time of offer, the concern must represent to the contracting officer for the particular contract that it has submitted a complete application to SBA for VO SBC or SDVO SBC certification.

(i) If a concern becomes the apparent successful offeror while its application for VO or SDVO SBC certification is pending, the contracting officer for the particular contract must immediately inform SBA's D/GC. SBA will then prioritize the concern's VO or SDVO SBC application and make a determination regarding the firm's status within 15 calendar days from the date that SBA received the contracting officer's notification.

(ii) If the contracting officer does not receive an SBA determination within 15 calendar days after the SBA's receipt of the notification, the contracting officer may presume that the apparently successful offeror is not an eligible VO SBC or SDVO SBC and may award the subject contract accordingly to the next highest evaluated offeror, unless the contracting officer grants SBA an extension to the 15-day response period.

(b) *Joint ventures.* A business concern seeking a VO SBC or SDVO SBC contract as a joint venture may submit an offer if the joint venture meets the requirements as set forth in § 128.402.

(c) *Non-manufacturers.* A certified VO SBC or SDVO SBC which is a non-manufacturer may submit an offer on a VO or SDVO contract for supplies if it meets the requirements of the non-manufacturer rule set forth at § 121.406(b)(1) of this chapter.

(d) *Multiple Award Contracts*—(1) *VO or SDVO status.* With respect to Multiple Award Contracts, orders issued against a Multiple Award Contract, and Blanket Purchase Agreements issued against a Multiple Award Contract:

(i) SBA determines VO or SDVO small business eligibility for the underlying Multiple Award Contract as of the date a business concern certifies its status as a certified VO or SDVO small business concern as part of its initial offer (or other formal response to a solicitation), which includes price, unless the firm was required to recertify under paragraph (e) of this section.

(A) *Unrestricted Multiple Award Contracts or set-aside Multiple Award Contracts for other than VO or SDVO.* For an unrestricted Multiple Award Contract or other Multiple Award Contract not specifically set aside for VO or SDVO small business concerns, if a business concern is a certified as a VO or SDVO small business concern at the time of offer and contract-level recertification for the Multiple Award Contract, it is a VO or SDVO small business concern for goaling purposes for each order issued against the contract, unless a contracting officer requests recertification as a VO or SDVO small business for a specific order or Blanket Purchase Agreement. Except for orders and Blanket Purchase Agreements issued under any Federal Supply Schedule contract, if an order or a Blanket Purchase Agreement under an unrestricted Multiple Award Contract is set aside exclusively for VO or SDVO small business concerns, a concern must recertify that it qualifies as a VO or SDVO small business concern at the time it submits its initial offer, which includes price, for the particular order or Blanket Purchase Agreement. However, where the underlying Multiple Award Contract has been awarded to a pool of concerns for which certified VO or SDVO small business status is required, if an order or a Blanket Purchase Agreement under that Multiple Award Contract is set aside exclusively for concerns in the certified VO or SDVO small business pool, concerns need not recertify their status as VO or SDVO small business concerns (unless a contracting officer requests size certifications with respect to a specific order or Blanket Purchase Agreement).

(B) *VO or SDVO set-aside Multiple Award Contracts.* For a Multiple Award Contract that is specifically set aside for a VO or SDVO small business concern, if a business concern is a VO or SDVO small business concern at the time of offer and contract-level recertification for the Multiple Award Contract, it is a VO or SDVO small business concern for each order issued against the contract, unless a contracting officer requests recertification as a VO or SDVO small business concern for a specific order or Blanket Purchase Agreement.

(ii) SBA will determine VO or SDVO small business status at the time of initial offer (or other formal response to a solicitation), which includes price, for an order or an Agreement issued against a Multiple Award Contract if the contracting officer requests a new VO or SDVO small business certification for the order or Agreement.

(2) *Total set-aside contracts.* The VO SBC or SDVO SBC must comply with the applicable limitations on subcontracting provisions (*see* § 125.6 of this chapter) and the nonmanufacturer rule (*see* § 121.406(b) of this chapter), if applicable, in the performance of a contract totally set aside for VO SBCs or

SDVO SBCs. However, the contracting officer, in their discretion, may require the concern to perform the applicable amount of work or comply with the nonmanufacturer rule for each order awarded under the contract.

(3) *Partial set-aside contracts.* For orders awarded under a partial set-aside contract, the VO SBC or SDVO SBC must comply with the applicable limitations on subcontracting provisions (*see* § 125.6 of this chapter) and the nonmanufacturer rule (*see* § 121.406(b) of this chapter), if applicable, during each performance period of the contract (*e.g.,* during the base term and then during each option period thereafter). For orders awarded under the non-set-aside portion, the VO SBC or SDVO SBC need not comply with any limitations on subcontracting or nonmanufacturer rule requirements. However, the contracting officer, in their discretion, may require the concern to perform the applicable amount of work or comply with the nonmanufacturer rule for each order awarded under the contract.

(4) *Orders.* The VO SBC or SDVO SBC must comply with the applicable limitations on subcontracting provisions (*see* § 125.6 of this chapter) and the nonmanufacturer rule (*see* § 121.406(b) of this chapter), if applicable, in the performance of each individual order that has been set aside for VO SBCs or SDVO SBCs.

(5) *Reserves.* The VO SBC or SDVO SBC must comply with the applicable limitations on subcontracting provisions (*see* § 125.6 of this chapter) and the nonmanufacturer rule (*see* § 121.406(b) of this chapter), if applicable, in the performance of an order that is set aside for VO SBCs or SDVO SBCs. However, the VO SBC or SDVO SBC will not have to comply with the limitations on subcontracting provisions and the nonmanufacturer rule for any order issued against the Multiple Award Contract if the order is competed amongst VO SBCs or SDVO SBCs and one or more other-than-small business concerns.

(e) *Recertification.* (1) A concern that qualifies as a VO SBC or SDVO SBC at the time of initial offer (or other formal response to a solicitation), which includes price, including a Multiple Award Contract, is considered a VO SBC or SDVO SBC throughout the life of that contract. This means that if a VO SBC or SDVO SBC is qualified at the time of initial offer for a Multiple Award Contract, then it will be considered a VO SBC or SDVO SBC for each order issued against the contract, unless a contracting officer requests a new VO SBC or SDVO SBC eligibility review in connection with a specific order. Where a concern later fails to qualify as a VO SBC or SDVO SBC, the procuring agency may exercise options and still count the award as an award to a VO SBC or SDVO SBC. However, the following exceptions apply to this paragraph (e)(1):

(i) Where a contract is novated to another business concern, the concern that will continue performance on the contract must recertify its status as a VO SBC or SDVO SBC to the procuring agency or inform the procuring agency that it does not qualify as a VO SBC or SDVO SBC within 30 days of the novation approval. If the concern is not a VO SBC or SDVO SBC, the agency can no longer count the options or orders issued pursuant to the contract from that point forward towards its VO or SDVO goals.

(ii) Where a concern that is performing a contract acquires, is acquired by, or merges with another concern and contract novation is not required, the concern must, within 30 days of the transaction becoming final, recertify its VO SBC or SDVO SBC status to the procuring agency or inform the procuring agency that it no longer qualifies as a VO SBC or SDVO SBC. If the contractor is not a VO SBC or SDVO SBC, the agency can no longer count the options or orders issued pursuant to the contract from that point forward towards its VO or SDVO goals. The agency and the contractor must immediately revise all applicable Federal contract databases to reflect the new status.

(iii) Where there has been a VO SBC or SDVO SBC status protest on the solicitation or contract, *see* part 134 of this chapter for the effect of the status determination on the contract award.

(2) For the purposes of VO SBC or SDVO SBC contracts (including Multiple Award Contracts) with durations of more than five years (including options), a contracting officer must request that a business concern recertify its VO SBC or SDVO SBC status no more than 120 calendar days prior to the end of the fifth year of the contract, and no more than 120 calendar days prior to exercising any option. If the business is unable to recertify its VO or SDVO status, the procuring agency may no longer be able to count the options or orders issued pursuant to the contract, from that point forward, towards its VO or SDVO goals.

(3) A business concern that did not certify itself as a VO SBC or SDVO SBC, either initially or prior to an option being exercised, may recertify itself as a VO SBC or SDVO SBC for a subsequent option period if it meets the eligibility requirements in this part at that time.

(4) Recertification does not change the terms and conditions of the contract. The limitations on subcontracting (*see* § 125.6 of this chapter), nonmanufacturer (*see* § 121.406(b) of this chapter), and subcontracting plan requirements (*see* § 125.3(a) of this chapter) in effect at the time of contract award remain in effect throughout the life of the contract.

(5) Where the contracting officer explicitly requires concerns to recertify their status in response to a solicitation for an order, SBA will determine eligibility as of the date the concern submits its response to the solicitation for the order.

(6) A concern's status may be determined at the time of a response to a solicitation for an Agreement and each order issued pursuant to the Agreement.

(f) *Limitations on subcontracting.* A business concern seeking a VO SBC or SDVO SBC requirement must also meet the applicable limitations on subcontracting requirements as set forth in § 125.6 of this chapter for the performance of VO SBC or SDVO SBC contracts (both sole source and those totally set aside for VO SBC or SDVO SBC), the performance of the set-aside portion of a partial set-aside contract, or the performance of orders set-aside for VO SBC or SDVO SBC.

(g) *Ostensible subcontractor.* Where a subcontractor that is not similarly situated performs primary and vital requirements of a set-aside or sole source service contract or order, or where a prime contractor is unduly reliant on a small business that is not similarly situated to perform the set-aside or sole source service contract or order, the prime contractor is not eligible for award of a VO or SDVO contract.

(1) When the subcontractor is small for the size standard assigned to the procurement, the issue in paragraph (g) introductory text may be grounds for a VO or SDVO status protest, as described in subpart E of this part. When the subcontractor is other than small or alleged to be other than small for the size standard assigned to the procurement, the issue in paragraph (a) introductory text may be grounds for a size protest subject to the ostensible subcontractor rule, as described at § 121.103(h)(2) of this chapter.

(2) SBA will find that a prime VO or SDVO contractor is performing the primary and vital requirements of a contract or order and is not unduly reliant on one or more non-similarly situated subcontracts where the prime contractor can demonstrate that it, together with any similarly situated entity, will meet the limitations on

subcontracting provisions set forth in § 125.6 of this chapter.

§ 128.402 May a joint venture submit an offer on a VO SBC or SDVO SBC requirement?

(a) *Certification.* For VA contracts, a VO SBC or SDVO SBC joint venture must be certified to submit an offer on a VO SBC or SDVO SBC contract, as set forth in 48 CFR part 819. For all other SDVO SBC contracts, joint ventures may apply for certification. To be eligible for inclusion, a joint venture must demonstrate that:

(1) The underlying VO SBC or SDVO SBC upon which eligibility is based is certified in accordance with this part; and

(2) The joint venture agreement complies with the requirements set forth in this part.

(b) *General.* A VO SBC or SDVO SBC may enter into a joint venture agreement with one or more other SBCs or its SBA-approved mentor for the purpose of performing a VO or SDVO contract if the joint venture meets all of the following requirements:

(1) *Size of concerns to a VO or SDVO SBC joint venture.* (i) A joint venture of at least one certified VO SBC or SDVO SBC and one or more other business concerns may submit an offer as a small business for a competitive VO SBC or SDVO SBC procurement or sale, or be awarded a sole source VO or SDVO contract, so long as each concern is small under the size standard corresponding to the NAICS code assigned to the procurement or sale.

(ii) A joint venture between a protégé firm certified as a VO SBC or SDVO SBC and its SBA-approved mentor (*see* § 125.9 of this chapter) will be deemed small provided the protégé qualifies as small for the size standard corresponding to the NAICS code assigned to the VO or SDVO procurement or sale.

(2) *Contents of joint venture agreement.* Every joint venture agreement to perform a VO or SDVO contract, including those between a protégé firm certified as a VO SBC or SDVO SBC and its SBA-approved mentor authorized by § 125.9 of this chapter, must contain a provision:

(i) Setting forth the purpose of the joint venture;

(ii) Designating a certified VO SBC or SDVO SBC as the managing venturer of the joint venture and designating a named employee of the certified VO SBC or SDVO SBC managing venturer as the manager with ultimate responsibility for performance of the contract (the ''Responsible Manager'');

(A) The managing venturer is responsible for controlling the day-to-day management and administration of the contractual performance of the joint venture, but other partners to the joint venture may participate in all corporate governance activities and decisions of the joint venture as is commercially customary;

(B) The individual identified as the Responsible Manager of the joint venture need not be an employee of the certified VO SBC or SDVO SBC at the time the joint venture submits an offer, but, if he or she is not, there must be a signed letter of intent that the individual commits to be employed by the certified VO SBC or SDVO SBC if the joint venture is the successful offeror. The individual identified as the Responsible Manager cannot be employed by the mentor and become an employee of the certified VO SBC or SDVO SBC for purposes of performance under the joint venture; and

(C) Although the joint venture managers responsible for orders issued under an indefinite delivery/indefinite quantity contract need not be employees of the protégé, those managers must report to and be supervised by the joint venture's Responsible Manager;

(iii) Stating that with respect to a separate legal entity joint venture, the certified VO SBC or SDVO SBC must own at least 51% of the joint venture entity;

(iv) Stating that the certified VO SBC or SDVO SBC must receive profits from the joint venture commensurate with the work performed by the certified VO SBC or SDVO SBC, or a percentage agreed to by the parties to the joint venture whereby the certified VO SBC or SDVO SBC receives profits from the joint venture that exceed the percentage commensurate with the work performed by the certified VO or SDVO SBC;

(v) Providing for the establishment and administration of a special bank account in the name of the joint venture. This account must require the signature or consent of all parties to the joint venture for any payments made by the joint venture to its members for services performed. All payments due the joint venture for performance on a VO or SDVO contract will be deposited in the special account; all expenses incurred under the contract will be paid from the account as well;

(vi) Itemizing all major equipment, facilities, and other resources to be furnished by each party to the joint venture, with a detailed schedule of cost or value of each, where practical. If a contract is indefinite in nature, such as an indefinite quantity contract or a multiple award contract where the level of effort or scope of work is not known, the joint venture must provide a general description of the anticipated major equipment, facilities, and other resources to be furnished by each party to the joint venture, without a detailed schedule of cost or value of each, or in the alternative, specify how the parties to the joint venture will furnish such resources to the joint venture once a definite scope of work is made publicly available;

(vii) Specifying the responsibilities of the parties with regard to negotiation of the contract, source of labor, and contract performance, including ways that the parties to the joint venture will ensure that the joint venture and the certified VO or SDVO small business partner(s) to the joint venture will meet the performance of work requirements set forth in paragraph (b)(3) of this section, where practical. If a contract is indefinite in nature, such as an indefinite quantity contract or a multiple award contract where the level of effort or scope of work is not known, the joint venture must provide a general description of the anticipated responsibilities of the parties with regard to negotiation of the contract, source of labor, and contract performance, not including the ways that the parties to the joint venture will ensure that the joint venture and the certified VO or SDVO small business partner(s) to the joint venture will meet the performance of work requirements set forth in paragraph (d) of this section, or in the alternative, specify how the parties to the joint venture will define such responsibilities once a definite scope of work is made publicly available;

(viii) Obligating all parties to the joint venture to ensure performance of the VO or SDVO contract and to complete performance despite the withdrawal of any member;

(ix) Designating that accounting and other administrative records relating to the joint venture be kept in the office of the certified VO SBC or SDVO SBC managing venturer, unless approval to keep them elsewhere is granted by the District Director or his/her designee upon written request;

(x) Requiring that the final original records be retained by the certified VO SBC or SDVO SBC managing venturer upon completion of the VO or SDVO contract performed by the joint venture;

(xi) Stating that quarterly financial statements showing cumulative contract receipts and expenditures (including salaries of the joint venture's principals) must be submitted to SBA not later than 45 days after each operating quarter of the joint venture; and

(xii) Stating that a project-end profit and loss statement, including a statement of final profit distribution, must be submitted to SBA no later than 90 calendar days after completion of the contract.

(3) *Performance of work.* (i) For any VO or SDVO contract, including those between a protégé and a mentor authorized by § 125.9 of this chapter, the joint venture must perform the applicable percentage of work required by § 125.6 of this chapter.

(ii) The certified VO SBC or SDVO SBC partner(s) to the joint venture must perform at least 40% of the work performed by the joint venture.

(A) The work performed by the certified VO SBC or SDVO SBC partner(s) to a joint venture must be more than administrative or ministerial functions so that they gain substantive experience.

(B) The amount of work done by the partners will be aggregated and the work done by the certified VO SBC or, in the case of an SDVO SBC, SDVO SBC partner(s) must be at least 40% of the total done by all partners. In determining the amount of work done by a non-VO SBC or, in the case of an SDVO SBC, SDVO SBC partner, all work done by the non-VO SBC or, in the case of an SDVO SBC, SDVO SBC partner and any of its affiliates at any subcontracting tier will be counted.

(4) *Certification of compliance.* Prior to the performance of any VO or SDVO contract as a joint venture, the certified VO SBC or SDVO SBC partner to the joint venture must submit a written certification to the contracting officer and SBA, signed by an authorized official of each partner to the joint venture, stating as follows:

(i) The parties have entered into a joint venture agreement that fully complies with paragraph (b)(2) of this section;

(ii) The parties will perform the contract in compliance with the joint venture agreement and with the performance of work requirements set forth in paragraph (b)(3) of this section.

(5) *Capabilities, past performance, and experience.* When evaluating the capabilities, past performance, experience, business systems, and certifications of an entity submitting an offer for a VO or SDVO contract as a joint venture established pursuant to this section, a procuring activity must consider work done and qualifications held individually by each partner to the joint venture as well as any work done by the joint venture itself previously. A procuring activity may not require the certified VO SBC or SDVO SBC to individually meet the same evaluation or responsibility criteria as that required of other offerors generally. The partners to the joint venture in the aggregate must demonstrate the past performance, experience, business systems, and certifications necessary to perform the contract.

(6) *Contract execution.* The procuring activity will execute a VO or SDVO contract in the name of the joint venture entity or the certified VO SBC or SDVO SBC, but in either case will identify the award as one to a VO or SDVO joint venture or a VO or SDVO mentor-protégé joint venture, as appropriate.

(7) *Inspection of records.* The joint venture partners must allow SBA's authorized representatives, including representatives authorized by the SBA Inspector General, during normal business hours, access to its files to inspect and copy all records and documents relating to the joint venture.

(8) *Performance of work reports.* A certified VO SBC or SDVO SBC partner to a joint venture must describe how it is meeting or has met the applicable performance of work requirements for each VO or SDVO contract it performs as a joint venture.

(i) The certified VO SBC or SDVO SBC partner to the joint venture must annually submit a report to the relevant contracting officer and to SBA, signed by an authorized official of each partner to the joint venture, explaining how and certifying that the performance of work requirements are being met.

(ii) At the completion of every VO or SDVO contract awarded to a joint venture, the certified VO SBC or SDVO SBC partner to the joint venture must submit a report to the relevant contracting officer and to SBA, signed by an authorized official of each partner to the joint venture, explaining how and certifying that the performance of work requirements were met for the contract, and further certifying that the contract was performed in accordance with the provisions of the joint venture agreement that are required under paragraph (b)(2) of this section.

(iii) Any person with information concerning a joint venture's compliance with the performance of work requirements may report that information to SBA and/or the SBA Office of Inspector General.

(9) *Basis for suspension or debarment.* The Government may consider the following as a ground for suspension or debarment as a willful violation of a regulatory provision or requirement applicable to a public agreement or transaction:

(i) Failure to enter a joint venture agreement that complies with paragraph (b)(2) of this section;

(ii) Failure to perform a contract in accordance with the joint venture agreement or performance of work requirements in paragraph (b)(3) of this section; or

(iii) Failure to submit the certification required by paragraph (b)(4) of this section or comply with paragraph (b)(7) of this section.

(10) *Limitation on offers from joint venture partners.* A VO SBC or SDVO SBC cannot be a joint venture partner on more than one joint venture that submits an offer for a specific contract set aside or reserved for VO SBCs or SDVO SBCs.

§ 128.403 What requirements are not available for VO or SDVO contracts?

For VA procurements, a contracting officer may award a VO or SDVO contract as set forth in the VAAR. For non-VA SDVO contracts, a contracting activity may not make a requirement available for a SDVO contract if:

(a) The contracting activity otherwise would fulfill that requirement through award to Federal Prison Industries, Inc. under 18 U.S.C. 4124 or 4125, or to Javits-Wagner-O'Day Act participating non-profit agencies for the blind and severely disabled, under 41 U.S.C. 8501 *et seq.,* as amended; or

(b) An 8(a) Participant currently is performing that requirement or SBA has accepted that requirement for performance under the authority of the section 8(a) program, unless SBA has consented to release of the requirement from the section 8(a) program.

§ 128.404 When may a contracting officer set aside a procurement for VO SBCs or SDVO SBCs?

(a) *VA procurements.* For VA procurements, a contracting officer may set aside a contract for a VO SBC or SDVO SBC as set forth in the VAAR. For non-VA procurements, the contracting officer first must review a requirement to determine whether it is excluded from SDVO contracting pursuant to § 128.403.

(b) *Contracting among small business programs*—(1) *Acquisitions valued at or below the simplified acquisition threshold.* For VA procurements, a contracting officer may award at or below the simplified acquisition threshold as set forth in the VAAR. For non-VA procurements, the contracting officer shall set aside any acquisition with an anticipated dollar value exceeding the micro-purchase threshold but not exceeding the simplified acquisition threshold (defined in the FAR at 48 CFR 2.101) for small business concerns, regardless of the place of performance, when there is a reasonable

expectation that offers will be obtained from at least two small business concerns that are competitive in terms of quality and delivery and award will be made at fair market prices. The requirement in this paragraph (b)(1) does not preclude a contracting officer from making an award to a small business under the 8(a) BD, Historically Underutilized Business Zone (HUBZone), SDVO SBC, or WOSB Programs.

(2) *Acquisitions valued above the simplified acquisition threshold.* (i) For VA procurements, a contracting officer may award above the simplified acquisition threshold as set forth in the VAAR. For non-VA procurements, the contracting officer shall set aside any acquisition with an anticipated dollar value exceeding the simplified acquisition threshold (defined in the FAR at 48 CFR 2.101) for small business concerns, regardless of the place of performance, when there is a reasonable expectation that offers will be obtained from at least two small business concerns that are competitive in terms of quality and delivery and award will be made at fair market prices. However, after conducting market research, the contracting officer shall first consider a set-aside or sole source award (if the sole source award is permitted by statute or regulation) under the 8(a) BD, HUBZone, SDVO SBC, or WOSB programs before setting aside the requirement as a small business set-aside. There is no order of precedence among the 8(a) BD, HUBZone, SDVO SBC, or WOSB programs. The contracting officer must document the contract file with the rationale used to support the specific set-aside, including the type and extent of market research conducted. In addition, the contracting officer must document the contract file showing that the apparent successful offeror's certifications in the System for Award Management (SAM) (or any successor system) and associated representations were reviewed.

(ii) SBA believes that progress in fulfilling the various small business goals, as well as other factors such as the results of market research, programmatic needs specific to the procuring agency, anticipated award price, and the acquisition history, will be considered in making a decision as to which program to use for the acquisition.

(c) *SDVO SBC set-asides.* If the contracting officer decides to set aside the requirement for competition restricted to SDVO SBCs, the contracting officer must:

(1) Have a reasonable expectation that at least two responsible SDVO SBCs will submit offers; and

(2) Determine that the award can be made at fair market price.

(d) *Prohibition on combined set-asides.* A procuring activity cannot restrict an SDVO SBC competition (for either a contract or order) to require certifications other than SDVO SBC certification (*i.e.,* a competition cannot be limited only to business concerns that are both SDVO SBC and 8(a), SDVO SBC and HUBZone, or SDVO SBC and WOSB).

§ 128.405 When may a contracting officer award sole source contracts to VO SBCs and SDVO SBCs?

For VA procurements, a contracting officer may award a sole source contract to a VO SBC or SDVO SBC as set forth in the VAAR. A contracting officer may award a sole source contract to an SDVO SBC for non-VA procurements only when the contracting officer determines that:

(a) None of the provisions of § 128.403 or § 128.404 apply;

(b) The anticipated award price of the contract, including options, will not exceed:

(1) $7,000,000 for a contract assigned a manufacturing NAICS code; or

(2) $4,000,000 for all other contracts;

(c) A SDVO SBC is a responsible contractor able to perform the contract; and

(d) Contract award can be made at a fair and reasonable price.

§ 128.406 Are there VO or SDVO contracting opportunities at or below the simplified acquisition threshold?

For VA procurements, a contracting officer may award at or below the simplified acquisition threshold as set forth in 48 CFR part 819 of the VAAR. If the non-VA SDVO requirement is at or below the simplified acquisition threshold, the contracting officer may set aside the requirement for consideration among SDVO SBCs using simplified acquisition procedures or may award a sole source contact to an SDVO SBC.

§ 128.407 May SBA appeal a contracting officer's decision not to make a procurement available for award as an SDVO contract?

The SBA Administrator may appeal a contracting officer's decision not to make a particular requirement available for award as an SDVO sole source or a SDVO set-aside contract at or above the simplified acquisition threshold.

§ 128.408 What is the process for such an appeal?

(a) *Notice of appeal.* When the contracting officer rejects a recommendation by SBA's Procurement Center Representative to make a requirement available for award as an SDVO contract, the contracting officer must notify the Procurement Center Representative as soon as practicable. If the SBA Administrator intends to appeal the decision, SBA must notify the contracting officer no later than five business days after receiving notice of the contracting officer's decision.

(b) *Suspension of action.* Upon receipt of notice of SBA's intent to appeal, the contracting officer must suspend further action regarding the procurement until the Secretary of the department or head of the agency issues a written decision on the appeal, unless the Secretary of the department or head of the agency makes a written determination that urgent and compelling circumstances which significantly affect the interests of the United States compel award of the contract.

(c) *Deadline for appeal.* Within 15 business days of SBA's notification to the contracting officer, SBA must file its formal appeal with the Secretary of the department or head of the agency, or the appeal will be deemed withdrawn.

(d) *Decision.* The Secretary of the department or head of the agency must specify in writing the reasons for a denial of an appeal brought under this section.

Subpart E—Protests Concerning VO SBCs and SDVO SBCs

§ 128.500 What are the requirements for filing a VO SBC and SDVO SBC status protest?

(a) If an interested party challenges the inclusion in the database of a VO SBC or SDVO SBC based on the status of the concern as a small business concern or the ownership or control of the concern, the challenge shall be heard by the Office of Hearings and Appeals of the Small Business Administration in accordance with part 134 of this chapter. The decision of the Office of Hearings and Appeals shall be considered final agency action.

(b) The protest procedures described in part 134 of this chapter are separate from those governing size protests and appeals. All protests relating to whether an eligible VO SBC or SDVO SBC is a ''small'' business for purposes of any Federal program are subject to part 121 of this chapter and must be filed in accordance with that part. If a protester protests both the size of the VO SBC or SDVO SBC and whether the concern

meets the VO SBC or SDVO SBC requirements set forth in § 128.200, SBA will process each protest concurrently under the procedures set forth in parts 121 and 134 of this chapter. SBA does not review issues concerning the administration of a VO or SDVO contract.

Subpart F—Penalties and Retention of Records

§ 128.600 What are the requirements for representing VO SBC or SDVO SBC status, and what are the penalties for misrepresentation?

(a) *Presumption of loss based on the total amount expended.* In every contract, subcontract, cooperative agreement, cooperative research and development agreement, or grant which is set aside, reserved, or otherwise classified as intended for award to VO SBCs or SDVO SBCs, there shall be a presumption of loss to the United States based on the total amount expended on the contract, subcontract, cooperative agreement, cooperative research and development agreement, or grant whenever it is established that a business concern other than a VO SBC or SDVO SBC willfully sought and received the award by misrepresentation.

(b) *Deemed certifications.* The following actions shall be deemed affirmative, willful, and intentional certifications of VO SBC or SDVO SBC status:

(1) Submission of a bid, proposal, application or offer for a Federal grant, contract, subcontract, cooperative agreement, or cooperative research and development agreement reserved, set aside, or otherwise classified as intended for award to VO SBCs or SDVO SBCs.

(2) Submission of a bid, proposal, application or offer for a Federal grant, contract, subcontract, cooperative agreement or cooperative research and development agreement which in any way encourages a Federal agency to classify the bid or proposal, if awarded, as an award to a VO SBC or SDVO SBC.

(3) Registration on any Federal electronic database for the purpose of being considered for award of a Federal grant, contract, subcontract, cooperative agreement, or cooperative research and development agreement, as a VO SBC or SDVO SBC.

(c) *Signature requirement.* Each offer, proposal, bid, or application for a Federal contract, subcontract, or grant shall contain a certification concerning the VO SBC or, in the case of an SDVO SBC, SDVO SBC status of a business concern seeking the Federal contract, subcontract, or grant. An authorized official must sign the certification on the same page containing the SDVO SBC status claimed by the concern.

(d) *Limitation of liability.* Paragraphs (a) through (c) of this section may be determined not to apply in the case of unintentional errors, technical malfunctions, and other similar situations that demonstrate that a misrepresentation of VO SBC or SDVO SBC status was not affirmative, intentional, willful, or actionable under the False Claims Act, 31 U.S.C. 3729, *et seq.* A prime contractor acting in good faith should not be held liable for misrepresentations made by its subcontractors regarding the subcontractors' VO SBC or SDVO SBC status. Relevant factors to consider in making this determination may include the firm's internal management procedures governing VO SBC or SDVO SBC status representations or certifications, the clarity or ambiguity of the representation or certification requirement, and the efforts made to correct an incorrect or invalid representation or certification in a timely manner. An individual or firm may not be held liable where Government personnel have erroneously identified a concern as a VO SBC or SDVO SBC without any representation or certification having been made by the concern and where such identification is made without the knowledge of the individual or firm.

(e) *Penalties for misrepresentation*—(1) *Suspension or debarment.* The SBA suspension and debarment official or the agency suspension and debarment official may suspend or debar a person or concern for misrepresenting a firm's status as a VO SBC or SDVO SBC pursuant to the procedures set forth in 48 CFR part 9, subpart 9.4.

(2) *Civil penalties.* Persons or concerns are subject to severe penalties under the False Claims Act, 31 U.S.C. 3729–3733, the Program Fraud Civil Remedies Act, 31 U.S.C. 3801–3812, and any other applicable laws or regulations, including part 142 of this chapter.

(3) *Criminal penalties.* Persons or concerns are subject to severe criminal penalties for knowingly misrepresenting the VO or SDVO SBC status of a concern in connection with procurement programs pursuant to section 16(d) of the Small Business Act, 15 U.S.C. 645(d), as amended, 18 U.S.C. 1001, 18 U.S.C. 287, and any other applicable laws. Persons or concerns are subject to criminal penalties for knowingly making false statements or misrepresentations to SBA for the purpose of influencing any actions of SBA pursuant to section 16(a) of the Small Business Act, 15 U.S.C. 645(a), as amended, including failure to correct ''continuing representations'' that are no longer true.

§ 128.601 What must a concern do in order to be identified as a SDVO SBC in any Federal procurement databases?

(a) In order to be identified as an SDVO SBC in the System for Award Management (SAM) database (or any successor thereto), a concern must certify its SDVO SBC status in connection with specific eligibility requirements at least annually.

(b) If a firm identified as a VO SBC or SDVO SBC in SAM fails to certify its status within one year of a status certification, the firm will not be listed as a VO SBC or SDVO SBC in SAM, unless and until the firm recertifies its VO SBC or SDVO SBC status.

Subpart G—Surplus Personal Property for Veteran-Owned Small Business Programs

§ 128.700 How does a small business concern owned and controlled by veterans obtain Federal surplus personal property?

(a) *General.* (1) Pursuant to 15 U.S.C. 657b(g), eligible small business concerns owned and controlled by veterans may receive surplus Federal Government property from State Agencies for Surplus Property (SASPs). The procedures set forth in 41 CFR part 102–37 and this section will be used to transfer surplus personal property to such concerns.

(2) The surplus personal property which may be transferred to SASPs for further transfer to eligible small business concerns owned and controlled by veterans includes all surplus personal property which has become available for donation pursuant to 41 CFR 102–37.30.

(b) *Eligibility to receive Federal surplus personal property.* To be eligible to receive Federal surplus personal property, on the date of transfer a concern must:

(1) Be a small business concern owned and controlled by veterans, that has been certified by SBA under this part;

(2) Not be debarred, suspended, or declared ineligible under title 2 or title 48 of the CFR; and

(3) Be engaged or expect to be engaged in business activities making the item useful to it.

(c) *Use of acquired surplus personal property.* (1) Eligible concerns may acquire Federal surplus personal property from the SASP in the state(s) where the concern is located and

operates, provided the concern represents and agrees in writing:

(i) As to what the intended use of the surplus personal property is to be;

(ii) That it will use the surplus personal property to be acquired in the normal conduct of its business activities or be liable for the fair rental value from the date of its receipt;

(iii) That it will not sell or transfer the surplus personal property to be acquired to any party other than the Federal Government as required by General Services Administration (GSA) and SASP requirements and guidelines;

(iv) That, at its own expense, it will return the surplus personal property to a SASP if directed to do so by SBA, including where the concern has not used the property as intended within one year of receipt;

(v) That, should it breach its agreement not to sell or transfer the surplus personal property, it will be liable to the Federal Government for the established fair market value or the sale price, whichever is greater, of the property sold or transferred; and

(vi) That it will give GSA and the SASP access to inspect the surplus personal property and all records pertaining to it.

(2) A concern receiving surplus personal property pursuant to this section assumes all liability associated with or stemming from the use of the property, and all costs associated with the use and maintenance of the property.

(d) *Costs.* Concerns acquiring surplus personal property from a SASP may be required to pay a service fee to the SASP in accordance with 41 CFR 102–37.280. In no instance will any SASP charge a concern more for any service than their established fees charged to other transferees.

(e) *Title.* Upon execution of the SASP distribution document, the firm receiving the property has only conditional title to the property during the applicable period of restriction. Full title to the property will vest in the recipient concern only after the recipient concern has met all of the requirements of this part and the requirements of GSA and the SASP that it received the property from.

Isabella Casillas Guzman,

Administrator.

[FR Doc. 2022–13563 Filed 7–5–22; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0808; Project Identifier MCAI–2022–00100–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1 and AS332L2 helicopters. This proposed AD was prompted by reports of a crack in the front upper hoist attachment fitting. This proposed AD would require inspecting each affected hoist attachment fitting (fitting) and depending on the results, removing any cracked fitting from service and reporting information. This proposed AD also prohibits installing an affected fitting unless the required actions are accomplished, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 22, 2022.

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

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

For EASA material that is proposed for IBR in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find the EASA material on the EASA website at *https://ad.easa.europa.eu.* For Airbus Helicopters service information identified in this NPRM, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (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. The EASA material is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0808.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0808; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Kristin Bradley, COS Program Manager, COS Program Management Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@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–2022–0808; Project Identifier MCAI–2022–00100–R'' 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 Kristin Bradley, COS Program Manager, COS Program Management Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD 2022–0016–E, dated January 26, 2022 (EASA AD 2022–0016–E), to correct an unsafe condition for Airbus Helicopters (AH), formerly Eurocopter, Eurocopter France, Aerospatiale, Model AS 332 C, AS 332 C1, AS 332 L, AS 332 L1, and AS 332 L2 helicopters, equipped with front upper fitting manufacturer part number (MP/N) 332A87–1116–21, rear upper fitting MP/N 332A87–1117–20, or lower fitting MP/N 332A87–1176–20.

This proposed AD was prompted by an occurrence of a front upper fitting crack reported on a helicopter equipped with a double hoist design, installed per a supplemental type certificate (STC). The STC has not been validated by the FAA; however, the FAA is proposing this AD because other hoists may have design similarities with the affected fitting installed. The FAA is proposing this AD to detect and address this unsafe condition, which if not corrected, could affect the structural integrity of a fitting, possibly leading to an in-flight detachment of the hoist support, and consequent damage to the helicopter or injury to a person being lifted. EASA considers its AD to be an interim action and further AD action may follow. See EASA AD 2022–0016–E for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0016–E requires a one-time inspection of the front upper fitting MP/N 332A87–1116–21, rear upper fitting MP/N 332A87–1117–20, and lower fitting MP/N 332A87–1176–20 for a crack. If there is a crack, EASA AD 2022–0016–E requires replacing the affected fitting. EASA AD 2022–0016–E also prohibits installing an affected fitting on any helicopter unless it passes the required inspection.

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

The FAA reviewed Airbus Helicopters Emergency Alert Service Bulletin 25.03.95, Revision 0, dated January 25, 2022. This service information specifies procedures for inspecting and replacing an affected fitting. This service information also specifies reporting certain information to Airbus Helicopters, and for a cracked fitting, returning the fitting to Airbus Helicopters.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2022–0016–E, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and EASA AD 2022–0016–E.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2022–0016–E by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0016–E in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0016–E does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0016–E. Service information referenced in EASA AD 2022–0016–E for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0808 after the FAA final rule is published.

Differences Between This Proposed AD and EASA AD 2022–0016–E

The EASA AD requires a compliance time of before next hoist operation or within 30 days, whichever occurs first after the effective date of EASA AD 2022–0016–E, whereas this proposed AD would require a compliance time of within 30 hours time in service or within 30 days, whichever occurs first after the effective date of this proposed AD. Where the service information referenced in the EASA AD specifies to perform dye penetrant inspection ''if you are not sure,'' this proposed AD would not require that action. Where EASA AD 2022–0016–E requires returning a fitting that was required to be removed as a result of the inspection, this proposed AD would not.

Interim Action

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

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 7 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Inspecting all hoist attachment fittings would take about 0.5 work-hour for an estimated cost of $42.50 per helicopter and $298 for the U.S. fleet.

Replacing the front upper fitting would take about 4 hours and parts would cost $834 for an estimated cost of $1,174 per front upper fitting.

Replacing the rear upper fitting would take about 4 hours and parts would cost $1,040 for an estimated cost of $1,380 per rear upper fitting.

Replacing the lower fitting would take about 4 hours and parts would cost $1,874 for an estimated cost of $2,214 per lower fitting.

The FAA estimates that it would take about 1 hour per product to comply with the proposed reporting requirement in this proposed 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 $595 or $85 per product.

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

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:

Airbus Helicopters: Docket No. FAA–2022–0808; Project Identifier MCAI–2022–00100–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by August 22, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, and AS332L2 helicopters, certificated in any category, with a front upper hoist attachment fitting manufacturer part number (MP/N) 332A87–1116–21, rear upper hoist attachment fitting MP/N 332A87–1117–20, or lower hoist attachment fitting MP/N 332A87–1176–20, installed.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of a crack on the front upper hoist attachment fitting. The FAA is issuing this AD to detect and address this unsafe condition, which could affect the structural integrity of a hoist attachment fitting, possibly leading to an in-flight detachment of the hoist support, and consequent damage to the helicopter or injury to a person being lifted.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) Emergency AD 2022–0016–E, dated January 26, 2022 (EASA AD 2022–0016–E).

(h) Exceptions to EASA AD 2022–0016–E

(1) Where EASA AD 2022–0016–E refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2022–0016–E requires a compliance time of before next hoist operation or within 30 days, whichever occurs first after the effective date of EASA AD 2022–0016–E, this AD requires a compliance time of within 30 hours time in service or within 30 days, whichever occurs first after the effective date of this AD.

(3) Where the service information referenced in EASA AD 2022–0016–E specifies discarding parts, this AD requires removing those parts from service.

(4) Where EASA AD 2022–0016–E specifies replacing parts and the service information referenced in EASA AD 2022–0016–E specifies returning parts to the manufacturer, this AD requires removing those parts from service.

(5) Where the service information referenced in EASA AD 2022–0016–E specifies reporting inspection results to Airbus Helicopters immediately after each inspection, this AD requires reporting inspection results at the following compliance times:

(i) If there is not a crack, within 30 days after the inspection.

(ii) If there is a crack, before the next hoist operation.

(6) Where the service information referenced in EASA AD 2022–0016–E specifies to perform dye penetrant inspection ''if you are not sure,'' this AD does not require a dye penetrant inspection.

(7) This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2022–0016–E.

(i) 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 (j)(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.

(j) Related Information

(1) For EASA AD 2022–0016–E, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu*. You may find the EASA 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. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0808.

(2) For more information about this AD, contact Kristin Bradley, COS Program Manager, COS Program Management Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *Kristin.Bradley@faa.gov*.

Issued on June 29, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–14325 Filed 7–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–623]

Schedules of Controlled Substances: Placement of 4-hydroxy-N,N-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-alpha-methyltryptamine (5-MeO-AMT), 5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-N,N-diethyltryptamine (5-MeO-DET), and N,N-diisopropyltryptamine (DiPT) in Schedule I; Announcement of Hearing

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of hearing on proposed rulemaking.

SUMMARY: This is notice that the Drug Enforcement Administration will hold a hearing with respect to the proposed placement of five tryptamine hallucinogens, as identified in the proposed rule, in schedule I of the Controlled Substances Act. The control of the five tryptamines was initially proposed in a Notice of Proposed Rulemaking published in the **Federal Register** on January 14, 2022.

DATES: Interested persons desiring to participate in this hearing must provide written notice of desired participation as set out below, on or before August 5, 2022.

The hearing will commence on August 22, 2022, at 9 a.m. ET at the DEA Hearing Facility, 1550 Crystal Drive, Suite 901, Arlington, Virginia 22202.

ADDRESSES: To ensure proper handling of notification, please reference ''Docket No. DEA–623'' on all correspondence. Written notification sent via regular or express mail should be sent to Drug Enforcement Administration, Attn: Hearing Clerk, Office of the Administrative Law Judges, 8701 Morrissette Drive, Springfield, Virginia 22152. Electronic notification should be sent to *ECF-DEA@dea.gov,* with a copy simultaneously sent to: *DEA.Registration.Litigation@dea.gov.*

FOR FURTHER INFORMATION CONTACT: Hearing Clerk, Office of the Administrative Law Judges, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–8188.

SUPPLEMENTARY INFORMATION:

Background

On January 14, 2022, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (87 FR 2376) to place five tryptamine substances in schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801, *et seq.*). Specifically, in this NPRM, DEA proposed to schedule the following five controlled substances in schedule I of the CSA, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- 4-Hydroxy-N,N-diisopropyltryptamine (4-OH-DiPT),
- 5-Methoxy-alphamethyltryptamine (5-MeO-AMT),
- N-Isopropyl-5-Methoxy-N-Methyltryptamine (5-MeO-MiPT),
- N,N-Diethyl-5-methoxytryptamine (5-MeO-DET), and
- N,N-Diisopropyltryptamine (DiPT).

The proposal in the NPRM to place these substances in schedule I was based primarily on the scientific and medical evaluations and recommendations provided by the Department of Health and Human Services (HHS) to DEA. In those submissions to DEA, HHS concluded that these five substances meet the criteria for placement in schedule I as they all have a high potential for abuse, no currently medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. DEA is bound by the recommendations of HHS as to scientific and medical matters.

The NPRM invited interested persons to submit comments, objections, and requests for a hearing on or before February 14, 2022, and received 589 comments and multiple requests for a hearing. In requesting a hearing, the requestors stated that their intention is to present factual information and expert opinion concerning the significance and reliability of the medical, scientific, and other bases that DEA provided in support of the proposed scheduling of the five tryptamine substances.

Hearing Notification

In response to these requests, pursuant to 21 U.S.C. 811(a), 21 CFR 1308.44, and 21 CFR 1316.47, DEA is convening a hearing on the NPRM. Accordingly, notice is hereby given that a hearing in connection with this proposed scheduling action will commence on August 22, 2022, at 9 a.m. ET at the DEA Hearing Facility, 1550 Crystal Drive, Suite 901, Arlington, Virginia 22202. The hearing will be conducted pursuant to the provisions of 5 U.S.C. 556 and 557, and 21 CFR 1308.41–1308.45, and 1316.41–1316.68.

Every interested person (defined by 21 CFR 1300.01(b) as ''any person adversely affected or aggrieved by any rule or proposed rule issuable'' under 21 U.S.C. 811) who wishes to participate in the hearing shall file either by mail or email a written notice of intention to participate. If filing via mail, the written notice must be filed with the Hearing Clerk, Office of the Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, and must be received on or before August 5, 2022. If filing electronically, the written notice must be filed with the Office of the Administrative Law Judges at *ECF-DEA@dea.gov,* with a copy simultaneously sent to DEA counsel at *DEA.Registration.Litigation@dea.gov,* on or before 11:59 p.m. Eastern Time on

August 5, 2022. Further, each notice of intention to participate must be in the form prescribed in 21 CFR 1316.48. No person who has previously filed a request for hearing need now file a notice of intention to participate.

Signing Authority

This document of the Drug Enforcement Administration was signed on June 30, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–14372 Filed 7–5–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–130675–17]

RIN 1545–BO06

Definition of Foreign Currency Contract Under Section 1256

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that define the term ''foreign currency contract'' under section 1256 of the Internal Revenue Code (the ''Code'') to include only foreign currency forward contracts. The proposed regulations affect certain holders of foreign currency options.

DATES: Written or electronic comments and requests for a public hearing must be received by September 6, 2022.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–130675–17) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The IRS expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable. The Department of the Treasury (''Treasury Department'') and the IRS will publish for public availability any comment submitted electronically, and to the extent practicable on paper, to its public docket.

Send paper submissions to: CC:PA:LPD:PR (REG–130675–17), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**. For those requesting to speak during the hearing, send an outline of topic submissions electronically via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–130675–17).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, D. Peter Merkel or Karen Walny at (202) 317–6938; concerning submissions of comments or requests for a public hearing, Regina L. Johnson at (202) 317–5177 (not toll-free numbers) or by sending an email to *publichearings@irs.gov*.

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed regulations that would provide that the term foreign currency contract as defined in section 1256(g)(2) of the Code applies only to a foreign currency forward contract.

I. Statutory Development of Section 1256

A. Section 1256 Generally

Section 1256(a)(1) provides that each section 1256 contract held by a taxpayer at the close of the taxable year is treated as sold for its fair market value on the last business day of that taxable year (and any gain or loss is taken into account for the taxable year). Section 1256(a)(2) provides that proper adjustment must be made in the amount of any gain or loss subsequently realized to take into account the gain or loss previously recognized under section 1256(a)(1). Generally, section 1256(a)(3) provides that any gain or loss on a section 1256 contract is treated as 60 percent long-term capital gain or loss and 40 percent short-term capital gain or loss (''60/40 treatment'').

Section 1256(b)(1) defines a section 1256 contract as any regulated futures contract, any foreign currency contract, any nonequity option, any dealer equity option, and any dealer securities futures contract. Section 1256(b)(2) excludes the following contracts from the definition of a section 1256 contract: (1) any securities futures contract or option on such a contract unless it is a dealer securities futures contract, or (2) any interest rate swap, currency swap, basis swap, interest rate cap, interest rate floor, commodity swap, equity swap, equity index swap, credit default swap, or similar agreement.

Section 1256(g)(2)(A) defines the term foreign currency contract as a contract that (1) requires delivery of, or the settlement of which depends on the value of, a foreign currency which is a currency in which positions are also traded through regulated futures contracts, (2) is traded in the interbank market, and (3) is entered into at arm's length at a price determined by reference to the price in the interbank market. Section 1256(g)(2)(B) grants the Secretary authority to prescribe regulations as may be necessary or appropriate to carry out the purposes of the foreign currency contract definition, including the authority to exclude any contract or type of contract from that definition if it would be inconsistent with those purposes.

Section 1256(g)(3) defines the term nonequity option as any listed option (generally, an option traded on or subject to the rules of a qualified board or exchange) that is not an equity option.

Section 1256(f)(2) provides that 60/40 treatment does not apply to gain or loss that otherwise would be ordinary. Section 988(a)(1) provides that if a futures contract, forward contract, option, or similar financial instrument is a section 988 transaction, the gains and losses from the transaction are treated as ordinary, absent an election for certain transactions. However, regulated futures contracts and nonequity options that are marked-to-market under section 1256 are not section 988 transactions unless a taxpayer makes an election to treat the contract as a section 988 transaction. *See* section 988(c)(1)(D)(i) and (ii).

B. Scope of Section 1256 When Enacted in 1981

When it was enacted in 1981, section 1256 applied only to regulated futures contracts, including regulated futures contracts involving foreign currency.

See Economic Recovery Tax Act of 1981 (''ERTA''), Public Law 97–34 (95 Stat. 172, section 503(a) (1981)). One of the hallmarks of regulated futures contracts is the daily cash settlement, mark-to-market system employed by U.S. futures exchanges to determine margin requirements. In contrast to U.S. futures exchanges, the interbank market and other over-the-counter (''OTC'') markets did not employ a daily cash settlement, mark-to-market system for margin requirements.

C. Technical Corrections Act of 1982

As originally enacted, section 1256 applied to regulated futures contracts requiring the delivery of foreign currency, but not to similar foreign currency forward contracts that were traded in the OTC market rather than on an exchange. In 1983, Congress extended the application of the statute to foreign currency contracts traded in the interbank market and provided a definition in section 1256(g)(1) for the term foreign currency contract. *See* Technical Corrections Act of 1982, Public Law 97–448, section 105(c)(5)(B) and (C) (96 Stat. 2365 (1983)). In adding section 1256(g)(1), Congress specified that the term foreign currency contract included only a contract that requires delivery of the foreign currency.

The legislative history explains that this expansion was grounded in the economic comparability of trading foreign currency through forward contracts in the interbank market to trading foreign currency through regulated futures contracts and the interchangeability of the two types of contracts by traders. H.R. Rep. No. 97–794, at 23 (1982). In addition, the pricing of these foreign currency forward contracts was readily available because they trade through the larger, liquid interbank market. *Id.* Nothing in the statute or legislative history indicates Congress intended to include option contracts, which are not generally economically comparable to regulated futures contracts. Moreover, while the definition of foreign currency contract enacted in 1983 required the delivery of foreign currency, option contracts will not always result in settlement (either by physical delivery or delivery of the cash equivalent value).

D. Deficit Reduction Act of 1984

In 1984, Congress further expanded the types of contracts to which section 1256 applied to include nonequity options and dealer equity options. *See* Deficit Reduction Act of 1984, Public Law 98–369 at section 102(a)(3) (98 Stat. 494 (1984)). It also amended the definition of a foreign currency contract to allow for cash settlement. *Id.* The Deficit Reduction Act of 1984 also added section 1256(g)(2)(B), which provides the Treasury Department with authority to issue regulations that are necessary or appropriate to carry out the purposes of the foreign currency contract definition. *Id.*

Before this 1984 amendment, the term foreign currency contract applied only to contracts that required the physical delivery of the foreign currency. However, the futures contract and forward contract market had developed in a manner that no longer required physical delivery. Instead, contracts permitted the parties to settle contracts for their cash equivalent value. The definition of regulated futures contract was amended in 1983 to remove the requirement of delivery of personal property. *See* H.R. Conf. Rep. 97–986, at 26–27 (1982). The amendment to the definition of foreign currency contract in 1984 was intended similarly to treat the delivery requirement as met where the contract provides for a settlement determined by reference to the value of foreign currency. Specifically, the House Report explained the reason for the 1984 amendment as follows:

Present Law

The Technical Corrections Act of 1982 provided that certain foreign currency contracts entered into after May 11, 1982 (or earlier, if certain elections were made) will be treated as regulated futures contracts and therefore be taxed on the marked-to-market system with a maximum tax rate of 32 percent. In order for a contract to qualify as a foreign currency contract, the contract must require delivery of a foreign currency which is a currency in which positions are also traded through regulated futures contracts.

Explanation of Provision

Because certain contracts may call for a cash settlement by reference to the value of the foreign currency rather than actual delivery of the currency, the bill provides that the delivery of a foreign currency requirement is met where the contract provides for a settlement determined by reference to the value of the foreign currency.

H.R. Rep. 98–432 Part 2, at 1646 (1984). At the same time, Congress addressed foreign currency options by adding nonequity options to the list of section 1256 contracts, as described above. Consequently, listed foreign currency options became subject to section 1256 by explicit Congressional action. While the legislative history expressly stated that Congress amended the definition of a foreign currency contract to include cash-settled foreign currency forward contracts, the legislative history does not indicate that Congress intended also to expand the scope of section 1256 to include OTC foreign currency options regardless of whether they may be cash-settled.

E. Technical and Miscellaneous Revenue Act of 1988

The legislative history with respect to a 1988 amendment to section 988 also indicates that Congress understood that a foreign currency contract, as defined by section 1256(g)(2), does not include a foreign currency option. Section 988 generally applies to forward contracts, futures contracts, options, and similar financial instruments if the amount that a taxpayer is entitled to receive or is required to pay is denominated in terms of a nonfunctional currency or determined by reference to the value of one or more nonfunctional currencies. *See* section 988(c)(1)(A) and (B)(iii); *see also* section 988(c)(1)(D) (providing an exception to section 988(c)(1)(B)(iii) for certain regulated futures contracts and nonequity options). In 1988, Congress amended section 988 to add section 988(c)(1)(E). Technical and Miscellaneous Revenue Act of 1988, Public Law 100–647, at section 6130(b) (102 Stat. 3342 (1988)). Section 988(c)(1)(E) provides that any instrument described in section 988(c)(1)(B)(iii) (that is, any forward contract, futures contract, option, or similar financial instrument) is not a section 988 transaction if it is held by certain partnerships (each, a ''qualified fund'') and would be marked to market under section 1256. Section 988(c)(1)(E)(iv)(I) further provides that any bank forward contract, any foreign currency futures contract traded on a foreign exchange, or any similar instrument to the extent provided in regulations that is not otherwise a section 1256 contract is treated as a section 1256 contract for purposes of section 1256 when held by a qualified fund.

The legislative history indicates that Congress believed that the term foreign currency contract generally meant bank forward contracts on foreign currency, and that OTC foreign currency options were not already section 1256 contracts. *See* H.R. Conf. Rep. No. 100–1104 (Vol. 2), at 189, *reprinted in* 1988–3 C.B. 473, 679 (''[T]he [conference] agreement expands the definition of section 1256 contracts to generally include . . . bank forwards: that is, foreign currency contracts (as that term is defined in section 1256(g)(2) of the Code), and [certain other contracts] . . . . [T]he [conference] agreement provides the Treasury with regulatory authority to treat other similar instruments (*for example, options*) held by qualified

funds as section 1256 contracts.'') (emphasis added).

II. Listed Transactions Using Offsetting Foreign Currency Options

Taxpayers entered into tax avoidance transactions that relied upon treating OTC foreign currency options, in a currency in which regulated futures were traded, as section 1256(g)(2) foreign currency contracts. On December 22, 2003, the IRS published Notice 2003–81, 2003–51 I.R.B. 1223, which identified a tax avoidance transaction involving offsetting foreign currency options. This transaction is often referred to as a ''major-minor'' transaction because it involved the taxpayer purchasing call and put options in a ''major'' foreign currency (one in which regulated futures contracts traded) and writing call and put options in a ''minor'' currency (one in which regulated futures contracts were not traded). The purchased and written foreign currency options were in two different currencies that historically had a high positive correlation, such that the taxpayer could be reasonably certain to have offsetting gains and losses in the options. The taxpayer treated its major currency options as foreign currency contracts under section 1256(g)(2) and treated its options on the minor currency as not subject to section 1256. When there was unrecognized gain and loss on the options, the taxpayer assigned the purchased major currency option with a loss to a charity, and the charity assumed the offsetting written minor currency option from the taxpayer (the taxpayer, however, retained the premium received on the written option). The taxpayer treated the assignment of the major currency option as a mark-to-market recognition event under section 1256(c), claiming a loss upon the assignment. However, the taxpayer did not report the recognition of gain on the offsetting minor currency option assumed by the charity because the option was a non-section 1256 contract and the taxpayer treated the assumption as a non-recognition event. The ''Facts'' section of Notice 2003–81 stated, without legal analysis, that the purchased major currency options were foreign currency contracts within the meaning of section 1256(g)(2)(A) because the major currency was traded through regulated futures contracts. Notice 2003–81 identified this transaction as a listed transaction and indicated that the taxpayer would be required under the Code to account for the gain attributable to the premium originally received by the taxpayer for writing the minor currency option.

On August 27, 2007, the IRS published Notice 2007–71 (2007–35 I.R.B. 472), which modified and supplemented Notice 2003–81. Notice 2007–71 explained that ''foreign currency options, whether or not the underlying currency is one in which positions are traded through regulated futures contracts, are [not] foreign currency contracts as defined in § 1256(g)(2).'' Notice 2007–71 explained that the ''Facts'' section of Notice 2003–81 included ''an erroneous conclusion of law.'' Notice 2007–71 corrected this error in the ''Facts'' section of Notice 2003–81, stating that the pertinent sentence should have read as follows: '' 'The taxpayer takes the position that the purchased options are 'foreign currency contracts' within the meaning of § 1256(g)(2)(A) of the Internal Revenue Code and § 1256 contracts within the meaning of § 1256(b).' ''

III. Judicial Interpretations of Section 1256(g)(2)

The IRS challenged taxpayers' characterization of the major-minor transactions in several cases before the United States Tax Court (''Tax Court''). In a series of rulings on motions for partial summary judgment, the Tax Court held that foreign currency options were not ''foreign currency contracts'' under section 1256. In one case, however, the Sixth Circuit disagreed and held that a foreign currency option could be a foreign currency contract.

A. Summitt v. Commissioner

The IRS successfully challenged the listed transactions described in Notice 2003–81 in *Summitt* v. *Commissioner,* 134 T.C. 248 (2010). The Tax Court held that a foreign currency option is not a foreign currency contract as defined by section 1256(g)(2).

Explaining that the plain meaning of the statutory language controls the decision, the Tax Court held that the term foreign currency contract does not include an option contract and that the major currency option was not subject to the mark-to-market rules of section 1256. *Id.* at 264, 266. The court noted that forwards and options confer different rights and obligations to the parties to these contracts. *Id.* at 264. The court found that it was clear that the words ''or the settlement of which depends on the value of'' in section 1256(g)(2)(A)(i) meant that a foreign currency contract must require settlement at expiration and that the reference in the statute to settlements was included to permit a foreign currency contract to be physically settled or cash-settled. *Id.* at 265. In contrast, an option may expire without any settlement occurring. The court further observed that ''[t]here is no evidence in the legislative history that a literal reading of the statute will defeat Congress' purpose in enacting it.'' *Id.*

Subsequently, the Tax Court followed its decision in *Summitt* in two other cases. *See Garcia* v. *Commissioner,* T.C. Memo. 2011–85; *Wright* v. *Commissioner,* T.C. Memo. 2011–292. In both cases, the Tax Court noted that the taxpayers did not show a material factual difference between their cases and the earlier Tax Court opinion on the same issue. *Garcia,* T.C. Memo. 2011–85; *Wright,* T.C. Memo. 2011–292.

B. Wright v. Commissioner

The taxpayer appealed the Tax Court's decision in *Wright.* The Sixth Circuit reversed the Tax Court, holding that a foreign currency option could be a foreign currency contract based on the plain meaning of section 1256(g)(2). *Wright* v. *Commissioner,* 809 F.3d 877, 885 (6th Cir. 2016). Specifically, the Sixth Circuit found that the plain language of section 1256(g)(2)(A)(i) (''which requires delivery of, or the settlement of which depends on the value of, a foreign currency which is a currency in which positions are also traded through regulated futures contracts'') does not require settlement. *Id.* at 883. The court reasoned that the plain meaning of section 1256(g)(2)(A)(i) provides that a ''foreign currency contract'' is ''(1) 'a contract . . . which requires delivery of . . . a foreign currency' or (2) 'a contract . . . the settlement of which depends on the value of . . . a foreign currency.' '' *Id.* Therefore, it found that a contract is a ''foreign currency contract'' if the settlement of the contract depends on the value of a foreign currency, even if the contract does not mandate settlement. *Id.* In concluding that the statutory language in section 1256(g)(2)(A) was unambiguous, the Sixth Circuit noted that the Treasury Department and the IRS had express authority to change this result for future taxpayers. *Id.* at 885.

Explanation of Provisions

Under the authority of section 1256(g)(2)(B), and to carry out the purposes of section 1256(g)(2)(A), these proposed regulations provide that only a forward contract on foreign currency is a ''foreign currency contract'' as defined in section 1256(g)(2). The legislative history to section 1256, as discussed in part I of this preamble, indicates that Congress's purpose in amending the definition of foreign currency contract in 1984 was merely to include cash-settled foreign currency

forward contracts within the definition of foreign currency contract. It would be inconsistent with this purpose to construe the term foreign currency contract as including options or other derivatives.

These proposed regulations do not change the status of foreign currency options that otherwise qualify as section 1256 contracts. Specifically, nonequity options are separately listed as section 1256 contracts in section 1256(b)(1)(C). Section 1256(g)(3) provides that a nonequity option is any listed option which is not an equity option. Section 1256(g)(5) defines a listed option as ''any option . . . which is traded on (or subject to the rules of) a qualified board or exchange.'' Therefore, a foreign currency option that is listed on a qualified board or exchange is a ''nonequity option'' and remains subject to section 1256.

These proposed regulations do not define the term forward contract. For purposes of these proposed regulations, whether a derivative contract is properly characterized as a forward contract for U.S. federal income tax purposes is determined under current law. In addition, the IRS may consider applying existing anti-abuse rules and judicial doctrines to a contract and any related transactions in order to evaluate whether a transaction is properly characterized as a forward contract or whether a transaction characterized as some other type of derivative contract should be treated as a forward contract.

Proposed Applicability Date

These proposed rules are proposed to apply to contracts entered into on or after the date that is 30 days after the date of publication of the Treasury decision adopting these proposed rules as final regulations in the **Federal Register** (the ''proposed applicability date''). This proposed applicability date is intended to provide taxpayers in the Sixth Circuit with time to transition from the holding in *Wright* v. *Commissioner* to the rule described in these proposed regulations. However, for contracts entered into before the proposed applicability date by taxpayers in other circuits, the IRS intends to continue to adhere to its prior published position that foreign currency options are not foreign currency contracts under section 1256(g)(2). *See* Notice 2007–71, 2007–35 I.R.B. 472. A taxpayer may rely on these proposed regulations for taxable years ending on or after July 6, 2022, provided the taxpayer and its related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), consistently follow the proposed regulations for all contracts entered into during the taxable year ending on or after July 6, 2022 through the proposed applicability date of the final regulations.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

II. Regulatory Flexibility Act

The proposed rule affects any taxpayer that enters into a foreign currency option contract in the interbank market and that would otherwise treat the option as a ''foreign currency contract'' within the meaning of section 1256(g), contrary to the position set forth by the IRS in Notice 2007–71. No data is available about the number of small entities that are taking such a position. However, the Secretary has determined that the economic impact on any small entities affected by the proposed rule would not be significant.

The proposed rule clarifies that a ''foreign currency contract'' as defined in section 1256(g)(2) means only a foreign currency forward contract (and not a foreign currency option contract). The proposed rule does not require taxpayers to collect additional information to determine whether section 1256 applies to the taxpayer's option contracts. Taxpayers that would have otherwise reported these over-the-counter foreign currency options on IRS Form 6781 (Gains and Losses from Section 1256 Contracts and Straddles) as section 1256 contracts may collect less information under the proposed rule since the options will not be treated as section 1256 contracts. In addition, the proposed rule does not impose any new costs on taxpayers since it reaffirms the IRS's published position that over-the-counter foreign currency options are not ''foreign currency contracts'' within the meaning of section 1256(g). Similarly, the proposed rule does not affect a taxpayer's reporting obligation with respect to over-the-counter foreign currency options since the same amount of information is required to be reported.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the Secretary hereby certifies that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities. The Treasury Department and the IRS invite comment from members of the public about potential impacts on small entities.

III. Section 7805(f)

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

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This proposed rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These proposed regulations do not have federalism implications and do not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Statement of Availability of IRS Documents

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

Comments and Request for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble

under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules. Any electronic comments submitted, and to the extent practicable any paper comments submitted, will be made available at *www.regulations.gov* or upon request.

A public hearing will be scheduled if requested in writing by any person that timely submits electronic or written comments. Requests for a public hearing are also encouraged to be made electronically by sending an email to *publichearings@irs.gov*. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**.

Announcement 2020–4, 2020–17 I.R.B. 667 (April 20, 2020), provides that until further notice, public hearings conducted by the IRS will be held telephonically. Any telephonic hearing will be made accessible to people with disabilities.

Drafting Information

The principal authors of these regulations are D. Peter Merkel and Karen Walny of the Office of Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 1.1256(g)–2 also issued under 26 U.S.C. 1256(g)(2)(B).

* * * * *

■ **Par. 2.** Section 1.1256(g)–2 is added to read as follows:

§ 1.1256(g)–2 Foreign currency contract defined.

(a) *Foreign currency contract.* For purposes of section 1256, the term *foreign currency contract* means a forward contract that—

(1) Requires delivery of, or the settlement of which depends on the value of, a foreign currency that is a currency in which positions are also traded through regulated futures contracts;

(2) Is traded in the interbank market; and

(3) Is entered into at arm's length at a price determined by reference to the price in the interbank market.

(b) *Applicability date.* This section applies to contracts entered into on or after [date 30 days after date of publication of the final rule in the **Federal Register**].

Paul J. Mamo,

Acting Deputy Commissioner for Services and Enforcement.

[FR Doc. 2022–14318 Filed 7–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FF09E21000 FXES1111090FEDR 223]

Endangered and Threatened Wildlife and Plants; Three Species Not Warranted for Listing as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notification of findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce findings that three species are not warranted for listing as endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best available scientific and commercial information, we find that it is not warranted at this time to list the evening fieldslug (*Deroceras hesperium*), Mammoth Spring crayfish (*Faxonius marchandi*), and Weber's Whitlow grass (*Draba weberi*). However, we ask the public to submit to us at any time any new information relevant to the status of any of the species mentioned above or their habitats.

DATES: The findings in this document were made on July 6, 2022.

ADDRESSES: Detailed descriptions of the bases for these findings are available on the internet at *https://www.regulations.gov* under the following docket numbers:

Species	Docket No.
Evening fieldslug	FWS–R1–ES–2022–0058
Mammoth Spring crayfish	FWS–R3–ES–2022–0059
Weber's Whitlow grass	FWS–R6–ES–2022–0060

Those descriptions are also available by contacting the appropriate person as specified under **FOR FURTHER INFORMATION CONTACT**. Please submit any new information, materials, comments, or questions concerning this finding to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Species	Contact information
Evening fieldslug	Brad Thompson, Field Supervisor, Washington Fish and Wildlife Office, *brad_thompson@fws.gov,* (360)–753–9440.
Mammoth Spring crayfish	Karen Herrington, Field Supervisor, Missouri Ecological Services Field Office, *karen_herrington@fws.gov,* (573)–234–2132.
Weber's Whitlow grass	Ann Timberman, Field Supervisor, Colorado Field Office, *ann_timberman@fws.gov,* (970)–ndash;7181.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States

should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), we are required to make a finding on whether or not a petitioned action is warranted within 12 months after receiving any petition for which we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted (''12-month finding''). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted, but precluded by other listing activity. We must publish a notification of these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife and Plants (Lists). The Act defines ''species'' as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature (16 U.S.C. 1532(16)). The Act defines ''endangered species'' as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and ''threatened species'' as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the Act's definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

In conducting our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether the Mammoth Spring crayfish meets the Act's definition of ''endangered species'' or ''threatened species,'' we considered and thoroughly evaluated the best scientific and commercial information available regarding the past, present, and future stressors and threats. In conducting our evaluation of the evening fieldslug and Weber's Whitlow grass, we determined that these species do not meet the definition of a ''species'' under the Act, and, as a result, we conclude that they are not listable entities. We reviewed the petitions, information available in our files, and other available published and unpublished information for all of these species. Our evaluation may include information from recognized experts; Federal, State, and Tribal governments; academic institutions; foreign governments; private entities; and other members of the public.

The species assessment form for the Mammoth Springs crayfish contains more detailed biological information, a thorough analysis of the listing factors, a list of literature cited, and an explanation of why we determined that this species does not meet the Act's definition of an ''endangered species'' or a ''threatened species.'' A thorough review of the taxonomy, life history, and ecology of the Mammoth Spring crayfish is presented in the species' species status assessment (SSA) report. The species assessment forms for the evening fieldslug and Weber's Whitlow grass contain more detailed taxonomic information, a list of literature cited, and an explanation of why we determined that these species do not meet the Act's definition of a ''species.'' This supporting information can be found on the internet at *https://www.regulations.gov* under the appropriate docket number (see **ADDRESSES**, above). The following are

informational summaries of the findings in this document.

Evening Fieldslug

Previous Federal Actions

On March 17, 2008, the U.S. Fish and Wildlife Service (Service) received a petition from the Center for Biological Diversity (CBD), Conservation Northwest, the Environmental Protection Information Center, the Klamath-Siskiyou Wildlands Center, and Oregon Wild, requesting that the Service list 32 species and subspecies of mollusks in the Pacific Northwest, including the evening fieldslug (*Deroceras hesperium*), as endangered or threatened species under the Act. The petition also requested that the Service designate critical habitat concurrent with listing. In an April 13, 2009, email, CBD requested that the petition be amended to include only 29 species and subspecies, due to taxonomic revisions. The request was treated as an amendment to the original petition. In a 90-day finding published in the **Federal Register** on October 5, 2011 (76 FR 61826), the Service found that the petition presented substantial scientific or commercial information indicating that 26 of the 29 petitioned species or subspecies, including evening fieldslug, may be warranted for listing. This document constitutes our 12-month finding on the March 17, 2008, petition to list evening fieldslug under the Act.

Summary of Finding

We have carefully assessed the best scientific and commercial information available regarding the evening fieldslug and evaluated the petitioners' claim that the species warrants listing under the Act. Subsequent to the 90-day finding, a genetic and morphometric analysis demonstrated that the evening fieldslug is not a unique species but is synonymous with the meadow fieldslug (*D. laeve*), a common species with a Holarctic distribution (Roth et al. 2013, entire). This study has been accepted by the relevant scientific community, The Xerces Society for Invertebrate Conservation, and Federal and State agencies. Given that the evening fieldslug is no longer recognized as a unique taxon, we conclude that it does not meet the definition of a species or subspecies under the Act. Consequently, it does not warrant listing under the Act. A detailed discussion of the basis for this finding can be found in the evening fieldslug species assessment form (see **ADDRESSES**, above).

Mammoth Spring Crayfish

Previous Federal Actions

On April 20, 2010, we received a petition from the Center for Biological Diversity, Alabama Rivers Alliance, Clinch Coalition, Dogwood Alliance, Gulf Restoration Network, Tennessee Forests Council, and West Virginia Highlands Conservancy to list 404 aquatic, riparian, and wetland species, including Mammoth Spring crayfish (*Faxonius marchandi;* then *Orconectes marchandi*), as an endangered or threatened species under the Act. On September 27, 2011, we published a 90-day finding in the **Federal Register** (76 FR 59836) concluding that the petition presented substantial scientific or commercial information indicating that listing may be warranted for 374 of the 404 species, including Mammoth Spring crayfish. This document constitutes our 12-month finding on the April 20, 2010, petition to list Mammoth Spring crayfish under the Act.

Summary of Finding

The Mammoth Spring crayfish is a medium-sized, reddish-brown crayfish with blackish specks on its broad pincers. It has a very localized distribution in the central and eastern portion of the Spring River watershed in Fulton, Lawrence, Randolph, and Sharp Counties in northeastern Arkansas and in Howell and Oregon Counties in southern Missouri. The Mammoth Spring crayfish occurs in both intermittent and perennial streams but appears to occur in higher densities in intermittent streams. Small Mammoth Spring crayfish individuals occur in the highest densities in shallow (less than 35 centimeters (14 inches)) stream margins of pools and runs in areas of emergent vegetation. Both small and large Mammoth Spring crayfish individuals are associated with a diverse composition of substrates dominated by cobble and pebble, and negatively associated with increasing current velocity.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Mammoth Spring crayfish, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these threats. The primary threats with potential to affect the Mammoth Spring crayfish's biological status include periodically degraded water quality, sedimentation, extreme events, and nonnative crayfish invasion of the gap ringed crayfish (*Faxonius neglectus chaenodactylus*). However, these threats have not reduced the species' resiliency, redundancy, or representation.

The best available information indicates that the range of the Mammoth Spring crayfish has not contracted. Mammoth Spring crayfish density is higher in intermittent streams than in perennial streams, and based on surveys conducted in 1998–1999 and 2010–2011, occupancy of the Mammoth Spring crayfish was relatively unchanged between the periods of 1998–1999 and 2010–2011. In addition, density of the Mammoth Spring crayfish was also compared between time periods and increased significantly from 1998–1999 to 2010–2011. Therefore, we conclude that Mammoth Spring crayfish is not in danger of extinction throughout all of its range and does not meet the Act's definition of an endangered species.

We then considered the primary threat to the species in the foreseeable future (potential invasion of the gap ringed crayfish) to determine if the Mammoth Spring crayfish meets the definition of a threatened species. The SSA report also considered the effects of other stressors such as climate change and land-use changes into the future for the Mammoth Spring crayfish. However, species experts only considered the potential invasion of the gap ringed crayfish as the primary species-level influence for the Mammoth Spring crayfish into the future. Therefore, the predictive modeling effort in the SSA only included the spread of gap ringed crayfish and its effect on the Mammoth Spring crayfish, although we considered the effect of other stressors qualitatively. The SSA's analysis of future scenarios over a 50-year timeframe encompasses the best available information for future projections under reasonable worst, mostly likely, and reasonable best future scenarios. We determined that this 50-year timeframe enabled us to consider the threats and stressors acting on the species and draw reliable predictions about the species' response to these factors. Under the reasonable best and most likely future scenarios, we predict the gap ringed crayfish will not invade the range of the native Mammoth Spring crayfish within the 50-year timeframe, although under the reasonable worst scenario it may reach the edge of the Mammoth Spring crayfish's range in approximately 15 years, and continue to spread throughout the range. Although under the reasonably worst scenario, the gap ringed crayfish does invade the Mammoth Spring crayfish range, it will take greater than 100 years to invade the entire range of the species and 4 of the 6 representation units (RPUs) will not

be fully invaded. The reasonably worst scenario still leaves the species with ample redundancy and representation, such that the best available information does not indicate that the Mammoth Spring Crayfish's viability will decline within the foreseeable future such that the species meets the definition of a threatened species. Thus, after assessing the best available information, we determine that the Mammoth Spring crayfish is not likely to become in danger of extinction within the foreseeable future throughout all of its range and does not meet the Act's definition of a threatened species.

We found no biologically meaningful portion of the Mammoth Spring crayfish range where threats are impacting individuals differently from how they are affecting the species elsewhere in its range, or where the condition of the species differs from its condition elsewhere in its range such that the status of the species in that portion differs from any other portion of the species' range. Thus, after assessing the best available information, we determine that Mammoth Spring crayfish is not in danger of extinction now or likely to become so within the foreseeable future throughout all or a significant portion of its range.

Therefore, we find that listing the Mammoth Spring crayfish as an endangered species or threatened species under the Act is not warranted. A detailed discussion of the basis for this finding can be found in the Mammoth Spring crayfish species assessment form and other supporting documents (see **ADDRESSES**, above).

Weber's Whitlow Grass

Previous Federal Actions

On July 30, 2007, the Service received a petition from Forest Guardians (now WildEarth Guardians) requesting that the Service list 206 species the Mountain-Prairie Region, including Weber's Whitlow grass (*Draba weberi*), as endangered or threatened species, and designate critical habitat, under the Act. On August 18, 2009, the Service published in the **Federal Register** (74 FR 41649) a partial 90-day finding indicating that listing may be warranted for 29 species, including Weber's Whitlow grass. As a result, the Service initiated a status review for Weber's Whitlow grass. This document announces the 12-month finding on the July 30, 2007, petition to list Weber's Whitlow grass under the Act.

Summary of Finding

We have carefully assessed the best scientific and commercial information available regarding Weber's Whitlow grass and evaluated the petition's claims that the species warrants listing under the Act. A new genetic analysis indicates that Weber's Whitlow grass is not a distinct species. Weber's Whitlow grass is not genetically distinguishable from another similar plant species (Colorado Divide Whitlow-grass, or alpine tundra draba (*Draba streptobrachia*)) in the *Draba* genus, which occurs in at least 16 counties in Colorado and has a wider range than Weber's Whitlow grass (Naibauer and McGlaughlin 2021, entire; NatureServe 2022a, entire). Therefore, Weber's Whitlow grass does not meet the definition of a ''species'' under the Act, and, as a result, does not warrant listing under the Act. A detailed discussion of the basis for this finding can be found in the Weber's Whitlow grass species assessment form and other supporting documents (see **ADDRESSES**, above).

New Information

We request that you submit any new information concerning the taxonomy of, biology of, ecology of, status of, or stressors to evening fieldslug, Mammoth Spring crayfish, or Weber's Whitlow grass to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**, whenever it becomes available. New information will help us monitor these species and make appropriate decisions about their conservation and status. We encourage local agencies and stakeholders to continue cooperative monitoring and conservation efforts.

References Cited

A list of the references cited in this petition finding is available in the relevant species assessment form, which is available on the internet at *https://www.regulations.gov* in the appropriate docket (see **ADDRESSES**, above) and upon request from the appropriate person (see **FOR FURTHER INFORMATION CONTACT**, above).

Authors

The primary authors of this document are the staff members of the Species Assessment Team, Ecological Services Program.

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–14296 Filed 7–5–22; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 87, No. 128
Wednesday, July 6, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Missouri Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Missouri Advisory Committee (Committee) will hold a meeting on Thursday, July 21, 2022 at 12:00 p.m.–1:00 p.m. Central time. The Committee will continue orientation and begin identifying potential civil rights topics for their first study of the 2022–2026 term.

DATES: The meeting will take place on Thursday, July 21, 2022 at 12:00 p.m. Central Time.

Public Call Information: Dial: 800–360–9505, Confirmation Code: 2762 947 4340#

Web Access: Join from the meeting link *https://civilrights.webex.com/civilrights/j.php?MTID=m6c6b6041e21edc7797e4768f365a85ea*

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or (312) 353–8311.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call in number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individual who is deaf, deafblind and hard of hear hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and confirmation code.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324, or emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Mississippi Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome and roll call

II. Introductions

III. Discuss Civil Rights Topics

IV. Public comment

V. Next steps

VI. Adjournment

Dated: June 30, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–14356 Filed 7–5–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Mississippi Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Mississippi Advisory Committee (Committee) will hold a meeting on Monday, July 25, 2022 at 12:00 p.m.–1:30 p.m. Central time. The Committee will continue identifying potential civil rights topics for their first study of the 2021–2025 term.

DATES: The meeting will take place on Monday, July 25, 2022 at 12:00 p.m. Central Time.

Public Call Information: Dial: 800–360–9505, Confirmation Code: 2764 845 1247#.

Join from the meeting link: https://civilrights.webex.com/civilrights/j.php?MTID=mcfdf4f099d33c1dde8e4316a935a28b3.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or (312) 353–8311.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call in number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individual who is deaf, deafblind and hard of hear hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and confirmation code.

Members of the public are entitled to submit written comments; the

comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324, or emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Mississippi Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome and roll call
II. Discuss Civil Rights Topics
III. Public comment
IV. Next steps
V. Adjournment

Dated: June 30, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–14353 Filed 7–5–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–201–846]

Agreement Suspending the Countervailing Duty Investigation on Sugar From Mexico: Final Results of the 2020 Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) continues to find that the signatories, the Government of Mexico (GOM), and the respondent companies selected for individual examination, respectively, Impulsora Azucarera Del Trópico, S.A. de C.V. and its affiliate (collectively, Grupo Del Tropico), and Ingenio Huixtla SA de C.V. and its affiliates (collectively, Grupo Porres) (together, we refer to Grupo Del Tropico and Grupo Porres as ''Respondents''), were in compliance with the terms of the Agreement Suspending the Countervailing Duty Investigation on Sugar from Mexico, as amended (CVD Agreement), during the period of review (POR) from January 1, 2020, through December 31, 2020, except for certain instances of inconsequential non-compliance. Commerce also continues to find that the CVD Agreement met the statutory requirements under sections 704(c) and (d) of the Tariff Act of 1930, as amended (the Act) during the POR. However, we intend to address certain issues identified in this review by opening consultations with the GOM under Section VIII.D.4 of the CVD Agreement.

DATES: Applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Sally C. Gannon or David Cordell, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0162 or (202) 482–0408, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 7, 2022, Commerce published the *Preliminary Results* of this administrative review.[1]

On February 14, 2022, the American Sugar Coalition and its members (petitioners) [2] and Respondents filed case briefs, and the GOM filed a letter in lieu of a case brief.[3]

On February 22, 2022, petitioners and Respondents filed rebuttal briefs, and the GOM filed a letter in lieu of a rebuttal brief.[4]

Scope of the CVD Agreement

The product covered by this CVD Agreement is raw and refined sugar of all polarimeter readings derived from sugar cane or sugar beets. Merchandise covered by this CVD Agreement is typically imported under the following headings of the HTSUS: 1701.12.1000, 1701.12.5000, 1701.13.1000, 1701.13.5000, 1701.14.1020, 1701.14.1040, 1701.14.5000, 1701.91.1000, 1701.91.3000, 1701.99.1015, 1701.99.1017, 1701.99.1025, 1701.99.1050, 1701.99.5015, 1701.99.5017, 1701.99.5025, 1701.99.5050, and 1702.90.4000.[5] The tariff classification is provided for convenience and customs purposes; however, the written description of the scope of this CVD Agreement is dispositive.[6]

Analysis

Commerce continues to determine that the CVD Agreement met the statutory requirements under sections 704(c) and (d) of the Act, during the POR. We also continue to find, based on record evidence, that the GOM and Respondents, Grupo Del Tropico and Grupo Porres, were in compliance with the terms of the CVD Agreement during the POR, except for certain instances of inconsequential non-compliance. During the review, Commerce identified issues related to recordkeeping and certain complex transactions referred to as ''swap transactions.'' We intend to consult with the GOM under Section VIII.D.4 of the CVD Agreement (''Operations Consultations'') to ensure compliance with the CVD Agreement. Such consultations are necessary to demonstrate adherence to the statutory requirements of the CVD Agreement and to ensure that any potential administrative challenges to effective monitoring are diminished.

The issues raised in the case and rebuttal briefs are addressed in the accompanying Issues and Decision Memorandum and business proprietary memorandum.[7] The issues are identified in the Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and

[1] *See Agreement Suspending the Countervailing Duty Investigation on Sugar from Mexico; Preliminary Results of the 2020 Administrative Review,* 87 FR 938 (January 7, 2022) (*Preliminary Results*), and accompanying Preliminary Issues and Decision Memorandum.

[2] The members of the American Sugar Coalition are as follows: American Sugar Cane League; American Sugarbeet Growers Association; American Sugar Refining, Inc.; Florida Sugar Cane League; Rio Grande Valley Sugar Growers, Inc.; Sugar Cane Growers Cooperative of Florida; and the United States Beet Sugar Association.

[3] *See* Petitioners' Letter, ''Case Brief on Behalf of the American Sugar Coalition,'' dated February 14, 2022; Respondents' Letter, ''Case Brief'' dated February 14, 2022; and GOM's Letter, ''Letter In Lieu of Case Brief,'' dated February 14, 2022.

[4] *See* Petitioners' Letter, ''Rebuttal Brief on Behalf of the American Sugar Coalition,'' dated February 22, 2022; Respondents' Letter, ''Rebuttal Brief,'' dated February 22, 2022; and GOM's Letter, ''Letter In Lieu of Rebuttal Brief,'' dated February 22, 2022.

[5] Prior to July 1, 2016, merchandise covered by the CVD Agreement was classified in the HTSUS under subheading 1701.99.1010. Prior to January 1, 2020, merchandise covered by the CVD Agreement was classified in the HTSUS under subheadings 1701.14.1000 and 1701.99.5010.

[6] For a complete description of the Scope of the CVD Agreement, *see* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2020 Administrative Review of the Agreement Suspending the Countervailing Duty Investigation on Sugar from Mexico, as Amended,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *See* Issues and Decision Memorandum; Memorandum, ''Final Results Analysis of Proprietary Information in the 2020 Administrative Review of the Agreement Suspending the Countervailing Duty Investigation on Sugar from Mexico, as Amended,'' dated concurrently with the Issues and Decision Memorandum.

Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results of review in accordance with sections 751(a)(l) and 777(i)(l) of the Act and 19 CFR 351.213 and 19 CFR 351.221(b)(5).

Dated: June 29, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy & Negotiations, Enforcement and Compliance.

Appendix

Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Agreement
IV. Discussion of the Issues
1. Alleged Violations and Consultations with the GOM
2. Allocation Reduction
3. Swap Transactions
V. Recommendation

[FR Doc. 2022–14282 Filed 7–5–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–845]

Agreement Suspending the Antidumping Duty Investigation on Sugar From Mexico: Final Results of the 2019–2020 Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) continues to find that the respondents selected for individual examination, respectively, Impulsora Azucarera Del Trópico, S.A. de C.V. (Impulsora Del Tropico) and its affiliates and Ingenio Huixtla SA de C.V. (Ingenio Huixtla) and its affiliates (collectively, Respondents) were in compliance with the terms of the Agreement Suspending the Antidumping Duty Investigation on Sugar from Mexico, as amended (AD Agreement) during the period of review (POR) from January 1, 2020, through December 31, 2020. Commerce also continues to find that the AD Agreement met the statutory requirements under sections 734(c) and (d) of the Tariff Act of 1930, as amended (the Act) during the POR.

DATES: Applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Sally C. Gannon or David Cordell, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0162 or (202) 482–0408, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 7, 2022, Commerce published the *Preliminary Results* of this administrative review.[1] On February 14, 2022, Respondents filed a case brief.[2] On February 22, 2022, the American Sugar Coalition and its members (petitioners) [3] filed a rebuttal brief.[4]

Scope of the AD Agreement

The product covered by this AD Agreement is raw and refined sugar of all polarimeter readings derived from sugar cane or sugar beets. Merchandise covered by this AD Agreement is typically imported under the following headings of the HTSUS: 1701.12.1000, 1701.12.5000, 1701.13.1000, 1701.13.5000, 1701.14.1020, 1701.14.1040, 1701.14.5000, 1701.91.1000, 1701.91.3000, 1701.99.1015, 1701.99.1017, 1701.99.1025, 1701.99.1050, 1701.99.5015, 1701.99.5017, 1701.99.5025, 1701.99.5050, and 1702.90.4000.[5] The tariff classification is provided for convenience and customs purposes; however, the written description of the scope of this AD Agreement is dispositive.[6]

Analysis

Commerce continues to find, based on record evidence, that Respondents, Impulsora Del Tropico and Ingenio Huixtla, were in compliance with the terms of the AD Agreement during the POR. We also determine that the AD Agreement met the statutory requirements under sections 734(c) and (d) of the Act, during the POR. However, during the review, Commerce identified issues related to recordkeeping and certain complex transactions referred to as ''swap transactions.'' We intend to consult with the Signatories to the AD Agreement under Section VII.E.2 (Operations Consultations) to ensure sufficient recordkeeping with respect to swap transactions. Such recordkeeping is necessary to demonstrate compliance with the AD Agreement and to ensure that any potential administrative challenges to effective monitoring are diminished.

The issues raised in the case and rebuttal briefs are addressed in the accompanying Issues and Decision Memorandum and business proprietary memorandum.[7] The issues are identified in the Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative

[1] *See Agreement Suspending the Antidumping Duty Investigation on Sugar from Mexico; Preliminary Results of the 2019–2020 Administrative Review,* 87 FR 972 (January 7, 2022) (*Preliminary Results*), and accompanying Preliminary Issues and Decision Memorandum.

[2] *See* Respondents' Letter, ''Case Brief,'' dated February 14, 2022.

[3] The members of the American Sugar Coalition are as follows: American Sugar Cane League; American Sugarbeet Growers Association; American Sugar Refining, Inc.; Florida Sugar Cane League; Rio Grande Valley Sugar Growers, Inc.; Sugar Cane Growers Cooperative of Florida; and the United States Beet Sugar Association.

[4] *See* Petitioners' Letter, ''Rebuttal Brief of the American Sugar Coalition and its Members,'' dated February 22, 2022.

[5] Prior to July 1, 2016, merchandise covered by the AD Agreement was classified in the HTSUS under subheading 1701.99.1010. Prior to January 1, 2020, merchandise covered by the AD Agreement was classified in the HTSUS under subheadings 1701.14.1000 and 1701.99.5010.

[6] For a complete description of the Scope of the AD Agreement, *see* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2019–2020 Administrative Review of the Agreement Suspending the Antidumping Duty Investigation on Sugar from Mexico, as Amended,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *See* Issues and Decision Memorandum; *see also* Memorandum, ''Final Analysis of Proprietary Information: Impulsora Azucarera Del Trópico and its Affiliates,'' dated concurrently with the Issues and Decision Memorandum.

protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results of review in accordance with sections 751(a)(l) and 777(i)(l) of the Act and 19 CFR 351.213 and 19 CFR 351.221(b)(5).

Dated: June 29, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy & Negotiations, Enforcement and Compliance.

Appendix

Issues and Decision Memorandum

I. Summary
II. Background
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IV. Discussion of the Issues
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V. Recommendation

[FR Doc. 2022–14281 Filed 7–5–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–967; C–570–968]

Aluminum Extrusions From the People's Republic of China: Final Results of Changed Circumstances Reviews, and Revocation, in Part, of the Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S Department of Commerce (Commerce) is revoking, in part, the antidumping duty (AD) and countervailing duty (CVD) orders on aluminum extrusions from the People's Republic of China (China) with respect to certain rectangular wire.

DATES: Applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Mark Flessner or Erin Kearney, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6312 or (202) 482–0167, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 26, 2011, Commerce published the AD and CVD orders on aluminum extrusions from China.[1]

On January 6, 2014, Commerce issued the final results of changed circumstances reviews (CCR), in which it revoked the *Orders,* in part, based on a request from 3M Company (3M) with regard to a similar product, and added the following language to the scope of the *Orders:*

> Also excluded from the scope of the order is certain rectangular wire produced from continuously cast rolled aluminum wire rod, which is subsequently extruded to dimension to form rectangular wire. The product is made from aluminum alloy grade 1070 or 1370, with no recycled metal content allowed. The dimensions of the wire are 5 mm (+/−0.05 mm) in width and 1.0 mm (+/−0.02 mm) in thickness. Imports of rectangular wire are provided for under HTSUS category 7605.19.000.[2]

On March 23, 2022, 3M requested that Commerce initiate CCRs to revoke, in part, the *Orders* with respect to certain rectangular wire, pursuant to section 751(b)(l) of the Tariff Act of 1930, as amended (the Act).[3] 3M requested that Commerce exercise its discretion to extend the effective date back by one additional day, setting an effective date of the revocation of the *Orders* to entries entered on or after April 30, 2021. 3M stated that it is a U.S. importer of certain rectangular wire and, as such, is an interested party pursuant to section 771(9)(A) of the Act.

On April 13, 2022, the Aluminum Extrusions Fair Trade Committee (the petitioner) submitted comments in support of partially revoking the *Orders* with regard to the certain rectangular wire defined in the CCR Request.[4] The petitioner submitted data demonstrating that it represents ''substantially all'' of the production of the domestic like product.[5] The petitioner also supported 3M's request that the partial revocation of the *Orders* with respect to the certain rectangular wire defined in the CCR Request include unliquidated entries of the certain rectangular wire that was entered on or after April 30, 2021.[6]

On May 12, 2022, we published the initiation of the requested CCRs.[7] In the *Initiation Notice,* we invited interested parties to provide comments and/or factual information regarding these CCRs, including comments on the harmonization of the language of the of the *2014 Revocation in Part* with the certain rectangular wire defined in the current CCR Request, and the setting of an effective date of the partial revocation of the *Orders* to entries entered on or after April 30, 2021.

On May 19, 2022, 3M submitted comments[8] on the *Initiation Notice,* in which 3M provided revised language to harmonize the language of the products that are the subject of these CCRs with the language that Commerce adopted in the *2014 Revocation in Part* to yield a single exclusion on rectangular wire, as follows:

> Also excluded from the scope of the orders is certain rectangular wire, imported in bulk rolls or precut strips and produced from continuously cast rolled aluminum wire rod, which is subsequently extruded to dimension to form rectangular wire with or without rounded edges. The product is made from aluminum alloy grade 1070 or 1370, with no recycled metal content allowed. The dimensions of the wire are 2.95 mm to 6.05 mm in width, and 0.65 mm to 1.25 mm in thickness. Imports of rectangular wire are provided for under HTSUS categories 7605.19.000, 7604.29.1090, or 7616.99.5190.

3M continued to request that Commerce set an effective date of the partial revocation of the *AD Order* to entries entered on or after April 30, 2021 (which had already been supported by the petitioner[9]). On May 20, 2022, the petitioner submitted comments[10] in which it agreed with the harmonization of the language from the *2014 Revocation in Part* with the language proposed by 3M in the CCR

[1] *See Aluminum Extrusions from the People's Republic of China: Antidumping Duty Order,* 76 FR 30650 (May 26, 2011) (*AD Order*); and *Aluminum Extrusions from the People's Republic of China: Countervailing Duty Order,* 76 FR 30653 (May 26, 2011) (*CVD Order*) (collectively, *Orders*).

[2] *See Aluminum Extrusions from the People's Republic of China: Final Results of Changed Circumstances Reviews; Partial Revocation of Antidumping and Countervailing Duty Orders,* 79 FR 634 (January 6, 2014) (*2014 Revocation in Part*).

[3] *See* 3M's Letter, ''Aluminum Extrusions from the People's Republic of China: Changed Circumstances Review Request,'' dated March 23, 2022 (CCR Request).

[4] *See* Petitioner's Letter, ''Aluminum Extrusions from the People's Republic of China: Letter in Support of 3M Changed Circumstances Review Request,'' dated April 13, 2022 (Petitioner's Support Letter).

[5] *Id.* at 2–3.

[6] *Id.* at 3.

[7] *See Aluminum Extrusions from the People's Republic of China: Initiation of Changed Circumstances Reviews,* 87 FR 29110 (May 12, 2022) (*Initiation Notice*).

[8] *See* 3M's Letter, ''Aluminum Extrusions from the People's Republic of China: Comments of 3M Regarding Changed Circumstances Review on Certain Rectangular Wire,'' dated May 19, 2022 (3M Comments).

[9] *See* Petitioner's Support Letter at 3.

[10] *See* Petitioner's Letter, ''Aluminum Extrusions from the People's Republic of China: Letter in Support of 3M Changed Circumstances Review,'' dated May 20, 2022.

Request to create a single, revised exclusion regarding certain rectangular wire using the language cited above in the 3M Comments. No other party commented on the *Initiation Notice.*

On June 17, 2022, Commerce published in the **Federal Register** the notice of the preliminary results of these CCRs and its intent to revoke the *Orders,* pursuant to section 751(b)(1) of the Act and 19 CFR 351.216(b), with respect to certain rectangular wire.[11] We invited interested parties to comment on the *Preliminary Results.* We received no comments.

Final Results of Changed Circumstances Reviews and Intent To Revoke the Orders, In Part

Because no party submitted comments opposing the *Preliminary Results,* and the record contains no other information or evidence that calls into question the *Preliminary Results,* Commerce determines, pursuant to sections 751(d)(1) and 782(h) of the Act, and 19 CFR 351.222(g), that there are changed circumstances which warrant revocation of the *Orders,* in part. Specifically, because the producers accounting for substantially all of the production of the domestic like product to which the *Orders* pertain have not expressed interest in maintaining the relief provided by the *Orders* with respect to certain rectangular wire, as described below,[12] Commerce is revoking the *Orders,* in part, with respect to the certain rectangular wire; to effect this revocation, in part, Commerce will henceforth include the following language in the scope of the *Orders:*

> Also excluded from the scope of the *Orders* is certain rectangular wire, imported in bulk rolls or precut strips and produced from continuously cast rolled aluminum wire rod, which is subsequently extruded to dimension to form rectangular wire with or without rounded edges. The product is made from aluminum alloy grade 1070 or 1370, with no recycled metal content allowed. The dimensions of the wire are 2.95 mm to 6.05 mm in width, and 0.65 mm to 1.25 mm in thickness. Imports of rectangular wire are provided for under HTSUS categories 7605.19.000, 7604.29.1090, or 7616.99.5190.

Scope of the Orders

The merchandise covered by the *Orders* is aluminum extrusions which are shapes and forms, produced by an extrusion process, made from aluminum alloys having metallic elements corresponding to the alloy series designations published by the Aluminum Association commencing with the numbers 1, 3, and 6 (or proprietary equivalents or other certifying body equivalents). Specifically, the subject merchandise made from aluminum alloy with an Aluminum Association series designation commencing with the number 1 contains not less than 99 percent aluminum by weight. The subject merchandise made from aluminum alloy with an Aluminum Association series designation commencing with the number 3 contains manganese as the major alloying element, with manganese accounting for not more than 3.0 percent of total materials by weight. The subject merchandise is made from an aluminum alloy with an Aluminum Association series designation commencing with the number 6 contains magnesium and silicon as the major alloying elements, with magnesium accounting for at least 0.1 percent but not more than 2.0 percent of total materials by weight, and silicon accounting for at least 0.1 percent but not more than 3.0 percent of total materials by weight. The subject aluminum extrusions are properly identified by a four-digit alloy series without either a decimal point or leading letter. Illustrative examples from among the approximately 160 registered alloys that may characterize the subject merchandise are as follows: 1350, 3003, and 6060.

Aluminum extrusions are produced and imported in a wide variety of shapes and forms, including, but not limited to, hollow profiles, other solid profiles, pipes, tubes, bars, and rods. Aluminum extrusions that are drawn subsequent to extrusion (drawn aluminum) are also included in the scope.

Aluminum extrusions are produced and imported with a variety of finishes (both coatings and surface treatments), and types of fabrication. The types of coatings and treatments applied to subject aluminum extrusions include, but are not limited to, extrusions that are mill finished (*i.e.,* without any coating or further finishing), brushed, buffed, polished, anodized (including brightdip anodized), liquid painted, or powder coated. Aluminum extrusions may also be fabricated, *i.e.,* prepared for assembly. Such operations would include, but are not limited to, extrusions that are cut-to-length, machined, drilled, punched, notched, bent, stretched, knurled, swedged, mitered, chamfered, threaded, and spun. The subject merchandise includes aluminum extrusions that are finished (coated, painted, *etc.*), fabricated, or any combination thereof.

Subject aluminum extrusions may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, window frames, door frames, solar panels, curtain walls, or furniture. Such parts that otherwise meet the definition of aluminum extrusions are included in the scope. The scope includes the aluminum extrusion components that are attached *(e.g.,* by welding or fasteners) to form subassemblies, *i.e.,* partially assembled merchandise unless imported as part of the finished goods 'kit' defined further below. The scope does not include the non-aluminum extrusion components of subassemblies or subject kits.

Subject extrusions may be identified with reference to their end use, such as fence posts, electrical conduits, door thresholds, carpet trim, or heat sinks (that do not meet the finished heat sink exclusionary language below). Such goods are subject merchandise if they otherwise meet the scope definition, regardless of whether they are ready for use at the time of importation. The following aluminum extrusion products are excluded: aluminum extrusions made from aluminum alloy with an Aluminum Association series designations commencing with the number 2 and containing in excess of 1.5 percent copper by weight; aluminum extrusions made from aluminum alloy with an Aluminum Association series designation commencing with the number 5 and containing in excess of 1.0 percent magnesium by weight; and aluminum extrusions made from aluminum alloy with an Aluminum Association series designation commencing with the number 7 and containing in excess of 2.0 percent zinc by weight.

The scope also excludes finished merchandise containing aluminum extrusions as parts that are fully and permanently assembled and completed at the time of entry, such as finished windows with glass, doors with glass or vinyl, picture frames with glass pane and backing material, and solar panels. The scope also excludes finished goods containing aluminum extrusions that are entered unassembled in a ''finished goods kit.'' A finished goods kit is understood to mean a packaged combination of parts that contains, at the time of importation, all of the necessary parts to fully assemble a final finished good and requires no further finishing or fabrication, such as cutting or punching, and is assembled ''as is''

[11] *See Aluminum Extrusions from the People's Republic of China: Preliminary Results of Changed Circumstances Reviews,* 87 FR 36461 (June 17, 2022) (*Preliminary Results*).

[12] *See* Petitioner's Support Letter at 1–2 and Exhibit 1.

into a finished product. An imported product will not be considered a ''finished goods kit'' and therefore excluded from the scope of the *Orders* merely by including fasteners such as screws, bolts, *etc.* in the packaging with an aluminum extrusion product.

The scope also excludes aluminum alloy sheet or plates produced by other than the extrusion process, such as aluminum products produced by a method of casting. Cast aluminum products are properly identified by four digits with a decimal point between the third and fourth digit. A letter may also precede the four digits. The following Aluminum Association designations are representative of aluminum alloys for casting: 208.0, 295.0, 308.0, 355.0, C355.0, 356.0, A356.0, A357.0, 360.0, 366.0, 380.0, A380.0, 413.0, 443.0, 514.0, 518.1, and 712.0. The scope also excludes pure, unwrought aluminum in any form.

The scope also excludes collapsible tubular containers composed of metallic elements corresponding to alloy code 1080A as designated by the Aluminum Association where the tubular container (excluding the nozzle) meets each of the following dimensional characteristics: (1) length of 37 millimeters (''mm'') or 62 mm, (2) outer diameter of 11.0 mm or 12.7 mm, and (3) wall thickness not exceeding 0.13 mm.

Also excluded from the scope of these *Orders* are finished heat sinks. Finished heat sinks are fabricated heat sinks made from aluminum extrusions the design and production of which are organized around meeting certain specified thermal performance requirements and which have been fully, albeit not necessarily individually, tested to comply with such requirements.

Also excluded from the scope of the *Orders* is certain rectangular wire, imported in bulk rolls or precut strips and produced from continuously cast rolled aluminum wire rod, which is subsequently extruded to dimension to form rectangular wire with or without rounded edges. The product is made from aluminum alloy grade 1070 or 1370, with no recycled metal content allowed. The dimensions of the wire are 2.95 mm to 6.05 mm in width, and 0.65 mm to 1.25 mm in thickness. Imports of rectangular wire are provided for under HTSUS categories 7605.19.000, 7604.29.1090, or 7616.99.5190.

Imports of the subject merchandise are provided for under the following categories of the Harmonized Tariff Schedule of the United States (HTSUS): 6603.90.81.00, 7604.21.00.00, 7604.21.00.10, 7604.21.00.90, 7604.29.10.00, 7604.29.10.10, 7604.29.10.90, 7604.29.30.10, 7604.29.30.50, 7604.29.30.60, 7604.29.30.90, 7604.29.50.30, 7604.29.50.60, 7604.29.50.50, 7604.29.50.90, 7606.12.30.91, 7606.12.30.96, 7608.20.00.30, 7608.20.00.90, 7609.00.00, 7610.10.00, 7610.90.00, 7615.10.20.15, 7615.10.20.25, 7615.10.30, 7615.10.30.15, 7615.10.30.25, 7615.10.50.20, 7615.10.50.40, 7615.10.71, 7615.10.71.25, 7615.10.71.30, 7615.10.71.55, 7615.10.71.80, 7615.10.91, 7615.10.91.00, 7615.19.10, 7615.19.30, 7615.19.50, 7615.19.70, 7615.19.90, 7615.20.00, 7615.20.00.00, 7616.10.90.90, 7616.99.10, 7616.99.50, 7616.99.51, 8302.10.30.00, 8302.10.60.30, 8302.10.60.60, 8302.10.60.90, 8302.20.00.00, 8302.30.30.10, 8302.30.30.60, 8302.41.30.00, 8302.41.60.15, 8302.41.60.45, 8302.41.60.50, 8302.41.60.80, 8302.42.30.10, 8302.42.30.15, 8302.42.30.65, 8302.49.60.35, 8302.49.60.45, 8302.49.60.55, 8302.49.60.85, 8302.50.00.00, 8302.60.90.00, 8305.10.00.50, 8306.30.00.00, 8414.59.60.90, 8415.90.80.45, 8418.99.80.05, 8418.99.80.50, 8418.99.80.60, 8419.90.10.00, 8422.90.06.40, 8424.90.90.80, 8473.30.20.00, 8473.30.51.00, 8479.89.94, 8479.89.98, 8479.90.85.00, 8479.90.94, 8481.90.90.60, 8481.90.90.85, 8486.90.00.00, 8487.90.00.80, 8503.00.95.20, 8508.70.00.00, 8513.90.20, 8515.90.20.00, 8516.90.50.00, 8516.90.80.50, 8517.70.00.00, 8529.90.73.00, 8529.90.97.60, 8536.90.80.85, 8538.10.00.00, 8541.90.00.00, 8543.90.88.80, 8543.90.88.85, 8708.10.30.50, 8708.29.50.60, 8708.29.51.60, 8708.80.65.90, 8708.99.68.90, 8803.30.00.60, 9013.90.50.00, 9013.90.90.00, 9031.90.90.95, 9031.90.91.95, 9401.90.50.81, 9401.99.90.81, 9403.10.00, 9403.20.00, 9403.90.10.40, 9403.90.10.50, 9403.90.10.85, 9403.90.25.40, 9403.90.25.80, 9403.90.40.05, 9403.90.40.10, 9403.90.40.60, 9403.90.50.05, 9403.90.50.10, 9403.90.50.80, 9403.90.60.05, 9403.90.60.10, 9403.90.60.80, 9403.90.70.05, 9403.90.70.10, 9403.90.70.80, 9403.90.80.10, 9403.90.80.15, 9403.90.80.20, 9403.90.80.41, 9403.90.80.51, 9403.90.80.61, 9403.99.10.40, 9403.99.90.10, 9403.99.90.15, 9403.99.90.20, 9403.99.90.41, 9405.99.40.20, 9506.11.40.80, 9506.51.40.00, 9506.51.60.00, 9506.59.40.40, 9506.70.20.90, 9506.91.00.10, 9506.91.00.20, 9506.91.00.30, 9506.99.05.10, 9506.99.05.20, 9506.99.05.30, 9506.99.15.00, 9506.99.20.00, 9506.99.25.80, 9506.99.28.00, 9506.99.55.00, 9506.99.60.80, 9507.30.20.00, 9507.30.40.00, 9507.30.60.00, 9507.30.80.00, 9507.90.60.00, and 9603.90.80.50.

The subject merchandise entered as parts of other aluminum products may be classifiable under the following additional Chapter 76 subheadings: 7610.10, 7610.90, 7615.19, 7615.20, and 7616.99, as well as under other HTSUS chapters. In addition, fin evaporator coils may be classifiable under HTSUS numbers: 8418.99.80.50 and 8418.99.80.60. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of these *Orders* is dispositive.

Application of the Final Results of Reviews

3M requested that Commerce exercise its discretion to extend the effective date back by one additional day, setting an effective date of the revocation of the *AD Order* to entries entered on or after April 30, 2021.[13] The petitioner supported 3M's request that the partial revocation of the *Orders* with respect to the certain rectangular wire defined in the CCR Request include unliquidated entries of the certain rectangular wire that was entered on or after April 30, 2021.[14] We determined in the *Preliminary Results* that the effective date of the revocation of the AD *Order* will apply to entries entered on or after April 30, 2021, because setting the proposed effective date as the last day of the most-recently-completed period of review (POR) aids materially in the orderly administration of the *Orders* in that it permits: (a) liquidation of entries for the 2020–2021 POR exactly concurrent with that POR; and (b) the refund of cash deposits for entries in the 2021–2022 POR exactly concurrent with this POR.[15] For these final results, we continue to determine that the effective date of the revocation of the *AD Order* will apply to entries entered on or after April 30, 2021.

Section 751(d)(3) of the Act provides that ''{a} determination under this section to revoke an order . . . shall apply with respect to unliquidated entries of the subject merchandise which are entered, or withdrawn from warehouse, for consumption on or after

[13] *See* CCR Request at 1.

[14] *Id.* at 3.

[15] *See Preliminary Results,* 87 FR at 36463.

the date determined by the administering authority.'' Commerce's general practice is to instruct U.S. Customs and Border Protection (CBP) to liquidate without regard to ADs and CVDs, and to refund any estimated ADs and CVDs on, all unliquidated entries of the merchandise covered by a revocation that are not covered by the final results of an administrative review or automatic liquidation.[16] Consistent with this practice, we are applying the final results of these CCRs to all unliquidated entries of the merchandise covered by the revocations which have been entered, or withdrawn from warehouse, for consumption on or after January 1, 2021, for the *CVD Order.*

Instructions to CBP

Because we determine that there are changed circumstances that warrant the revocation of the *Orders,* in part, we will instruct CBP to liquidate without regard to ADs and CVDs, and to refund any estimated ADs and CVDs on, all unliquidated entries of the merchandise covered by this partial revocation on or after April 30, 2021, for purposes of the *AD Order,* and January 1, 2021, for purposes of the *CVD Order.*

Commerce intends to issue instructions to CBP no earlier than 35 days after the date of publication of these final results of CCRs in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the 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).

Administrative Protective Order

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

[16] *See, e.g., Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Changed Circumstances Reviews, and Revocation of the Antidumping and Countervailing Duty Orders, in Part,* 86 FR 71615 (December 17, 2021); *see also Certain Pasta from Italy: Final Results of Countervailing Duty Changed Circumstances Review and Revocation, In Part,* 76 FR 27634 (May 12, 2011); and *Stainless Steel Bar from the United Kingdom: Notice of Final Results of Changed Circumstances Review and Revocation of Order, in Part,* 72 FR 65706 (November 23, 2007).

Notification to Interested Parties

These final results of CCRs and this notice are published in accordance with sections 751(b) and 777(i) of the Act, and 19 CFR 351.216, 19 CFR 351.221(c)(3), and 19 CFR 351.222.

Dated: June 27, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

[FR Doc. 2022–14299 Filed 7–5–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–826]

Monosodium Glutamate From the Republic of Indonesia: Notice of Initiation and Preliminary Results of Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request for a changed circumstances review (CCR), the U.S. Department of Commerce (Commerce) is initiating a CCR of the antidumping duty (AD) order on monosodium glutamate (MSG) from the Republic of Indonesia (Indonesia). We preliminarily determine that PT. Daesang Ingredients Indonesia (PT. Daesang) is the successor-in-interest to PT. Miwon Indonesia (PT. Miwon). Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Gene H. Calvert, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

On November 26, 2014, Commerce published the AD order on MSG from Indonesia in the **Federal Register**.[1] In the most recent administrative review of the *Order* covering the period November 1, 2019, through October 31, 2020, PT. Miwon was assigned the cash deposit rate of 1.60 percent as a mandatory company respondent.[2]

On March 10, 2022, PT. Daesang requested that Commerce conduct an expedited CCR to find that PT. Daesang is the successor-in-interest to PT. Miwon due to a change in the company's name (*i.e.,* PT. Miwon to PT. Daesang).[3] In its submission, PT. Daesang addressed the factors Commerce analyzes with respect to successor-in-interest determinations in the AD context and provided supporting documentation.[4] Commerce received no comments from interested parties on PT. Daesang's CCR Request.

Scope of the Order

The merchandise covered by the *Order* is MSG from Indonesia. For a full description of the merchandise covered by the scope of the *Order, see* the Preliminary Decision Memorandum.[5]

Initiation of Changed Circumstances Review

Pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216, Commerce will conduct a CCR upon receipt of a request from an interested party for a review of an AD order that shows changed circumstances sufficient to warrant a review of the order.[6] The information submitted by PT. Daesang supporting its claim that PT. Daesang is the successor-in-interest to PT. Miwon demonstrates changed circumstances sufficient to initiate a review.[7]

The information submitted by PT. Daesang demonstrates that its request is based solely on a change in the name of the company from ''PT. Miwon Indonesia'' to ''PT. Daesang Ingredients Indonesia,'' effective November 2021.[8] Moreover, the evidence submitted in support of PT. Daesang's request

[1] *See Monosodium Glutamate from the People's Republic of China, and the Republic of Indonesia: Antidumping Duty Orders; and Monosodium Glutamate from the Republic of China: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 70505 (November 26, 2014) (*Order*).

[2] *See Monosodium Glutamate from the Republic of Indonesia: Final Results of Antidumping Duty Administrative Review; 2019–2020,* 87 FR 18767 (March 31, 2022).

[3] *See* PT. Daesang's Letter, ''Monosodium Glutamate (MSG) from Indonesia: Request to Initiate a Successor-in-Interest Changed Circumstances Review for PT. Daesang Ingredients Indonesia,'' dated March 10, 2022 (PT. Daesang's CCR Request).

[4] *Id.*

[5] *See* Memorandum, ''Decision Memorandum for the Initiation and Preliminary Results of the Changed Circumstances Review of the Antidumping Duty Order on Monosodium Glutamate from the Republic of Indonesia: PT. Daesang Ingredients Indonesia,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* 19 CFR 351.216(c).

[7] *See* 19 CFR.351.216(d).

[8] *See* PT. Daesang's CCR Request at Exhibit 2. The specific effective date of the name change is business proprietary information and is not available for public summary.

demonstrates that PT. Daesang is otherwise the same business entity as PT. Miwon. Therefore, in accordance with the regulation referenced above, Commerce is initiating a CCR to determine whether PT. Daesang is the successor-in-interest to PT. Miwon.

Preliminary Results of the Changed Circumstances Review

When Commerce concludes that expedited action is warranted, it may publish the notice of initiation and preliminary results of a CCR concurrently.[9] Commerce has combined the notice of initiation and preliminary results in successor-in-interest cases when sufficient documentation has been provided supporting the request to make a preliminary determination.[10] In this instance, because we have information on the record to support the request for a preliminary determination and no other interested party submitted comments, we find that expedited action is warranted, and we are combining the notice of initiation and the notice of preliminary results of review, in accordance with 19 CFR 351.221(c)(3)(ii).

In a CCR, Commerce generally consider a company to be the successor to another company for AD cash deposit purposes if the operations of the successor are not materially dissimilar from those of its predecessor.[11] In making this determination, Commerce examines a number of factors including, but not limited to, changes in: (1) management; (2) production facilities; (3) suppliers; and (4) customer base.[12] While no single factor or combination of factors is dispositive, Commerce will generally consider one company to be the successor to another if its resulting operations are essentially the same as that of its predecessor.[13] Thus, if the evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the prior company, Commerce will assign the new company the cash deposit rate of its predecessor.[14]

In its CCR request, PT. Daesang provided evidence demonstrating that its operations are not materially dissimilar from those of PT. Miwon. Based on the record, we preliminarily determine that PT. Daesang is the successor-in-interest to PT. Miwon. For a complete discussion of the information that PT. Daesang provided, including business proprietary information and the complete successor-in-interest analysis, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Determination Memorandum is included as the appendix to this notice. The Preliminary Determination 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.*

Public Comment

Any interested party may request a hearing within 14 days of publication of this notice, in accordance with 19 CFR 351.310(c).[15] Interested parties may submit case briefs no later than 14 days after the date of publication of this notice.[16] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the deadline for case briefs, in accordance with 19 CFR 351.309(d). Parties who submit case or rebuttal briefs in this CCR are requested to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[17] All comments are to be filed electronically using ACCESS, and must be served on interested parties. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the day it is due.[18] Please note that Commerce has temporarily modified certain requirements for serving documents containing business proprietary information, until further notice.[19]

Consistent with 19 CFR 351.216(e), we will issue the final results of this CCR no later than 270 days after the date on which this review was initiated, or within 45 days of publication of these preliminary results in the **Federal Register** if all parties agree to this preliminary finding.

Notification to Interested Parties

We are issuing and publishing this initiation and preliminary results notice in accordance with sections 751(b)(1) and 777(i) of the Act, 19 CFR 351.216, and 19 CFR 351.221(c)(3).

Dated: June 28, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Initiation and Preliminary Results of the Changed Circumstances Review
V. Success-in-Interest Determination
VI. Conclusion
VII. Recommendation

[FR Doc. 2022–14283 Filed 7–5–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–042]

Stainless Steel Sheet and Strip From the People's Republic of China: Final Results of Expedited 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 U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on stainless steel sheet and strip (SSSS) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Review'' section of this notice.

DATES: Applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, AD/CVD Operations, Office III, Enforcement and

[9] *See* 19 CFR 351.221(c)(3)(ii).

[10] *See, e.g., Certain Frozen Freshwater Shrimp from India: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 85 FR 57192 (September 15, 2020) (*Hyson CCR Initiation and Preliminary Results*), unchanged in *Certain Frozen Freshwater Shrimp from India: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 85 FR 70584 (November 5, 2020) (*Hyson CCR Final Results*).

[11] *Id.*

[12] *See, e.g., Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Turkey: Notice of Initiation and Preliminary Results of Changed Circumstances Review,* 86 FR 70443 (December 10, 2021) at 86 70444, unchanged in *Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Turkey: Final Results of Changed Circumstances Review,* 87 FR 3763 (January 25, 2022).

[13] *Id.*

[14] *See, e.g., Hyson CCR Initiation and Preliminary Results,* unchanged in *Hyson CCR Final Results.*

[15] Commerce is exercising its discretion under 19 CFR 351.310(c) to alter the time limit for requesting a hearing.

[16] Commerce is exercising its discretion under 19 CFR 351.309(c)(1)(ii) to alter the time limit for the filing of case briefs.

[17] *See* 19 CFR 351.309(c)(2) and (d)(2).

[18] *See* 19 CFR 351.303(b).

[19] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On March 1, 2022, Commerce published the notice of initiation of the sunset review of the AD order on SSSS from China,[1] pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On March 15, 2022, Commerce received a notice of intent to participate from the domestic interested parties within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested parties claimed domestic interested party status under section 771(9)(C) of the Act, as producers of the domestic like product in the United States.[4] On March 30, 2022, the domestic interested parties submitted a timely substantive response within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[5] Commerce did not receive a substantive response from any other interested parties with respect to the *Order* covered by this sunset review, nor was a hearing requested. On April 20, 2022, 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 is conducting an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The product covered by the *Order* is SSSS from China. For a full description of the scope, *see* the Issues and Decision Memorandum.[7]

[1] *See Stainless Steel Sheet and Strip from the People's Republic of China: Antidumping Duty Order,* 82 FR 16160 (April 3, 2017) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Review,* 87 FR 11416 (March 1, 2022).

[3] *See* Domestic Interested Parties' Letter, ''Five-Year (''Sunset'') Review of the Antidumping Duty Order on Stainless Steel Sheet and Strip from China—Domestic Interested Parties' Notice of Intent to Participate,'' dated March 15, 2022.

[4] *Id.* at 2.

[5] *See* Domestic Interested Parties' Letter, ''Five-Year ('Sunset') Review of Antidumping Duty Order on Stainless Steel from China: Domestic Industry Substantive Response to Notice of Initiation,'' dated March 30, 2022.

[6] *See* Commerce's Letter, ''Sunset Reviews Initiated on March 1, 2022,''dated April 20, 2022.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Expedited Sunset Review of Stainless Steel from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is included as the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* A complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNotices/ListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(c) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins of up to 76.64 percent.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely notification of the 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 these final results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218(e)(1)(ii)(C)(2) and 19 CFR 351.221(c)(5)(ii).

Dated: June 29, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2022–14315 Filed 7–5–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC142]

Taking of Marine Mammals Incidental to Specific Activities; Taking of Marine Mammals Incidental to Pile Driving and Removal Activities During the Metlakatla Seaplane Facility Refurbishment Project, Metlakatla, Alaska

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

ACTION: Notice; issuance of incidental harassment authorization.

SUMMARY: NMFS has received a request from the Alaska Department of Transportation and Public Facilities (AKDOT&PF) for the re-issuance of a previously issued incidental harassment authorization (IHA) with the only change being effective dates. The initial IHA authorized take of eight species of marine mammals, by Level B harassment only, incidental to pile driving and removal activities and down-the-hole (DTH) drilling activities associated with maintenance improvements to the existing Metlakatla Seaplane Facility (MSF), Metlakatla, Alaska. The project has been delayed and none of the work covered in the initial IHA has been conducted. The initial IHA was effective from August 1, 2021 through July 31, 2022. The AKDOT&PF has requested re-issuance with new effective dates of July 1, 2022 through June 30, 2023. The scope of the activities and anticipated effects remain the same, authorized take numbers are not changed, and the required mitigation, monitoring, and reporting remains the same as included in the initial IHA. NMFS is, therefore, issuing a second identical IHA to cover the incidental take analyzed and authorized in the initial IHA.

DATES: This authorization is effective from July 1, 2022 through June 30, 2023.

ADDRESSES: An electronic copy of the final 2021 IHA previously issued to the AKDOT&PF, the AKDOT&PF's application, and the **Federal Register** notices proposing and issuing the initial IHA may be obtained by visiting *https://www.fisheries.noaa.gov/action/incidental-take-authorization-alaska-department-transportation-metlakatla-*

seaplane-facility. In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Benjamin Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act (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 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.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

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).

Summary of Request

On August 6, 2021, NMFS published a final notice of our issuance of an IHA authorizing take of marine mammals incidental to the MSF project in Southeast Alaska (86 FR 43190). The effective dates of that IHA were August 1, 2021 through July 31, 2022. On May 4, 2022, the AKDOT&PF informed NMFS that the project was delayed. None of the work identified in the initial IHA (*e.g.,* pile driving activities, DTH) has occurred. The AKDOT&PF submitted a request on May 4, 2022 that we reissue an identical IHA that would be effective from July 1, 2022 through June 30, 2023, in order to conduct the construction work that was analyzed and authorized through the previously issued IHA. Therefore, re-issuance of the IHA is appropriate.

Summary of Specified Activity and Anticipated Impacts

The planned activities (including mitigation, monitoring, and reporting), authorized incidental take, and anticipated impacts on the affected stocks are the same as those analyzed and authorized through the previously issued IHA.

The purpose of this project is to make repairs to the MSF. The existing facility has deteriorated in recent years and AKDOT&PF has conducted several repair projects. The facility is near the end of its useful life, and replacement of all the existing float structures is required to continue safe operation in the future. Refurbishment of the MSF will require pile installation and removal using impact and vibratory driving methods, as well as DTH and is expected to take 26 days of in-water work. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the initial IHA. The mitigation and monitoring are also as prescribed in the initial IHA.

Species that are expected to be taken by the planned activity include: Minke whale (*Balaenoptera acutorostrata*), Humpback whale (*Megaptera novaeangliae*), Killer whale (*Orcinus orca*), Pacific White-Sided Dolphin (*Lagenorhynchus obliquidens*), Dall's porpoise (*Phocoenoides dalli*), Harbor porpoise (*Phocoena phocoena*), Steller Sea Lion (*Eumetopias jubatus*), and Harbor seal (*Phoca vitulina*). A description of the methods and inputs used to estimate take anticipated to occur and, ultimately, the take that was authorized is found in the previous documents referenced above. The data inputs and methods of estimating take are identical to those used in the initial IHA. NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts or take estimate under the initial IHA.

We refer to the documents related to the previously issued IHA, which include the **Federal Register** notice of the issuance of the initial 2021 IHA for the AKDOT&PF's construction work (86 FR 43190), the AKDOT&PF's application, the **Federal Register** notice of the proposed IHA (86 FR 34203), and all associated references and documents.

Determinations

The AKDOT&PF will conduct activities as analyzed in the initial 2021 IHA. As described above, the number of authorized takes of the same species and stocks of marine mammals are identical to the numbers that were found to meet the negligible impact and small numbers standards and authorized under the initial IHA and no new information has emerged that would change those findings. The re-issued 2022 IHA includes identical required mitigation, monitoring, and reporting measures as the initial IHA, and there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) the required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; and (4) the AKDOT&PF's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action.

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 with respect to environmental consequences on the human environment.

Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. This action is consistent with categories of activities identified in CE B4 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.

Endangered Species Act (ESA)

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 Alaska Regional Office (AKRO).

NMFS is authorizing take of Mexico DPS humpback whales which are listed under the ESA. The Permit and Conservation Division completed a Section 7 consultation with the AKRO for the issuance of this IHA and a biological opinion was issued on July 23, 2021. The AKRO's biological opinion states that the action is not likely to jeopardize the continued existence of Mexico DPS humpback whales. The July 23, 2021 biological opinion is still in effect.

Authorization

NMFS has issued an IHA to the AKDOT&PF for in-water construction activities associated with the specified activity from July 1, 2022 through June 30, 2023. All previously described mitigation, monitoring, and reporting requirements from the initial 2021 IHA are incorporated.

Dated: June 28, 2022.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–14191 Filed 7–5–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB760]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Geophysical Surveys in the Southeastern Gulf of Mexico

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

ACTION: Notice; issuance of an incidental harassment authorization (IHA).

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an IHA to Scripps Institution of Oceanography (Scripps) to incidentally harass marine mammals during marine geophysical surveys in the southeastern Gulf of Mexico.

DATES: This authorization is effective from June 29, 2022 through June 28, 2023.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed incidental harassment authorization is 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 March 17, 2020, NMFS received a request from Scripps for an IHA to take marine mammals incidental to low-energy geophysical surveys in the southeastern Gulf of Mexico, initially planned to occur in summer 2020. The application was deemed adequate and complete on May 26, 2020. On June 9, 2020, Scripps notified NMFS that the proposed survey had been postponed and tentatively rescheduled for summer 2021. On April 8, 2021, Scripps notified NMFS that the survey had been further postponed and is now expected to occur in July-August 2022. NMFS reviewed recent draft Stock Assessment Reports (SARs) and other scientific literature, and determined that neither this nor any other new information affects which species or stocks have the potential to be affected, the potential effects to marine mammals and their habitat as described in the IHA application, or any other aspect of the analysis. Therefore, NMFS determined that Scripps' IHA application remained adequate and complete. Scripps' request is for take of 20 species of marine mammals by Level B harassment only. Neither Scripps nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Activity

Overview

Scripps plans to support a research project that involves low-energy seismic surveys in the Gulf of Mexico during summer 2022. The study will be conducted on the R/V *Justo Sierra,* owned by Universidad Nacional Autónoma de México (UNAM), using a portable multi-channel seismic (MCS) system operated by marine technicians from Scripps. The survey will use a pair of low-energy Generator-Injector (GI) airguns with a total discharge volume of 90 cubic inches (in^3). The surveys will take place within the Exclusive Economic Zones (EEZs) of Mexico and Cuba in the southeastern Gulf of Mexico.

Dates and Duration

The specific dates of the survey have not been determined but the cruise is expected to occur in July to August 2022. The research cruise is expected to consist of 15 days at sea, including ~12 days of seismic operations (10 planned days and 2 contingency days) and ~3 days of transit. R/V *Justo Sierra* will depart from Tampamochaco, Mexico

and return to Progreso, Mexico after the program is completed.

Specific Geographic Region

The planned surveys take place in the Gulf of Mexico between ~22°–25° N and 83.8°–88° W (see Figure 1). Seismic acquisition will occur in two primary survey areas. The Yucatán Channel survey area is located in the deep-water channel between the Campeche and Florida escarpments, within the EEZ of Cuba in water depths ranging from ~1,500 to 3,600 meters (m; 4,921 to 11,811 feet (ft)). The Campeche Bank survey area is located in the northeastern flank of the Campeche escarpment, within the EEZs of Cuba and Mexico in waters ranging in depth from ~110 to 3,000 m (361 to 9,843 ft).

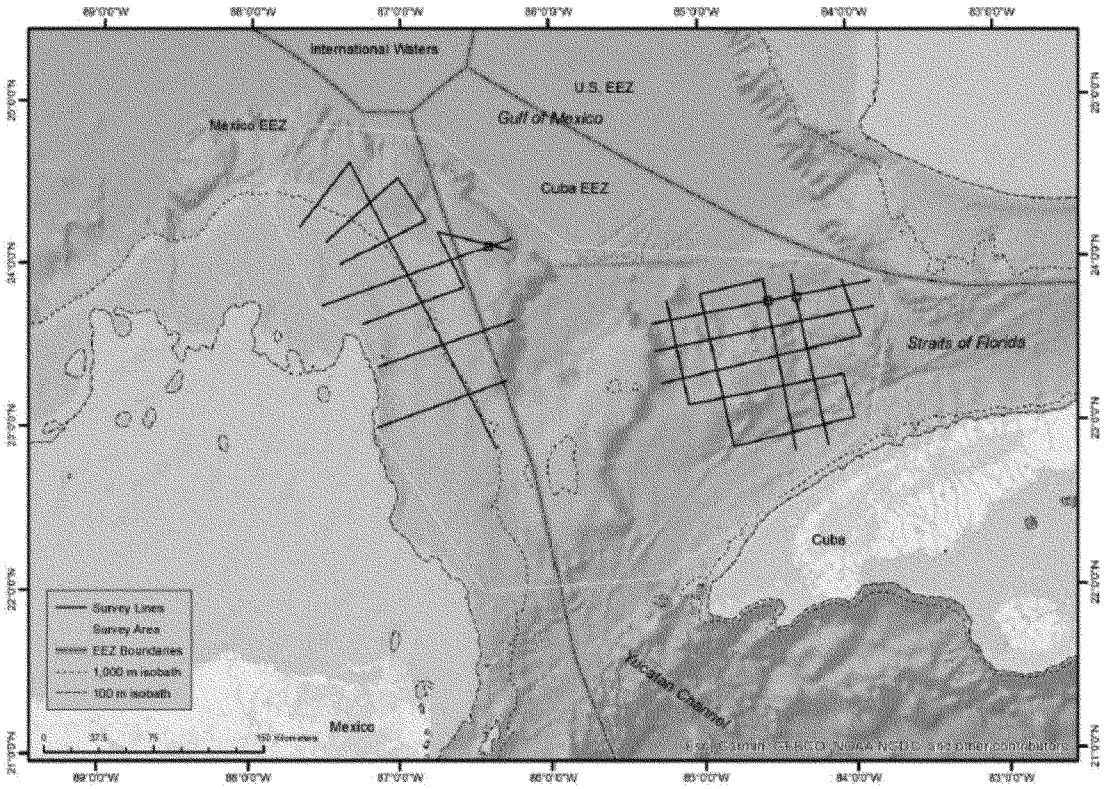

Figure 1. Location of the planned low-energy seismic surveys in the southeastern Gulf of Mexico

A detailed description of the planned geophysical survey project is provided in the **Federal Register** notice for the proposed IHA (86 FR 71427; December 16, 2021). Since that time, no changes have been made to the planned survey activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specified activity.

Mitigation, monitoring, and reporting measures are described in detail later in this document (please see Mitigation and Monitoring and Reporting).

Comments and Responses

A notice of proposed IHA was published in the **Federal Register** on December 16, 2021 (86 FR 71427). That notice described, in detail, Scripps' 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 did not receive any public comments.

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 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 is expected and has been authorized for this action, 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 most species, stock abundance estimates are based on sightings within the U.S. EEZ, however for some species, this geographic area may extend beyond U.S. waters. Other species may use survey abundance estimates. Survey abundance (as compared to stock or species abundance) is the total number of individuals estimated within the survey area, which may or may not align completely with a stock's geographic range as defined in the SARs. These surveys may also extend beyond U.S. waters. In this case, the planned survey area outside of the U.S. EEZ does not necessarily overlap with the ranges for stocks managed by NMFS. However, we assume that individuals of these species that may be encountered during the survey may be part of those stocks.

All managed stocks in this region are assessed in NMFS's U.S. Atlantic and Gulf of Mexico SARs (*e.g.,* Hayes *et al.,* 2021). All values presented in Table 1 are the most recent available at the time of publication and are available in the 2020 SARs (Hayes *et al.,* 2021) and draft 2021 SARs (available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

For the majority of species potentially present in the specified geographical region, NMFS has designated only a single generic stock (*i.e.,* ''Gulf of Mexico'') for management purposes, although there is currently no information to differentiate the stock from the Atlantic Ocean stock of the same species, nor information on whether more than one stock may exist in the GOM (Hayes *et al.,* 2017).

TABLE 1—MARINE MAMMALS THAT COULD OCCUR IN THE SURVEY AREA

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]	Gulf of Mexico population abundance (Roberts *et al.,* 2016) [4]
Order Cetartiodactyla—Cetacea—Superfamily Odontoceti (toothed whales, dolphins, and porpoises)							
Family Physeteridae:							
Sperm whale	*Physeter macrocephalus*	Gulf of Mexico	E/D; Y	1,180 (0.22, 983, 2018)	2	9.6	2,207
Family Kogiidae:							
Pygmy sperm whale [6]	*Kogia breviceps*	Gulf of Mexico	-/-; N	336 (0.35, 253, 2018)	2.5	31	4,373
Dwarf sperm whale [6]	*Kogia sima.*						
Family Ziphiidae (beaked whales):							
Cuvier's beaked whale [6].	*Ziphius cavirstris*	Gulf of Mexico	-/-; N	18 (0.75, 10, 2018)	0.1	5.2	3,768
Blainville's beaked whale [6].	*Mesoplodon densirostris*	Gulf of Mexico	-/-; N	98 (0.46, 68, 2018)	0.7	5.2	
Gervais' beaked whale [6].	*Mesoplodon europaeus*	Gulf of Mexico	-/-; N	20 (0.98, 10, 2018)	0.1	5.2	
Family Delphinidae:							
Rough-toothed dolphin.	*Steno bredanensis*	Gulf of Mexico	-/-; N	unknown (n/a, unknown, 2018).	undetermined	39	4,853
Bottlenose dolphin	*Tursiops truncatus*	Gulf of Mexico Oceanic.	-/-; N	7,462 (0.31, 5,769, 2018)	58	32	[6] 176,108
Pantropical spotted dolphin.	*Stenella attenuata*	Gulf of Mexico	-/-; N	37,195 (0.24, 30,377, 2018).	304	241	102,361
Atlantic spotted dolphin.	*Stenella frontalis*	Gulf of Mexico	-/-; N	21,506 (0.26, 17,339, 2018).	166	36	74,785
Spinner dolphin	*Stenella longirostris*	Gulf of Mexico	-/-; Y	2,991 (0.54, 1,954, 2018)	20	113	25,114
Clymene dolphin	*Stenella clymene*	Gulf of Mexico	-/-; Y	513 (1.03, 250, 2018)	2.5	8.4	11,895
Striped dolphin	*Stenella coeruleoalba*	Gulf of Mexico	-/-; Y	1,817 (0.56, 1,172, 2018)	12	13	5,229
Fraser's dolphin	*Lagenodelphis hosei*	Gulf of Mexico	-/-; N	213 (1.03, 104, 2018)	1	Unknown	1,665
Risso's dolphin	*Grampus griseus*	Gulf of Mexico	-/-; N	1,974 (0.46, 1,368, 2018)	14	5.3	3,764
Melon-headed whale	*Peponocephala electra*	Gulf of Mexico	-/-; N	1,749 (0.68, 1,039, 2018)	10	9.5	7,003
Pygmy killer whale	*Feresa attenuata*	Gulf of Mexico	-/-; N	613 (1.15, 283, 2018)	2.8	1.6	2,126
False killer whale	*Pseudorca crassidens*	Gulf of Mexico	-/-; N	494 (0.79, 276, 2018)	2.8	Unknown	3,204
Killer whale	*Orcinus orca*	Gulf of Mexico	-/-; N	267 (0.75, 152, 2018)	1.5	Unknown	185
Short-finned pilot whale.	*Globicephalus macrorhynchus.*	Gulf of Mexico	-/-; N	1,321 (0.43, 934, 2018)	7.5	3.9	1,981

[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/draft-marine-mammal-stock-assessment-reports.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[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] This information represents species- or guild-specific best abundance estimate predicted by habitat-based cetacean density models (Roberts et al., 2016). These models provide the best available scientific information regarding predicted density patterns of cetaceans in the U.S. Gulf of Mexico, and we provide the corresponding abundance predictions as a point of reference. Total abundance estimates were produced by computing the mean density of all pixels in the modeled area and multiplying by its area. For those 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 more information, see *https://seamap.env.duke.edu/models/Duke/GOM/.*

[5] Abundance estimates are in some cases reported for a guild or group of species when those species are difficult to differentiate at sea. Similarly, the habitat-based cetacean density models produced by Roberts *et al.* (2016) are based in part on available observational data which, in some cases, is limited to genus or guild in terms of taxonomic definition. NMFS's SARs present pooled abundance estimates for *Kogia* spp. and *Mesoplodon* spp., while Roberts *et al.* (2016) produced density models to genus level for *Kogia* spp. and as a guild for beaked whales (*Ziphius cavirostris* and *Mesoplodon* spp.). Finally, Roberts *et al.* (2016) produced a density model for bottlenose dolphins that does not differentiate between oceanic, shelf, and coastal stocks.

In Table 1 above, we report two sets of abundance estimates: those from NMFS SARs and those predicted by Roberts *et al.* (2016). Please see the table footnotes for more detail. As discussed in the notice of proposed IHA (86 FR 71427; December 16, 2021), we expect that the Roberts *et al.* (2016) estimates are generally more realistic and, for these purposes, represent the best available information. For purposes of assessing estimated exposures relative to abundance—used in this case to understand the scale of the predicted takes compared to the population—we generally believe that the Roberts *et al.* (2016) abundance predictions are most appropriate because they were used to generate the exposure estimates and therefore provide the most relevant comparison (see Estimated Take). Roberts *et al.* (2016) represents the best available scientific information regarding marine mammal occurrence and distribution in the Gulf of Mexico.

As the planned survey lines are outside of the U.S. EEZ, they do not directly overlap with the defined stock ranges within the Gulf of Mexico (Hayes *et al.,* 2021). However, some of the survey lines occur near the U.S. EEZ, and the distribution and abundance of species in U.S. EEZ waters are assumed representative of those in the survey area. As indicated above, all 20 species (with 20 representative stocks in the northern Gulf of Mexico) in Table 1 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have authorized it. All species that could potentially occur in the planned survey areas are included in Table 2 of the IHA application.

A detailed description of the species likely to be affected by the geophysical surveys, 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 Scripps' IHA application and summarized in the **Federal Register** notice for the proposed IHA (86 FR 71427; December 16, 2021); since that time, we are not aware of any changes in the status of these species or stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice and the IHA application for these descriptions. Please also refer to NMFS' website (*www.nmfs.noaa.gov/pr/species/mammals/*) for generalized species accounts.

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).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Twenty species of cetacean have the reasonable potential to co-occur with the planned survey activities. No pinnipeds are expected to be present or taken. Of the cetacean species that may be present, 18 are classified as mid-frequency cetaceans (*i.e.,* all delphinid and ziphiid species and the sperm whale) and two are classified as high-frequency cetaceans (*i.e., Kogia* spp.). No low-frequency cetaceans (*i.e.,* baleen whales) are expected to be present or taken.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from Scripps' geophysical survey activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the survey area. The notice of proposed IHA (86 FR 71427; December 16, 2021) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from Scripps' geophysical survey 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 notice of proposed IHA (86 FR 71427; December 16, 2021). The referenced information includes a summary and discussion of the ways that the specified activity may impact marine mammals and their habitat. Consistent with the analysis in our prior **Federal Register** notices for similar Scripps surveys and after independently evaluating the analysis in Scripps'

application, we determine that the survey is likely to result in the takes described in the Estimated Take section of this document and that other forms of take are not expected to occur.

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 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.

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which informs 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 are by Level B harassment only, as use of the acoustic sources (*i.e.,* seismic airgun) has the potential to result in disruption of behavioral patterns for individual marine mammals. Based on the nature of the activity and the anticipated effectiveness of the mitigation measures (*i.e.,* marine mammal exclusion zones) discussed in detail below in Mitigation section, Level A harassment is neither anticipated nor authorized. As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the estimated and authorized take.

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, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources.

Scripps' activity includes the use of impulsive seismic sources, and therefore the 160 dB re 1 μPa (rms) is applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). Scripps' activity includes the use of impulsive seismic sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT (PTS)

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$; 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$; 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$; 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$; 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$; 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

The survey entails the use of a 2-airgun array with a total discharge of 90 in^3 at a tow depth of 2–4 m. Lamont-Doherty Earth Observatory (L–DEO) model results are used to determine the 160 dB_{rms} radius for the 2-airgun array in deep water (> 1,000 m) down to a maximum water depth of 2,000 m. Received sound levels were predicted by L–DEO's model (Diebold *et al.,* 2010) as a function of distance from the airguns, for the two 45 in^3 airguns. This modeling approach uses ray tracing for the direct wave traveling from the array to the receiver and its associated source ghost (reflection at the air-water interface in the vicinity of the array), in a constant-velocity half-space (infinite homogenous ocean layer, unbounded by a seafloor). In addition, propagation measurements of pulses from a 36-airgun array at a tow depth of 6 m have been reported in deep water (~1,600 m), intermediate water depth on the slope (~600–1,100 m), and shallow water (~50 m) in the Gulf of Mexico in 2007–2008 (Tolstoy *et al.,* 2009; Diebold *et al.,* 2010).

For deep and intermediate water cases, the field measurements cannot be used readily to derive the Level A and Level B harassment isopleths, as at those sites the calibration hydrophone was located at a roughly constant depth of 350–550 m, which may not intersect all the sound pressure level (SPL) isopleths at their widest point from the sea surface down to the maximum relevant water depth (~2,000 m) for marine mammals. At short ranges, where the direct arrivals dominate and the effects of seafloor interactions are minimal, the data at the deep sites are suitable for comparison with modeled levels at the depth of the calibration hydrophone. At longer ranges, the comparison with the model—constructed from the maximum SPL through the entire water column at varying distances from the airgun array—is the most relevant.

In deep and intermediate water depths, comparisons at short ranges between sound levels for direct arrivals recorded by the calibration hydrophone and model results for the same array tow depth are in good agreement (see Figures 12 and 14 in Appendix H of NSF–USGS 2011). Consequently, isopleths falling within this domain can be predicted reliably by the L–DEO model, although they may be imperfectly sampled by measurements recorded at a single depth. At greater distances, the calibration data show that seafloor-reflected and sub-seafloor-refracted arrivals dominate, whereas the direct arrivals become weak and/or incoherent. Aside from local topography effects, the region around the critical distance is where the observed levels rise closest to the model curve. However, the observed sound levels are found to fall almost entirely below the model curve. Thus, analysis of the Gulf of Mexico calibration measurements demonstrates that although simple, the L–DEO model is a robust tool for conservatively estimating isopleths.

The planned surveys will acquire data with two 45-in^3 guns at a tow depth of 2–4 m. For deep water (≤1000 m), we use the deep-water radii obtained from L–DEO model results down to a maximum water depth of 2,000 m for the airgun array with 2-m airgun separation. The radii for intermediate water depths (100–1,000 m) are derived from the deep-water ones by applying a correction factor (multiplication) of 1.5, such that observed levels at very near offsets fall below the corrected mitigation curve (see Figure 16 in Appendix H of NSF–USGS 2011). No survey effort is planned to occur in shallow water (<100 m).

L–DEO's modeling methodology is described in greater detail in SIO's IHA application. The estimated distances to the Level B harassment isopleths for the planned airgun configuration in each water depth category are shown in Table 4.

TABLE 4—PREDICTED RADIAL DISTANCES FROM R/V JUSTO SIERRA SEISMIC SOURCE TO ISOPLETHS CORRESPONDING TO LEVEL B HARASSMENT THRESHOLD

Airgun configuration	Water depth (m)	Predicted distances (m) to 160 dB rms SPL received sound level
Two 45 in^3 guns, 2-m separation, 4-m tow depth	>1,000	[a] 539
	100–1,000	[b] 809

[a] Distance based on L–DEO model results.
[b] Distance based on L–DEO model results with a 1.5 × correction factor between deep and intermediate water depths.

Predicted distances to Level A harassment isopleths, which vary based on marine mammal hearing groups, were calculated based on modeling performed by L–DEO using the NUCLEUS software program and the NMFS User Spreadsheet. The updated acoustic thresholds for onset of hearing impacts from impulsive sounds (*e.g.,* airguns) contained in the Technical Guidance were presented as dual metric acoustic thresholds using both cumulative sound exposure level (SEL_{cum}) and peak sound pressure metrics (NMFS 2016a). As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* metric resulting in the largest isopleth). The SEL_{cum} metric considers both level and duration of exposure, as well as auditory weighting functions by marine mammal hearing group. In recognition of the fact that the

requirement to calculate Level A harassment ensonified areas could be more technically challenging to predict due to the duration component and the use of weighting functions in the new SEL_{cum} thresholds, NMFS developed an optional User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to facilitate the estimation of take numbers.

The SEL_{cum} for the 2–GI airgun array is derived from calculating the modified far-field signature. The far-field signature is often used as a theoretical representation of the source level. To compute the far-field signature, the source level is estimated at a large distance below the array (*e.g.,* 9 km), and this level is back projected mathematically to a notional distance of 1 m from the array's geometrical center. However, it has been recognized that the source level from the theoretical far-field signature is never physically achieved at the source when the source is an array of multiple airguns separated in space (Tolstoy *et al.,* 2009). Near the source (at short ranges, distances <1 km), the pulses of sound pressure from each individual airgun in the source array do not stack constructively as they do for the theoretical far-field signature. The pulses from the different airguns spread out in time such that the source levels observed or modeled are the result of the summation of pulses from a few airguns, not the full array (Tolstoy *et al.,* 2009). At larger distances, away from the source array center, sound pressure of all the airguns in the array stack coherently, but not within one time sample, resulting in smaller source levels (a few dB) than the source level derived from the far-field signature. Because the far-field signature does not take into account the interactions of the two airguns that occur near the source center and is calculated as a point source (single airgun), the modified far-field signature is a more appropriate measure of the sound source level for large arrays. For this smaller array, the modified far-field changes will be correspondingly smaller as well, but we use this method for consistency across all array sizes.

Scripps used the same acoustic modeling as for Level B harassment with a small grid step in both the inline and depth directions to estimate the SEL_{cum} and peak SPL. The propagation modeling takes into account all airgun interactions at short distances from the source including interactions between subarrays using the NUCLEUS software to estimate the notional signature and the MATLAB software to calculate the pressure signal at each mesh point of a grid. For a more complete explanation of this modeling approach, please see ''Appendix A: Determination of Mitigation Zones'' in Scripps' IHA application.

In order to more realistically incorporate the Technical Guidance's weighting functions over the seismic array's full acoustic band, unweighted spectrum data for the airgun array (modeled in 1 Hertz (Hz) bands) was used to make adjustments (dB) to the unweighted spectrum levels, by frequency, according to the weighting functions for each relevant marine mammal hearing group. These adjusted/weighted spectrum levels were then converted to pressures (μPa) in order to integrate them over the entire broadband spectrum, resulting in broadband weighted source levels by hearing group that could be directly incorporated within the User Spreadsheet (*i.e.,* to override the Spreadsheet's more simple weighting factor adjustment). Using the User Spreadsheet's ''safe distance'' methodology for mobile sources (described by Sivle *et al.,* 2014) with the hearing group-specific weighted source levels, and inputs assuming spherical spreading propagation and source velocities and shot intervals provided in Scripps' IHA application, potential radial distances to auditory injury zones were calculated for PTS thresholds. Calculated Level A harassment zones for all cetacean hearing groups are presented in Table 5 below (no pinnipeds are expected to occur in the survey area).

TABLE 5—MODELED RADIAL DISTANCES (m) TO ISOPLETHS CORRESPONDING TO LEVEL A HARASSMENT THRESHOLDS

Functional hearing group	Level A harassment zone (m)
Low-frequency cetaceans [1]	9.9
Mid-frequency cetaceans	1.0
High-frequency cetaceans	34.6

[1] Low-frequency cetaceans are not expected to be encountered or taken by Level A or Level B harassment during the survey.

Note that because of some of the assumptions included in the methods used, isopleths produced may be overestimates to some degree, which will ultimately result in some degree of overestimate of the potential for 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 mobile sources, such as the planned seismic survey, the User Spreadsheet predicts the closest distance at which a stationary animal would not incur PTS if the sound source traveled by the animal in a straight line at a constant speed.

Auditory injury is unlikely to occur for any functional hearing group given the very small modeled zones of injury (all estimated zones less than 35 meters (m)), and we therefore expect the potential for Level A harassment to be de minimis, even before the likely moderating effects of aversion and/or other compensatory behaviors (*e.g.,* Nachtigall *et al.,* 2018) are considered. Additionally, the method of estimating take as described below (see *Take Calculation and Estimation*) yielded only two species/guilds with calculated takes by Level A harassment, and the highest calculated take of those two groups was only two takes by Level A harassment (Table 9). We do not believe that Level A harassment is a likely outcome for any hearing group and have not authorized take by Level A harassment for any species.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

For the planned survey area in the southeast Gulf of Mexico, Scripps determined that the best source of density data for marine mammal species that might be encountered in the project area was habitat-based density modeling conducted by Roberts *et al.* (2016). The Roberts *et al.* (2016) data provide abundance estimates for species or species guilds within 10 km x 10 km grid cells (100 square kilometer (km^2)) within the U.S. EEZ in the Gulf of Mexico and Atlantic Ocean on a monthly or annual basis, depending on the species and location. In the Gulf of Mexico, marine mammals do not migrate seasonally, so a single estimate for each grid cell is provided and represents the predicted abundance of that species in that 100 km^2 location at any time of year.

As the planned survey lines are outside of the U.S. EEZ, they do not directly overlap the available spatial density data. However, some of the survey lines occur near the U.S. EEZ, and the distribution and abundance of species in U.S. EEZ waters are assumed representative of those in the nearby survey area. To select a representative

sample of grid cells for the calculation of densities in three different water depth categories (≤100 m, 100–1,000 m, and >1,000 m), a 200-km perimeter around the survey lines was created in GIS. The areas within this perimeter within the three depth categories was then used to select grid cells containing the estimates for each species in the Roberts *et al.* (2016) data (*i.e.,* <100 m, n = 157 grid cells; 100–1,000, n = 169 grid cells; >1,000 m, n = 410 grid cells). The average abundance for each species in each water depth category was calculated as the mean value of the grid cells within each category and then converted to density (individuals/1 km^2) by dividing by 100 km^2. Estimated densities for marine mammal species that could occur in the project area are shown in Table 6.

TABLE 6—MARINE MAMMAL DENSITIES IN THE SURVEY AREA

Species	Estimated density (#/km^2)	
	Intermediate water 100–1,000 m	Deep water >1,000 m
Sperm whale	0.00384	0.00579
Atlantic spotted dolphin	0.07022	0.00001
Beaked whale guild[a]	0.00498	0.00882
Common bottlenose dolphin	0.18043	0.00566
Clymene dolphin	0.00325	0.00403
False killer whale	0.00744	0.00748
Frasers dolphin	0.00386	0.00389
Killer whale	0.00007	0.00082
Melon-headed whale	0.00624	0.01186
Pantropical spotted dolphin	0.14764	0.31353
Short-finned pilot whales	0.00636	0.00128
Pygmy killer whale	0.00201	0.00648
Risso's dolphin	0.02315	0.00748
Rough-toothed dolphin	0.00890	0.00768
Spinner dolphin	0.15723	0.00412
Striped dolphin	0.00212	0.01268
Kogia spp.[b]	0.01052	0.00490

[a] Includes Cuvier's beaked whale, Blainville's beaked whale, and Gervais' beaked whale.
[b] Pygmy sperm whales and dwarf sperm whales.

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

The area expected to be ensonified was determined by entering the planned survey lines into ArcGIS and then using GIS to identify the relevant ensonified areas by ''drawing'' the 160-dB threshold buffer around each seismic line according to the depth category in which the lines occurred. The total ensonified area within each depth category was then divided by the total number of survey days to provide the proportional daily ensonified area within each depth category. The total ensonified area in each depth class was multiplied by 1.25 to add an additional 25 percent contingency to allow for additional airgun operations such as testing of the source or re-surveying lines with poor data quality. Due to uncertainties with respect to permitting for surveys in Cuban waters, ensonified areas were calculated separately for transect lines in Mexican and Cuban EEZs, for which 4.2 and 5.5 survey days were estimated, respectively (Table 7). If Scripps is unable to operate within the Cuban EEZ, they will conduct the entire survey within the Mexican EEZ, with the same estimated daily proportions of survey activity in each depth strata occurring over a total of 9.7 survey days. This scenario yields a total ensonified area of 3,595.6 km^2, with 1,848.6 km^2 in intermediate waters (100–1,000 m) and 1,747.0 km^2 in deep waters (>1,000 m).

TABLE 7—AREAS (km^2) IN MEXICAN AND CUBAN EEZS TO BE ENSONIFIED ABOVE LEVEL B HARASSMENT THRESHOLD

Water depth category	Relevant isopleth (m)	Ensonified area in Mexican EEZ (km^2)	Ensonified area in Cuban EEZ (km^2)	Total ensonified area (km^2)	Total area with 25% increase (km^2)
Intermediate (100–1000 m)	809	640.35	0	640.35	800.44
Deep (>1000)	539	605.14	1298.09	1903.23	2379.04
Total	.....	1245.49	1298.09	2543.58	3179.48

To estimate the total number of possible exposures, the total ensonified area within each depth category is multiplied by the densities in each depth category. Scripps does not expect to know whether surveying within Cuban waters will be permitted until immediately before the research cruise, therefore NMFS has authorized the highest calculated take number for each species across the two survey scenarios (Table 8).

TABLE 8—CALCULATED AND AUTHORIZED TAKES BY LEVEL B HARASSMENT, AND PERCENTAGE OF POPULATION EXPOSED

Species	Mexico and Cuba lines calculated level B	Mexico and Cuba lines calculated level A	Mexico only calculated level B	Mexico only calculated level A	Authorized level B	Authorized level A	Population size [a]	Percent of population
Sperm whale	17	0	17	0	17	0	2,207	0.78
Atlantic spotted dolphin	56	0	130	0	130	0	74,785	0.17
Beaked whale guild [c]	25	0	25	0	25	0	3,768	0.66
Common bottlenose dolphin	158	0	343	0	343	0	176,108	0.20
Clymene dolphin	[b] 90	0	[b] 90	0	[b] 90	0	11,895	0.76
False killer whale	[b] 28	0	[b] 28	0	[b] 28	0	3,204	0.87
Frasers dolphin	[b] 65	0	[b] 65	0	[b] 65	0	1,665	3.90
Killer whale	[b] 7	0	[b] 7	0	[b] 7	0	267	2.62
Melon-headed whale	[b] 100	0	[b] 100	0	[b] 100	0	7,003	1.43
Pantropical spotted dolphin	862	2	820	1	864	0	102,361	0.84
Pygmy killer whale	[b] 19	0	[b] 19	0	[b] 19	0	2,126	0.89
Risso's dolphin	36	0	56	0	56	0	3,764	1.48
Rough-toothed dolphin	[b] 56	0	[b] 56	0	[b] 56	0	4,853	1.15
Short-finned pilot whales	[b] 25	0	[b] 25	0	[b] 25	0	1,981	1.26
Spinner dolphin	136	0	298	0	298	0	25,114	1.19
Striped dolphin	[b] 46	0	[b] 46	0	[b] 46	0	5,229	0.88
Kogia spp	19	1	27	1	28	0	4,373	0.64

[a] 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.

[b] Calculated and authorized take increased to mean group size as presented by Maze-Foley and Mullin (2006).

[c] Cuvier's, Blainville's, and Gervais' beaked whales.

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.

Scripps indicated that it reviewed mitigation measures employed during seismic research surveys authorized by NMFS under previous incidental harassment authorizations, as well as recommended best practices in Richardson *et al.* (1995), Pierson *et al.* (1998), Weir and Dolman (2007), Nowacek *et al.* (2013), Wright (2014), and Wright and Cosentino (2015), and has incorporated a suite of mitigation measures into their project description based on the above sources.

To reduce the potential for disturbance from acoustic stimuli associated with the activities, Scripps will implement mitigation measures for marine mammals. Mitigation measures that must be adopted during the planned surveys include: (1) Vessel-based visual mitigation monitoring; (2) Establishment of a marine mammal exclusion zone (EZ) and buffer zone; (3) shutdown procedures; (4) ramp-up procedures; and (4) vessel strike avoidance measures.

Vessel-Based Visual Mitigation Monitoring

Visual monitoring requires the use of trained observers (herein referred to as visual Protected Species Observers (PSOs)) to scan the ocean surface visually for the presence of marine mammals. PSO observations must take place during all daytime airgun operations and nighttime start ups (if applicable) of the airguns. If airguns are operating throughout the night, observations must begin 30 minutes prior to sunrise. If airguns are operating after sunset, observations must continue until 30 minutes following sunset. Following a shutdown for any reason, observations must occur for at least 30 minutes prior to the planned start of airgun operations. Observations must also occur for 30 minutes after airgun operations cease for any reason. Observations must also be made during daytime periods when the R/V *Justo Sierra* is underway without seismic operations, such as during transits, to allow for comparison of sighting rates and behavior with and without airgun operations and between acquisition periods. Airgun operations must be suspended when marine mammals are observed within, or about to enter, the designated exclusion zone (EZ) (as described below).

During seismic operations, two visual PSOs must be on duty and conduct visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset). PSO(s) must be on duty in shifts of duration no longer than

4 hours. Other vessel crew must also be instructed to assist in detecting marine mammals and in implementing mitigation requirements (if practical). Before the start of the seismic survey, the crew must be given additional instruction in detecting marine mammals and implementing mitigation requirements.

The R/V *Justo Sierra* is a suitable platform from which PSOs would watch for marine mammals. Standard equipment for marine mammal observers must be 7 x 50 reticule binoculars and optical range finders. At night, night-vision equipment must be available. The observers must be in communication with ship's officers on the bridge and scientists in the vessel's operations laboratory, so they can advise promptly of the need for vessel strike avoidance measures (see *Vessel Strike Avoidance Measures* below) or seismic source shutdown.

The PSOs must have no tasks other than to conduct observational effort, record observational data, and communicate with and instruct relevant vessel crew with regard to the presence of marine mammals and mitigation requirements. PSO resumes must be provided to NMFS for approval. At least one PSO must have a minimum of 90 days prior at-sea experience working as a PSO during a seismic survey. One ''experienced'' visual PSO will be designated as the lead for the entire protected species observation team. The lead will serve as primary point of contact for the vessel operator.

Exclusion Zone (EZ) and Buffer Zone

An EZ is a defined area within which occurrence of a marine mammal triggers mitigation action intended to reduce the potential for certain outcomes, *e.g.,* auditory injury, disruption of critical behaviors. The PSOs must establish a minimum EZ with a 100 m radius for the airgun array. The 100-m EZ must be based on radial distance from any element of the airgun array (rather than being based around the vessel itself). With certain exceptions (described below), if a marine mammal appears within, enters, or appears on a course to enter this zone, the acoustic source must be shut down (see *Shutdown Procedures* below).

The 100-m radial distance of the standard EZ is precautionary in the sense that it would be expected to contain sound exceeding injury criteria for all marine mammal hearing groups (Table 5) while also providing a consistent, reasonably observable zone within which PSOs would typically be able to conduct effective observational effort. In the 2011 Programmatic Environmental Impact Statement for marine scientific research funded by the National Science Foundation or the U.S. Geological Survey (NSF–USGS 2011), Alternative B (the Preferred Alternative) conservatively applied a 100-m EZ for all low-energy acoustic sources in water depths >100 m, with low-energy acoustic sources defined as any towed acoustic source with a single or a pair of clustered airguns with individual volumes of ≤250 in^3. Thus the 100-m EZ required for this survey is consistent with the PEIS.

Our intent in prescribing a standard EZ distance is to (1) encompass zones within which auditory injury could occur on the basis of instantaneous exposure; (2) provide additional protection from the potential for more severe behavioral reactions (*e.g.,* panic, antipredator response) for marine mammals at relatively close range to the acoustic source; (3) provide consistency for PSOs, who need to monitor and implement the EZ; and (4) define a distance within which detection probabilities are reasonably high for most species under typical conditions.

PSOs must also establish and monitor a 100-m buffer zone beyond the EZ (for a total of 200 m). During use of the acoustic source, occurrence of marine mammals within the buffer zone (but outside the EZ) must be communicated to the operator to prepare for potential shutdown of the acoustic source. The buffer zone is discussed further under *Ramp-Up Procedures* below.

An extended EZ of 500 m must be established for all beaked whales and *Kogia* species as well as for aggregations of six or more large whales (*i.e.,* sperm whale) or a large whale with a calf (calf defined as an animal less than two-thirds the body size of an adult observed to be in close association with an adult).

Ramp-Up Procedures

Ramp-up of an acoustic source is intended to provide a gradual increase in sound levels following a shutdown, enabling animals to move away from the source if the signal is sufficiently aversive prior to its reaching full intensity. Ramp-up is required after the array is shut down for any reason for longer than 15 minutes. Ramp-up must begin with the activation of one 45 in^3 airgun, with the second 45 in^3 airgun activated after 5 minutes.

Two PSOs are required to monitor during ramp-up. During ramp up, the PSOs must monitor the EZ, and if marine mammals were observed within the EZ or buffer zone, a shutdown must be implemented as though the full array were operational. If airguns have been shut down due to PSO detection of a marine mammal within or approaching the EZ, ramp-up must not be initiated until all marine mammals have cleared the EZ, during the day or night. Criteria for clearing the EZ would be as described above.

Thirty minutes of pre-start clearance observation are required prior to ramp-up for any shutdown of longer than 30 minutes (*i.e.,* when the array is shut down during transit from one line to another). This 30-minute pre-start clearance period may occur during any vessel activity (*i.e.,* transit). If a marine mammal is observed within or approaching the 200-m buffer or 500-m extended EZ during this pre-start clearance period, ramp-up must not be initiated until all marine mammals cleared the relevant area. Criteria for clearing the EZ would be as described above. If the airgun array has been shut down for reasons other than mitigation (*e.g.,* mechanical difficulty) for a period of less than 30 minutes, it may be activated again without ramp-up if PSOs have maintained constant visual observation and no detections of any marine mammal have occurred within the EZ or buffer zone. Ramp-up must be planned to occur during periods of good visibility when possible. However, ramp-up is allowed at night and during poor visibility if the 100 m EZ and 200 m buffer zone have been monitored by visual PSOs for 30 minutes prior to ramp-up.

The operator is required to notify a designated PSO of the planned start of ramp-up as agreed-upon with the lead PSO; the notification time must not be less than 60 minutes prior to the planned ramp-up. A designated PSO must be notified again immediately prior to initiating ramp-up procedures and the operator must receive confirmation from the PSO to proceed. The operator must provide information to PSOs documenting that appropriate procedures were followed. Following deactivation of the array for reasons other than mitigation, the operator is required to communicate the near-term operational plan to the lead PSO with justification for any planned nighttime ramp-up.

Shutdown Procedures

If a marine mammal is detected outside the EZ but is likely to enter the EZ, the airguns must be shut down before the animal is within the EZ. Likewise, if a marine mammal is already within the EZ when first detected, the airguns must be shut down immediately.

Following a shutdown, airgun activity must not resume until the marine mammal has cleared the EZ. The animal

is considered to have cleared the EZ if the following conditions have been met:

- it is visually observed to have departed the EZ;
- it has not been seen within the EZ for 15 min in the case of small odontocetes; or
- it has not been seen within the EZ for 30 min in the case of large odontocetes, including sperm and beaked whales.

This shutdown requirement is in place for all marine mammals, with the exception of small delphinids under certain circumstances. As defined here, the small delphinid group is intended to encompass those members of the Family Delphinidae most likely to voluntarily approach the source vessel for purposes of interacting with the vessel and/or airgun array (*e.g.,* bow riding). This exception to the shutdown requirement would apply solely to specific genera of small dolphins—*Lagenodelphis, Stenella, Steno,* and *Tursiops.*

We include this small delphinid exception because shutdown requirements for small delphinids under all circumstances represent practicability concerns without likely commensurate benefits for the animals in question. Small delphinids are generally the most commonly observed marine mammals in the specific geographic region and would typically be the only marine mammals likely to intentionally approach the vessel. As described above, auditory injury is extremely unlikely to occur for mid-frequency cetaceans (*e.g.,* delphinids), as this group is relatively insensitive to sound produced at the predominant frequencies in an airgun pulse while also having a relatively high threshold for the onset of auditory injury (*i.e.,* permanent threshold shift).

A large body of anecdotal evidence indicates that small delphinids commonly approach vessels and/or towed arrays during active sound production for purposes of bow riding, with no apparent effect observed in those delphinids (*e.g.,* Barkaszi *et al.,* 2012, 2018). The potential for increased shutdowns resulting from such a measure would require the R/V *Justo Sierra* to revisit the missed track line to reacquire data, resulting in an overall increase in the total sound energy input to the marine environment and an increase in the total duration over which the survey is active in a given area. Although other mid-frequency hearing specialists (*e.g.,* large delphinids) are no more likely to incur auditory injury than are small delphinids, they are much less likely to approach vessels. Therefore, retaining a shutdown requirement for large delphinids would not have similar impacts in terms of either practicability for the applicant or corollary increase in sound energy output and time on the water. We do anticipate some benefit for a shutdown requirement for large delphinids in that it simplifies somewhat the total range of decision-making for PSOs and may preclude any potential for physiological effects other than to the auditory system as well as some more severe behavioral reactions for any such animals in close proximity to the source vessel.

Visual PSOs must use best professional judgment in making the decision to call for a shutdown if there is uncertainty regarding identification (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived or one of the species with a larger EZ).

Shutdown of the acoustic source is also required upon observation of a species for which authorization has not been granted (*e.g.,* baleen whales), or a species for which authorization has been granted but the authorized number of takes are met, observed approaching or within the Level B harassment zones.

Vessel Strike Avoidance Measures

Vessel strike avoidance measures are intended to minimize the potential for collisions with marine mammals. These requirements do not apply in any case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply.

The required measures include the following: Vessel operator and crew must maintain a vigilant watch for all marine mammals and slow down or stop the vessel or alter course to avoid striking any marine mammal. A visual observer aboard the vessel must monitor a vessel strike avoidance zone around the vessel according to the parameters stated below. Visual observers monitoring the vessel strike avoidance zone may be either third-party observers or crew members, but crew members responsible for these duties must be provided sufficient training to distinguish marine mammals from other phenomena. Vessel strike avoidance measures must be followed during surveys and while in transit.

The vessel must maintain a minimum separation distance of 100 m from large whales (*i.e.,* baleen whales and sperm whales). If a large whale is within 100 m of the vessel, the vessel must reduce speed and shift the engine to neutral, and must not engage the engines until the whale has moved outside of the vessel's path and the minimum separation distance has been established. If the vessel is stationary, the vessel must not engage engines until the whale(s) has moved out of the vessel's path and beyond 100 m. The vessel must maintain a minimum separation distance of 50 m from all other marine mammals, to the extent practicable. If an animal is encountered during transit, the vessel must attempt to remain parallel to the animal's course, avoiding excessive speed or abrupt changes in course. Vessel speeds must be reduced to 10 knots or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near the vessel.

We have carefully evaluated the suite of mitigation measures described here and considered a range of other measures in the context of ensuring that we prescribe the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Based on our evaluation of the required measures, NMFS has determined that the mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the planned survey 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).
- Mitigation and monitoring effectiveness.

Monitoring that is designed specifically to facilitate mitigation measures, such as monitoring of the EZ to inform potential shutdowns of the airgun array, are described above and are not repeated here. The required monitoring and reporting includes the following:

Vessel-Based Visual Monitoring

As described above, PSO observations must take place during daytime airgun operations and nighttime start-ups (if applicable) of the airguns. During seismic operations, visual PSOs must be based aboard the R/V *Justo Sierra.* PSOs must be appointed by Scripps with NMFS approval. The PSOs must have successfully completed relevant training, including completion of all required coursework and passing a written and/or oral examination developed for the training program, and must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences and a minimum of 30 semester hours or equivalent in the biological sciences and at least one undergraduate course in math or statistics. The educational requirements may be waived if the PSO has acquired the relevant skills through alternate training, including (1) secondary education and/or experience comparable to PSO duties; (2) previous work experience conducting academic, commercial, or government-sponsored marine mammal surveys; or (3) previous work experience as a PSO; the PSO must demonstrate good standing and consistently good performance of PSO duties.

During seismic operations in daylight hours (30 minutes before sunrise through 30 minutes after sunset), two PSOs must monitor for marine mammals around the seismic vessel. PSOs must be on duty in shifts of duration no longer than 4 hours. Other crew must also be instructed to assist in detecting marine mammals and in implementing mitigation requirements (if practical). During daytime, PSOs must scan the area around the vessel systematically with reticle binoculars (*e.g.,* 7 x 50 Fujinon) and with the naked eye. At night, PSOs must be equipped with night-vision equipment.

For data collection purposes, PSOs must use standardized data collection forms, whether hard copy or electronic. PSOs must record detailed information about any implementation of mitigation requirements, including the distance of animals to the acoustic source and description of specific actions that ensued, the behavior of the animal(s), any observed changes in behavior before and after implementation of mitigation, and if shutdown was implemented, the length of time before any subsequent ramp-up of the acoustic source. If required mitigation was not implemented, PSOs must record a description of the circumstances. At a minimum, the following information must be recorded:

- Vessel names (source vessel and other vessels associated with survey) and call signs;
- PSO names and affiliations;
- Dates of departures and returns to port with port name;
- Date and participants of PSO briefings;
- Dates and times (Greenwich Mean Time) of survey effort and times corresponding with PSO effort;
- Vessel location (latitude/longitude) when survey effort began and ended and vessel location at beginning and end of visual PSO duty shifts;
- Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;
- Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions changed significantly), including BSS and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon;
- Factors that may have contributed to impaired observations during each PSO shift change or as needed as environmental conditions changed (*e.g.,* vessel traffic, equipment malfunctions); and
- Survey activity information, such as acoustic source power output while in operation, number and volume of airguns operating in the array, tow depth of the array, and any other notes of significance (*i.e.,* pre-clearance, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, etc.).

The following information must be recorded upon visual observation of any protected species:

- Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
- PSO who sighted the animal;
- Time of sighting;
- Vessel location at time of sighting;
- Water depth;
- Direction of vessel's travel (compass direction);
- Direction of animal's travel relative to the vessel;
- Pace of the animal;
- Estimated distance to the animal and its heading relative to vessel at initial sighting;
- Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified) and the composition of the group if there is a mix of species;
- Estimated number of animals (high/low/best);
- Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);
- Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);
- Detailed behavior observations (*e.g.,* number of blows/breaths, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior);
- Animal's closest point of approach (CPA) and/or closest distance from any element of the acoustic source;
- Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, shooting, data acquisition, other); and
- Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up) and time and location of the action.

Reporting

A report must be submitted to NMFS within 90 days after the end of the cruise. The report must describe the operations that were conducted and sightings of marine mammals near the operations. The report must provide full documentation of methods, results, and interpretation pertaining to all

monitoring. The 90-day report must summarize the dates and locations of seismic operations, and all marine mammal sightings (dates, times, locations, activities, associated seismic survey activities).

The draft report must also include geo-referenced time-stamped vessel tracklines for all time periods during which airguns were operating. Tracklines must include points recording any change in airgun status (*e.g.,* when the airguns began operating, when they were turned off, or when they changed from full array to single gun or vice versa). GIS files must be provided in ESRI shapefile format and include the UTC date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates must be referenced to the WGS84 geographic coordinate system. In addition to the report, all raw observational data must be made available to NMFS. The report must summarize the data collected as described above and in the IHA. A final report must be submitted within 30 days following resolution of any comments on the draft report.

Reporting Injured or Dead Marine Mammals

Discovery of injured or dead marine mammals—In the event that personnel involved in survey activities covered by the authorization discover an injured or dead marine mammal, Scripps must report the incident to the Office of Protected Resources (OPR), NMFS and to the NMFS Southeast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Vessel strike—In the event of a ship strike of a marine mammal by any vessel involved in the activities covered by the authorization, Scripps must report the incident to OPR, NMFS and to the NMFS Southeast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measure were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;
- Species identification (if known) or description of the animal(s) involved;
- Estimated size and length of the animal that was struck;
- Description of the behavior of the animal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals present immediately preceding the strike;
- Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and
- To the extent practicable, photographs or video footage of the animal(s).

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, our analysis applies to all species listed in Table 1, given that NMFS expects the anticipated effects of the planned geophysical survey to be similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, NMFS has identified species-specific factors to inform the analysis.

NMFS does not anticipate that injury, serious injury or mortality would occur as a result of Scripps' planned survey, even in the absence of mitigation, and none is authorized. Similarly, non-auditory physical effects, stranding, and vessel strike are not expected to occur. Although a few incidents of Level A harassment were predicted through the quantitative exposure estimation process (see Estimated Take), NMFS has determined that this is not a realistic result due to the small estimated Level A harassment zones for the species (no greater than approximately 50 m) and the mitigation requirements, and no take by Level A harassment has been authorized. These estimated zones are larger than what would realistically occur, as discussed in the Estimated Take section.

We expect that takes would be in the form of short-term Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging (if such activity were occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007, Ellison *et al.,* 2012).

Marine mammal habitat may be impacted by elevated sound levels, but these impacts would be temporary. Prey species are mobile and are broadly distributed throughout the project area; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the relatively short duration (up to 12 days) and temporary nature of the disturbance, the availability of similar habitat and resources in the surrounding area, the impacts to marine mammals and the food sources that they utilize

are not expected to cause significant or long-term consequences for individual marine mammals or their populations. No biologically important areas, designated critical habitat, or other habitat of known significance would be impacted by the planned activities.

Negligible Impact Conclusions

The planned survey would be of short duration (up to 12 days of seismic operations), and the acoustic ''footprint'' of the survey would be small relative to the ranges of the marine mammals that would potentially be affected. Sound levels would increase in the marine environment in a relatively small area surrounding the vessel compared to the range of the marine mammals within the survey area. Short-term exposures to survey operations are expected to only temporarily affect marine mammal behavior in the form of avoidance, and the potential for longer-term avoidance of important areas is limited. Short-term exposures to survey operations are not likely to impact marine mammal behavior, and the potential for longer-term avoidance of important areas is limited.

The required mitigation measures are expected to reduce the number and/or severity of takes by allowing for detection of marine mammals in the vicinity of the vessel by visual observers, and by minimizing the severity of any potential exposures via shutdowns of the airgun array.

NMFS concludes that exposures to marine mammal species and stocks due to Scripps' planned survey would result in only short-term (temporary and short in duration) effects to individuals exposed, over relatively small areas of the affected animals' ranges. Animals may temporarily avoid the immediate area, but are not expected to permanently abandon the area. Major shifts in habitat use, distribution, or foraging success are not expected. NMFS does not anticipate the authorized take to impact annual rates of recruitment or survival.

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 Level A harassment, serious injury or mortality is anticipated or authorized;
- The planned activity is temporary and of relatively short duration (up to 12 days);
- The anticipated impacts of the planned activity on marine mammals would primarily be temporary behavioral changes in the form of avoidance of the area around the survey vessel;
- The availability of alternate areas of similar habitat value for marine mammals to temporarily vacate the survey area during the planned survey to avoid exposure to sounds from the activity;
- The potential adverse effects on fish or invertebrate species that serve as prey species for marine mammals from the planned survey would be temporary and spatially limited, and impacts to marine mammal foraging would be minimal; and
- The required mitigation measures, including visual monitoring, shutdowns, ramp-up, and prescribed measures based on energy size are expected to minimize potential impacts to marine mammals (both amount and severity).

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 Scripps' 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 NMFS has authorized is below one third of the estimated population abundance of all species (Roberts *et al.,* 2016). In fact, take of individuals is less than 4 percent of the abundance of the affected populations (see Table 8).

Based on the analysis contained herein of the planned activity (including the required mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review.

Endangered Species Act

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.

The NMFS Office of Protected Resources Interagency Cooperation Division issued a Biological Opinion under section 7 of the ESA, on the issuance of an IHA to Scripps under section 101(a)(5)(D) of the MMPA by the NMFS Office of Protected Resources

Permits and Conservation Division. The Biological Opinion concluded that the proposed action is not likely to jeopardize the continued existence of any listed marine mammal species.

Authorization

As a result of these determinations, NMFS has issued an IHA to Scripps for conducting geophysical surveys in the southeast Gulf of Mexico in summer 2022, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: June 30, 2022.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–14362 Filed 7–5–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committees—Defense Uniform Formulary Beneficiary Advisory Panel

AGENCY: Department of Defense (DoD).

ACTION: Charter renewal of federal advisory committee.

SUMMARY: The DoD is publishing this notice to announce that it is renewing the charter for the Uniform Formulary Beneficiary Advisory Panel (UFBAP).

FOR FURTHER INFORMATION CONTACT: Jim Freeman, DoD Advisory Committee Management Officer, 703–692–5952.

SUPPLEMENTARY INFORMATION: The UFBAP's charter is being renewed in accordance with 10 U.S.C. 1074g(c) and the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix) and 41 CFR 102–3.50(a). The charter and contact information for the UFBAP's Designated Federal Officer (DFO) are found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation*.

The UFBAP reports to the Secretary of Defense and Deputy Secretary of Defense (''the DoD Appointing Authority''), through the Under Secretary of Defense for Personnel and Readiness (USD(P&R), who shall consider the UFBAP's advice and recommendations before implementing changes to the uniform formulary in accordance with DoD policy and procedures.

Pursuant to 10 U.S.C. 1074g(c)(2), the UFBAP is composed of no more than 15 members and shall include members that represent: (a) Nongovernmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries; (b) Contractors responsible for the TRICARE retail pharmacy program; (c) Contractors responsible for the national mail-order pharmacy program; and (d) TRICARE network providers.

Authority to invite or appointment individuals to serve on the UFBAP rests solely with the DoD Appointing Authority for a term of service of one-to-four years, with annual renewals, in accordance with DoD policy and procedures. No member, unless approved by the DoD Appointing Authority, may serve more than two consecutive terms of service on the UFBAP or serve on more than two DoD Federal advisory committees at one time. The DoD Appointing Authority shall appoint the UFBAP's leadership from among the membership previously approved to serve on the UFBAP in accordance with DoD policy and procedures for term of service of one-to-two years, with annual renewal, not to exceed the member's approved appointment.

UFBAP members who are not full-time or permanent part-time Federal civilian officers or employees, or active duty members of the Uniformed Services, shall be appointed as experts or consultants pursuant to 5 U.S.C. 3109 to serve as special government employee members. UFBAP members who are full-time or permanent part-time Federal civilian officers or employees, or active duty members of the Uniformed Services, shall be appointed pursuant to 41 CFR 102–3.130(a) to serve as regular government employee members. All members of the UFBAP are appointed to exercise their own best judgment on behalf of the DoD, without representing any particular points of view, and to discuss and deliberate in a manner that is free from conflicts of interest. With the exception of reimbursement of official UFBAP-related travel and per diem, UFBAP members serve without compensation.

The public or interested organizations may submit written statements about the UFBAP's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the UFBAP. All written statements shall be submitted to the DFO for the UFBAP, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: June 30, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–14381 Filed 7–5–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Science and Technology Reinvention Laboratory Personnel Demonstration Project

AGENCY: Office of the Under Secretary of Defense for Research and Engineering (OUSD (R&E)), Department of Defense (DoD).

ACTION: This notice documents an enhanced pay authority for all science and technology reinvention laboratory (STRL) personnel demonstration (demo) projects authorized pursuant to section 4121 of title 10, United States Code (U.S.C.).

SUMMARY: STRLs with published demonstration project plans may implement the enhanced pay authority for positions classified above the GS–15 equivalent level, as described within this notice.

DATES: Implementation will begin no earlier than July 6, 2022.

FOR FURTHER INFORMATION CONTACT:

Department of Defense:

• Office of the Under Secretary of Defense (Research and Engineering), DoD Laboratories, FFRDCs & UARCs Office: Dr. Ben Petro, 571–286–6265, *James.B.Petro.civ@mail.mil.*

Department of the Air Force:

• Air Force Research Laboratory: Ms. Rosalyn Jones-Byrd, 937–656–9747, *Rosalyn.Jones-Byrd@us.af.mil.*

• Joint Warfare Analysis Center: Ms. Amy Balmaz, 540–653–8598, *Amy.T.Balmaz.civ@mail.mil.*

Department of the Army:

• Army Futures Command: Ms. Marlow Richmond, 830–469–2057, *Marlowe.Richmond.civ@army.mil.*

• Army Research Institute for the Behavioral and Social Sciences: Dr. Scott Shadrick, 254–288–3800, *Scottie.B.Shadrick.civ@army.mil.*

• Combat Capabilities Development Command Armaments Center: Mr. Mike Nicotra, 973–724–7764, *Michael.J.Nicotra.civ@mail.mil.*

• Combat Capabilities Development Command Army Research Laboratory: Mr. Christopher Tahaney, 410–278–9069, *Christopher.S.Tahaney.civ@army.mil.*

• Combat Capabilities Development Command Aviation and Missile Center:

Ms. Nancy Salmon, 256–876–9647, *Nancy.C.Salmon2.civ@army.mil.*

- Combat Capabilities Development Command Chemical Biological Center: Ms. Patricia Milwicz, 410–417–2343, *Patricia.L.Milwicz.civ@army.mil.*
- Combat Capabilities Development Command Command, Control, Communications, Computers, Cyber, Intelligence, Surveillance, and Reconnaissance Center: Ms. Angela Clybourn, 443–395–2110, *Angela.M.Clyborn.civ@army.mil.*
- Combat Capabilities Development Command Ground Vehicle Systems Center: Ms. Jennifer Davis, 586–306–4166, *Jennifer.L.Davis1.civ@army.mil.*
- Combat Capabilities Development Command Soldier Center: Ms. Joelle Montecalvo, 508–206–3421, *Joelle.K.Montecalvo.civ@army.mil.*
- Engineer Research and Development Center: Ms. Patricia Sullivan, 601–634–3065, *Patricia.M.Sullivan@usace.army.mil.*
- Medical Research and Development Command: Ms. Linda Krout, 301–619–7276, *Linda.J.Krout.civ@mail.mil.*
- Technical Center, Space and Missile Defense Command: Dr. Chad Marshall, 256–955–5697, *Chad.J.Marshall.civ@army.mil.*

Department of the Navy:

- Naval Air Warfare Center, Weapons Division and Aircraft Division: Mr. Richard Cracraft, 760–939–8115, *Richard.A.Cracraft2.civ@us.navy.mil.*
- Naval Facilities Engineering Command Engineering and Expeditionary Warfare Center: Ms. Lori Leigh, 805–901–5917, *Lori.A.Leigh@us.navy.mil.*
- Naval Information Warfare Centers:
  - Naval Information Warfare Center Atlantic: Mr. Michael Gagnon, 843–218–3871, *Michael.L.Gagnon2.civ@us.navy.mil.*
  - Naval Information Warfare Center Pacific: Ms. Angela Hanson, 619–553–0833, *Angela.Y.Hanson.civ@us.navy.mil.*
- Naval Medical Research Center: Dr. Jill Phan, 301–319–7645, *Jill.C.Phan.civ@mail.mil.*
- Naval Research Laboratory: Ms. Ginger Kisamore, 202–767–3792, *Ginger.Kisamore@nrl.navy.mil.*
- Naval Sea Systems Command Warfare Centers: Ms. Diane Brown, 215–897–1619, *Diane.J.Brown.civ@us.navy.mil.*
- Office of Naval Research: Ms. Margaret J. Mitchell, 703–588–2364, *Margaret.J.Mitchell@navy.mil.*

SUPPLEMENTARY INFORMATION:

1. Background

As authorized by section 4121 of title 10, United States Code (U.S.C.), the Secretary of Defense (SECDEF), through the USD(R&E), may conduct personnel demonstration projects at DoD laboratories designated as STRLs.

STRLs implementing the flexibility described herein must have an approved personnel demonstration project plan published in a **Federal Register** Notice (FRN) and must fulfill any collective bargaining obligations. Each STRL will establish internal operating procedures (IOPs) as appropriate.

The 21 current STRLs are:

- Air Force Research Laboratory
- Joint Warfare Analysis Center
- Army Futures Command
- Army Research Institute for the Behavioral and Social Sciences
- Combat Capabilities Development Command Armaments Center
- Combat Capabilities Development Command Army Research Laboratory
- Combat Capabilities Development Command Aviation and Missile Center
- Combat Capabilities Development Command Chemical Biological Center
- Combat Capabilities Development Command Command, Control, Communications, Computers, Cyber, Intelligence, Surveillance, and Reconnaissance Center
- Combat Capabilities Development Command Ground Vehicle Systems Center
- Combat Capabilities Development Command Soldier Center
- Engineer Research and Development Center
- Medical Research and Development Command
- Technical Center, US Army Space and Missile Defense Command
- Naval Air Systems Command Warfare Centers
- Naval Facilities Engineering Systems Command Engineering and Expeditionary Warfare Center
- Naval Information Warfare Centers, Atlantic and Pacific
- Naval Medical Research Center
- Naval Research Laboratory
- Naval Sea Systems Command Warfare Centers
- Office of Naval Research

2. Overview

I. Introduction

A. Purpose

With the approval of the service acquisition executive of the military department concerned, the STRLs may fill a specified number of positions using an enhanced pay authority in order to assist the military departments in attracting and retaining high-quality acquisition and technology experts in positions responsible for managing and performing complex, high-cost, research and technology development efforts in the STRLs.

B. Required Waivers to Law and Regulation

Pursuant to 10 U.S.C. 4121(a)(3), the Secretary of Defense is not limited by any lack of specific authority under 5 U.S.C., or any inconsistent provision of 5 U.S.C., related to prescribing the method of classifying positions and compensating or incentivizing employees. Pursuant to 10 U.S.C. 4121(a)(5), the pay limitations in 5 U.S.C. 5373, do not apply to the authority of the Secretary to prescribe salary schedules and other related benefits. Waivers and adaptations of any 5 U.S.C., provision and any rule or regulation prescribed under this title are required only to the extent that these statutory and regulatory provisions limit or are inconsistent with the actions authorized herein.

C. Participating Organizations and Employees

All DoD laboratories designated as STRLs by 10 U.S.C. 4121(b), as well as any additional laboratories designated as STRLs by SECDEF, with approved personnel demonstration project plans published in FRNs, may use the provisions described in this FRN.

II. Personnel System Changes

A. Description and Implementation

This authority may be used only to the extent necessary to competitively recruit or retain individuals exceptionally well qualified for positions as described herein. This authority may only be used for a total of 20 STRL positions across all DoD Components at any one time. Each Military Department may use the authority for up to five positions unless the USD(R&E) authorizes its use for additional positions.

The enhanced pay authority may be carried out only with approval of the service acquisition executive of the military department concerned. Implementation, as described herein, may be delegated to the STRL commander/director.

The positions eligible under this authority are positions that:

(a) Require expertise of an extremely high level in a scientific, technical, professional, or acquisition management field; and

(b) Are critical to the successful accomplishment of an important research or technology development mission.

The service acquisition executive of the military department concerned may

approve a rate of basic pay up to 150 percent of the rate of basic pay payable for Level I of the Executive Schedule. Upon approval of the secretary of the military department concerned, the rate of basic pay may be fixed at a rate in excess of 150 percent of the rate of basic pay payable for Level I of the Executive Schedule.

The position classification document will describe the important, regular and recurring duties and responsibilities assigned to the position. Positions classified under this authority are in the competitive service, are above a grade equivalent to GS–15, and are in the AD (administratively determined) pay plan. Classification authority for these positions resides with the STRL Director.

Public notice or other recognized recruitment sources (*e.g.* recruiter/headhunter, STRL website, professional journal publication, etc.) will be used to advertise positions approved for use of this authority. Applicable direct hire authorities may be used to appoint candidates.

Qualified individuals are those individuals who meet the minimum education requirements for the position as published in the Office of Personnel Management (OPM) operating manual, ''Qualification Standards for General Schedule Positions'', and who possess high-level experience managing and performing complex, high-cost research and technology development efforts.

Appointments using this authority will be temporary or term appointments. Temporary appointments are for a period of less than one year. Term appointments are for a period of more than one year and less than five years in duration. The first two years of a new term appointment will serve as the employee's trial period. Individuals appointed under this authority are eligible for employee programs and benefits comparable to those provided to similar employees at each STRL.

An employee appointed to a position using this authority may receive annual and/or merit pay increases, provided the rate of basic pay does not exceed 150 percent of the rate of basic pay payable for Level I of the Executive Schedule or the increased rate of basic pay is approved by the secretary of the military department concerned. Rates of basic pay established under this authority may be adjusted without higher level approval by the same percentage rate authorized in the annual pay adjustment for Level I of the Executive Schedule, as provided in an Executive Order or an act of Congress. Recruitment, relocation and retention incentives may be utilized in order to attract and retain individuals possessing the caliber of experience required of these positions. The aggregate limitation on pay in 5 U.S.C. 5307, is waived to permit payment of allowances, differentials, bonuses, awards or other similar cash payments when such payments would cause the total pay (basic pay and other cash payments) in a calendar year to exceed Level I of the Executive Schedule. Each STRL will document pay setting criteria in internal operating procedures.

Each STRL will develop performance plans to evaluate individuals appointed using this pay authority.

(a) The performance plan will identify performance/contribution factors that identify the successful outcomes of the organization's strategic goals and the position's assigned duties.

(b) The performance plan may provide a means for merit pay increases.

(c) Each STRL will determine the appropriate performance appraisal period under its respective appraisal program for individuals evaluated under this pay authority.

Appointments are documented citing the legal authority code (LAC)/legal authority used to appoint the individual (*e.g.,* STRL direct hire authority) and Z2U/10 U.S.C. 4121. Grade and step are documented as ''00''. Current Federal employees may be converted to a term appointment for up to five years.

B. Evaluation

Procedures for evaluating this authority will be incorporated into the STRL demonstration project evaluation processes conducted by the STRLs, OUSD(R&E), or specific military department headquarters, as appropriate.

C. Reports

STRLs will track and provide information and data on the use of this authority when requested by the Component headquarters or OUSD(R&E).

Dated: June 27, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

APPENDIX A—WAIVERS TO TITLE 5, U.S.C. AND TITLE 5 CFR

Title 5, United States Code	Title 5, Code of Federal Regulations
5 U.S.C. 5303(f)—Annual adjustments to pay schedules. Waived to the extent to allow pay rates as described in this FRN.	
5 U.S.C. 5306(e)—Pay fixed by administrative action. Waived to the extent to allow pay rates as described in this FRN.	
5 U.S.C. 5307—Limitation on certain payments. Waived to the extent to allow payment of allowances, differentials, bonus, awards, or other similar cash payment to cause compensation during calendar year to exceed Level I of the Executive Schedule as described in this FRN.	5 CFR Parts 530.201—203—Aggregate limitation on pay. Waived to the extent to allow payment of allowances, differentials, bonus, awards, or other similar cash payment to cause compensation during calendar year to exceed Level I of the Executive Schedule as described in this FRN.
5 U.S.C. 5376—Pay for Certain senior level positions. Waived to the extent to allow pay rates as described in this FRN.	

APPENDIX B—AUTHORIZED STRLS AND **Federal Register** NOTICES

STRL	**Federal Register** Notice
Air Force Research Laboratory	61 FR 60400 amended by 75 FR 53076.
Joint Warfare Analysis Center	85 FR 29414.
Army Futures Command	Not yet published.
Army Research Institute for Behavioral and Social Sciences	85 FR 76038.
Combat Capabilities Development Command Armaments Center	76 FR 3744.
Combat Capabilities Development Command Army Research Laboratory.	63 FR 10680.

APPENDIX B—AUTHORIZED STRLS AND **Federal Register** NOTICES—Continued

STRL	**Federal Register** Notice
Combat Capabilities Development Command Aviation and Missile Center.	62 FR 34906 and 62 FR 34876 amended by 65 FR 53142 (AVRDEC and AMRDEC merged together).
Combat Capabilities Development Command Chemical Biological Center.	74 FR 68936.
Command, Control, Communications, Cyber, Intelligence, Surveillance, and Reconnaissance Center.	66 FR 54872.
Combat Capabilities Development Command Ground Vehicle Systems Center.	76 FR 12508.
Combat Capabilities Development Command Soldier Center	74 FR 68448.
Engineer Research and Development Center	63 FR 14580 amended by 65 FR 32135.
Medical Research and Development Command	63 FR 10440.
Technical Center, US Army Space and Missile Defense Command	85 FR 3339.
Naval Air Systems Command Warfare Centers	76 FR 8530.
Naval Facilities Engineering Command Systems Engineering and Expeditionary Warfare Center.	86 FR 14084.
Naval Information Warfare Centers, Atlantic and Pacific	76 FR 1924.
Naval Medical Research Center	Not yet published.
Naval Research Laboratory	64 FR 33970.
Naval Sea Systems Command Warfare Centers	62 FR 64050.
Office of Naval Research	75 FR 77380.

[FR Doc. 2022–14308 Filed 7–5–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

National Committee on Foreign Medical Education and Accreditation

AGENCY: National Committee on Foreign Medical Education and Accreditation (NCFMEA), U.S. Department of Education.

ACTION: Request for nominations for appointment to serve on the National Committee on Foreign Medical Education and Accreditation (NCFMEA).

SUMMARY: Secretary of Education Miguel A. Cardona is seeking nomination(s) of medical experts for appointment of members to fill three NCFMEA member positions with a term of service due to expire on September 30, 2022.

DATES: Nominations must be received no later than Friday, August 5, 2022.

SUPPLEMENTARY INFORMATION: NCFMEA's Statutory Authority and Function: The NCFMEA is authorized per Section 102 of the Higher Education Act of 1965, as amended. The Secretary of Education is required by the Higher Education Act, as amended, to establish a panel of medical experts who shall: evaluate the standards of accreditation applied to foreign medical schools; and determine the comparability of those standards to standards for accreditation applied to United States medical schools. The NCFMEA shall be comprised of 11 voting members each appointed for a term of service as determined by the Secretary of Education. Due consideration shall be given to the appointment of individuals who are broadly knowledgeable about foreign medical education and accreditation and respected in the educational community. Per the authorizing legislation for the Committee, one currently serving member of the NCFMEA, is a medical student enrolled in an accredited medical school at the time of appointment by the Secretary of Education.

Any member appointed to fill a vacancy for a term of service not completed will serve for the remainder of the term of service of her/his predecessor. No member may serve for a period in excess of three consecutive terms. Members of the Committee will serve as Special Government Employees (SGEs), as defined in 18 U.S.C. 202(a). As SGEs, members are selected for their individual expertise, integrity, impartiality, and experience.

Nomination Process: Interested persons, stakeholders, or organizations (including individuals seeking reappointment by the Secretary of Education to serve on the NCFMEA) may nominate a qualified medical expert(s). To submit a nomination(s) or self-nominate for appointment to serve on the NCFMEA, please send a cover letter addressed to the Secretary of Education as follows: Honorable Miguel A. Cardona, Ed.D., Secretary of Education, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. In the letter, please note your reason(s) for submitting the nomination. Include a copy of the nominee's current resume/cv and contact information (mailing address, email address, and contact phone number). In addition, the cover letter must include a statement affirming the nominee (if you are nominating someone other than yourself) has agreed to be nominated and is willing to serve on the NCFMEA if appointed by the Secretary of Education. Please submit your nomination(s) including the requested attachments to the U.S. Department of Education, Office of the Secretary, Committee Management via email to: *cmtemgmtoffice@ed.gov* . (Please specify in the email subject line ''NCFMEA Nomination'').

For questions, please contact Karen Akins, U.S. Department of Education, Committee Management Officer, Office of the Secretary, via email at *Karen.Akins@ed.gov* .

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site, you can view this document, as well as all other documents of this Department published in the **Federal Register**.

Miguel A. Cardona,

Secretary of Education.

[FR Doc. 2022–14302 Filed 7–5–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF EDUCATION

Application for New Awards; Expanding Opportunity Through Quality Charter Schools Program (CSP)—Grants to State Entities (State Entity)

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

ACTION: Notice.

SUMMARY: The Department of Education is issuing a notice inviting applications for fiscal year (FY) 2022 for CSP Grants to State Entities, Assistance Listing Number (ALN) number 84.282A.

DATES:

Applications Available: July 6, 2022.

Deadline for Transmittal of Applications: August 5, 2022.

Deadline for Intergovernmental Review: September 6, 2022.

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 December 27, 2021 (86 FR 73264), and available at *www.federalregister.gov/d/2021-27979.* Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov*, a Data Universal Numbering System (DUNS) number, to the implementation of the Unique Entity Identifier (UEI). More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

FOR FURTHER INFORMATION CONTACT: Jill Gaitens, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–5970. Telephone: (202) 205–1224. Email: *FY2022_SE_Competition@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The CSP State Entity program, ALN 84.282A, is authorized under Title IV, Part C of the Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (ESEA) (20 U.S.C. 7221–7221j). Through the CSP State Entity competition, the Department awards grants to State entities that, in turn, award subgrants to eligible applicants for the purpose of opening new charter schools and replicating and expanding high-quality charter schools. State entities also may use grant funds to provide technical assistance to eligible applicants and authorized public chartering agencies in opening new charter schools and replicating and expanding high-quality charter schools, and to work with authorized public chartering agencies in the State to improve authorizing quality, including developing capacity for, and conducting, fiscal oversight and auditing of charter schools. State Entity grant funds may also be used for grant administration, which may include technical assistance and monitoring of subgrants for performance and fiscal and regulatory compliance, as required under 2 CFR 200.332(d).

The CSP State Entity program provides financial assistance to State entities to support charter schools that serve elementary and secondary school students in a given State. Charter schools receiving funds under the CSP State Entity program also may serve students in early childhood education programs or postsecondary students.

Background: The major purposes of the CSP are to expand opportunities for all students, particularly traditionally underserved students, to attend public charter schools and meet challenging State academic standards; provide financial assistance for the planning, program design, and initial implementation of charter schools; increase the number of high-quality charter schools available to students across the United States; evaluate the impact of charter schools on student achievement, families, and communities; share best practices between charter schools and other public schools; encourage States to provide facilities support to charter schools; and support efforts to strengthen the charter school authorizing process.

We have published elsewhere in this issue of the **Federal Register** a notice of final priorities, requirements, definitions, and selection criteria (2022 NFP) for use in this and future State Entity program competitions. The 2022 NFP supplements the program statute and is intended to help ensure the creation, replication, and expansion of high-quality charter schools that promote positive student outcomes, educator and community empowerment, and promising practices; and to promote school diversity. We also seek to promote greater fiscal and operational transparency and accountability for CSP-funded charter schools. In addition, and based on our experiences administering the CSP, we believe the application requirements and assurances associated with subgrant monitoring and the review of subgrant applications will help facilitate the proper peer review and evaluation of CSP grant applications. The priorities, application requirements, assurances, selection criteria, and definitions in this notice are designed to increase access to high-quality, diverse, and equitable learning opportunities in their communities, which should be a goal of all public schools.

Priorities: This notice includes one absolute priority, five competitive preference priorities, and one invitational priority. In accordance with 34 CFR 75.105(b)(2)(ii), the absolute priority and competitive preference priorities 1–5 are from section 4303(g)(2) of the ESEA (20 U.S.C. 7221b(g)(2)).

Absolute Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet the absolute priority.

This priority is:

Best Practices for Charter School Authorizers.

To meet this priority, an applicant must demonstrate that the State entity has taken steps to ensure that all authorized public chartering agencies implement best practices for charter school authorizing.

Competitive Preference Priorities: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award 1 additional point to an application that meets Competitive Preference Priority 1; 2 additional points to an application that meets Competitive Preference Priority 2; 1 additional point to an application that meets Competitive Preference Priority 3; up to 3 additional points to an application that meets Competitive Preference Priority 4; and up to 3 additional points to an application that meets Competitive Preference Priority 5.

Applicants must identify on the abstract form and in the project narrative section of its application the priority or priorities it wishes the Department to consider for purposes of earning the competitive preference priority points. The Department will not review or award points for any

competitive preference priority for an application that fails to clearly identify the competitive preference priority or priorities it wishes the Department to consider for purposes of earning the competitive preference priority points. An application may receive a total of up to 10 additional points under the competitive preference priorities.

These priorities are:

Competitive Preference Priority 1—At Least One Authorized Public Chartering Agency Other than a Local Educational Agency, or an Appeals Process (0 or 1 points).

To meet this priority, an applicant must demonstrate that it is located in a State that—

(a) Allows at least one entity that is not a local educational agency (LEA) to be an authorized public chartering agency for developers seeking to open a charter school in the State; or

(b) In the case of a State in which LEAs are the only authorized public chartering agencies, the State has an appeals process for the denial of an application for a charter school.

Competitive Preference Priority 2—Equitable Financing (Up to 2 points).

To be eligible to receive points under this priority, an applicant must demonstrate the extent to which the State in which the State entity is located ensures equitable financing, as compared to traditional public schools, for charter schools and students in a prompt manner.

Competitive Preference Priority 3—Best Practices to Improve Struggling Schools and LEAs (0 or 1 point).

To meet this priority, an applicant must demonstrate that the State entity is located in a State that uses best practices from charter schools to help improve struggling schools and LEAs.

Competitive Preference Priority 4—Charter School Facilities (up to 3 points).

To be eligible to receive points under this priority, an applicant must demonstrate the extent to which the State in which the State entity is located provides charter schools one or more of the following:

(a) Funding for facilities.

(b) Assistance with facilities acquisition.

(c) Access to public facilities.

(d) The ability to share in bonds or mill levies.

(e) The right of first refusal to purchase public school buildings.

(f) Low- or no-cost leasing privileges.

Competitive Preference Priority 5—Serving At-Risk Students (up to 3 points).

To be eligible to receive points under this priority, an applicant must demonstrate the extent to which the State entity supports charter schools that serve at-risk students through activities such as dropout prevention, dropout recovery, or comprehensive career counseling services.

Invitational Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority any preference over other applications.

This priority is:

Invitational Priority—Collaborations between Charter Schools and Traditional Public Schools or Districts that Benefit Students and Families across Schools.

(a) The Secretary is particularly interested in funding applications that propose to encourage, but not require, eligible applicants to propose projects that include a new collaboration, or the continuation of an existing collaboration, with at least one traditional public school or traditional school district that is designed to benefit students or families served by at least one member of the collaboration, is designed to lead to increased and improved educational opportunities for students served by at least one member of the collaboration, and includes implementation of one or more of the following—

(1) Co-developed or shared curricular and instructional resources or academic course offerings.

(2) Professional development opportunities for teachers and other educators, which may include professional learning communities, opportunities for teachers to earn additional certifications, such as in a high-need area or national board certification, and partnerships with educator preparation programs to support teaching residencies.

(3) Evidence-based (as defined in section 8101(21) of the ESEA) practices to improve academic performance for underserved students.

(4) Policies and practices to create safe, supportive, and inclusive learning environments, such as systems of positive behavioral intervention and support.

(5) Transparent enrollment and retention practices and processes that include clear and consistent disclosure to families of policies or requirements (*e.g.,* discipline policies, purchasing and wearing specific uniforms and other fees, or family participation), and any services that are or are not provided that could impact a family's ability to enroll or remain enrolled (*e.g.,* transportation services or participation in the National School Lunch Program).

(6) A shared transportation plan and system that reduces transportation costs for members of the collaboration and takes into consideration various transportation options, including public transportation and district-provided or shared transportation options, cost-sharing or free or reduced-cost fare options, and any distance considerations for prioritized bus services.

(7) A shared special education collaborative designed to address a significant barrier or challenge faced by participating charter schools and traditional public schools in improving academic or developmental outcomes and services for students with disabilities (as defined in section 8101 of the ESEA);

(8) A shared English learner collaborative designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in improving academic outcomes for English learners (as defined in section 8101 of the ESEA); or

(9) Other collaborations, such as the sharing of innovative and best practices, designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools and designed to improve academic outcomes for all students served by members of the collaboration.

(b) The State entity certifies that it will ask each eligible applicant that proposes a project that includes such a collaboration to—

(1) Provide in its subgrant application a description of the collaboration that—

(i) Describes each member of the collaboration and whether the collaboration would be a new or existing commitment;

(ii) States the purpose and duration of the collaboration;

(iii) Describes the anticipated roles and responsibilities of each member of the collaboration;

(iv) Describes how the collaboration will benefit one or more members of the collaboration, including how it will benefit students or families affiliated with a member and lead to increased or improved educational opportunities for students, and meet specific and measurable, if applicable, goals;

(vi) Describes the resources members of the collaboration will contribute; and

(vii) Contains any other relevant information; and

(2) Within 120 days of receiving a subgrant award or within 120 days of the date the collaboration is scheduled

to begin, whichever is later, provide evidence of participation in the collaboration (which may include, but is not required to include, an MOU).

Application Requirements:

These application requirements are from section 4303(f) of the ESEA (20 U.S.C. 7221b(f)) and from the 2022 NFP. The Department will not fund an application that does not meet each application requirement.

In addressing the application requirements, applicants must clearly identify which application requirement they are addressing. An applicant must address requirements (a)(1)(i), (a)(1)(vii), (a)(1)(ix), (a)(2)(ii), and (a)(2)(iii) in its response to paragraph (a)(1) of the Quality of the Project Design selection criterion; requirement (a)(8) in its response to paragraph (a)(4) of the Quality of the Project Design selection criterion; requirements (a)(1)(ii), (a)(1)(xiii), (a)(3)(i), (a)(3)(ii), (a)(3)(iii), (a)(5), and (a)(7) in its response to the Quality of Eligible Subgrant Applicants selection criterion; requirements (a)(1)(vi), (a)(1)(x), and (a)(9) in its response to paragraph (c)(1) of the State Plan selection criterion; requirements (a)(1)(iii), (a)(1)(iv), (a)(1)(viii), and (a)(1)(xi) in its response to paragraph (c)(3) of the State Plan selection criterion; and requirement (a)(4) in its response to paragraph (d)(1) of the Quality of the Management Plan selection criterion. An applicant must respond to the application requirements in paragraph (a) that are not listed above in the Project Narrative.

Applications for funding under the CSP State Entity program must contain the following:

(a) Description of Program—A description of the State entity's objectives in running a quality charter school program and how the objectives of the program will be carried out, including—

(1) A description of how the State entity will—

(i) Support the opening of charter schools through the startup of new charter schools and, if applicable, the replication of high-quality charter schools, and the expansion of high-quality charter schools (including the proposed number of new charter schools to be opened, high-quality charter schools to be opened as a result of the replication of a high-quality charter school, or high-quality charter schools to be expanded under the State entity's program) (4303(f));

(ii) Inform eligible charter schools, developers, and authorized public chartering agencies of the availability of funds under the program (4303(f));

(iii) Work with eligible applicants to ensure that the eligible applicants access all Federal funds that such applicants are eligible to receive, and help the charter schools supported by the applicants and the students attending those charter schools—

(A) Participate in the Federal programs in which the schools and students are eligible to participate;

(B) Receive the commensurate share of Federal funds the schools and students are eligible to receive under such programs; and

(C) Meet the needs of students served under such programs, including students with disabilities and English learners (4303(f));

(iv) Ensure that authorized public chartering agencies, in collaboration with surrounding LEAs where applicable, establish clear plans and procedures to assist students enrolled in a charter school that closes or loses its charter to attend other high-quality schools (4303(f));

(v) In the case of a State entity that is not a State educational agency (SEA)—

(A) Work with the SEA and charter schools in the State to maximize charter school participation in Federal and State programs for which charter schools are eligible; and

(B) Work with the SEA to operate the State entity's program under section 4303 of the ESEA, if applicable (4303(f));

(vi) Ensure that each eligible applicant that receives a subgrant under the State entity's program—

(A) Is using funds provided under this program for one of the activities described in section 4303(b)(1) of the ESEA; and

(B) Is prepared to continue to operate charter schools funded under section 4303 of the ESEA in a manner consistent with the eligible applicant's application for such subgrant once the subgrant funds under this program are no longer available (4303(f));

(vii) Support—

(A) Charter schools in LEAs with a significant number of schools identified by the State for comprehensive support and improvement under section 1111(c)(4)(D)(i) of the ESEA; and

(B) The use of charter schools to improve struggling schools, or to turn around struggling schools (4303(f));

(viii) Work with charter schools on—

(A) Recruitment and enrollment practices to promote inclusion of all students, including by eliminating any barriers to enrollment for educationally disadvantaged students (who include foster youth and unaccompanied homeless youth); and

(B) Supporting all students once they are enrolled to promote retention, including by reducing the overuse of discipline practices that remove students from the classroom (4303(f));

(ix) Share best and promising practices between charter schools and other public schools (4303(f));

(x) Ensure that charter schools receiving funds under the State entity's program meet the educational needs of their students, including children with disabilities and English learners (4303(f));

(xi) Support efforts to increase charter school quality initiatives, including meeting the quality authorizing elements described in section 4303(f)(2)(E) of the ESEA (4303(f));

(xii)(A) In the case of a State entity that is not a charter school support organization, a description of how the State entity will provide oversight of authorizing activity, including how the State will help ensure better authorizing, such as by establishing authorizing standards that may include approving, monitoring, and re-approving or revoking the authority of an authorized public chartering agency based on the performance of the charter schools authorized by such agency in the areas of student achievement, student safety, financial and operational management, and compliance with all applicable statutes and regulations; and

(B) In the case of a State entity that is a charter school support organization, a description of how the State entity will work with the State to support the State's system of technical assistance and oversight, as described in paragraph (xii)(A), of the authorizing activity of authorized public chartering agencies (4303(f)); and

(xiii) Work with eligible applicants receiving a subgrant under the State entity's program to support the opening of new charter schools or charter school models described in application requirement (a)(1)(i) that are high schools (4303(f));

(2) A description of the extent to which the State entity—

(i) Is able to meet and carry out Competitive Preference Priorities 1 through 5; [1]

(ii) Is working to develop or strengthen a cohesive statewide system to support the opening of new charter

[1] In accordance with 34 CFR 105(c)(2)(i), applications are not required to address competitive preference priorities but may receive additional points if they do so. However, to meet this application requirement, the *State entity* must describe the extent to which it is able to meet and carry out competitive preference priorities 1 through 5. If the *State entity* is unable to meet and carry out one or more of these competitive preference priorities, the description for that priority should state that the *State entity* is unable to meet or carry out the priority.

schools and, if applicable, the replication of high-quality charter schools, and the expansion of high-quality charter schools; and

(iii) Is working to develop or strengthen a cohesive strategy to encourage collaboration between charter schools and LEAs on the sharing of best practices (4303(f));

(3) A description of how the State entity will award subgrants, on a competitive basis, including—

(i) A detailed description of how the State entity will review applications from eligible applicants, including—

(A) How eligibility will be determined;

(B) How peer reviewers will be recruited and selected, including efforts the applicant will make to recruit peer reviewers from diverse backgrounds and underrepresented groups;

(C) How subgrant applications will be reviewed and evaluated;

(D) How cost analyses and budget reviews will be conducted to ensure that costs are necessary, reasonable, and allocable to the subgrant;

(E) How applicants will be assessed for risk (*i.e.,* fiscal, programmatic, compliance); and

(F) How funding decisions will be made (2022 NFP);

(ii) A description of the application each eligible applicant desiring to receive a subgrant will be required to submit, which application must include the following:

(A) A description of the roles and responsibilities of eligible applicants, partner organizations, and charter management organizations (CMO), including the administrative and contractual roles and responsibilities of such partners (4303(f));

(*1*) For any existing or proposed contract between a charter and a for-profit management organization (including a nonprofit management organization operated by or on behalf of a for-profit entity), without regard to whether the management organization or its related entities exercises full or substantial administrative control over the charter school or the CSP project, the applicant must provide the following information or equivalent information that the applicant has submitted to the authorized public chartering agency—

(*A*) A copy of the existing contract with the for-profit management organization or a description of the terms of the contract, including the name and contact information of the management organization; the cost (*i.e.,* fixed costs and estimates of any ongoing costs or fees), including the amount of CSP funds proposed to be used toward such cost, and the percentage such cost represents of the school's overall funding; the duration; roles and responsibilities of the management organization; and steps the applicant will take to ensure that it pays fair market value for any services or other items purchased or leased from the management organization, makes all programmatic decisions, maintains control over all CSP funds, and directly administers or supervises the administration of the grant in accordance with 34 CFR 75.701;

(*B*) A description of any business or financial relationship between the charter school developer and the management organization, including payments, contract terms, and any property owned, operated, or controlled by the management organization or related individuals or entities that will be used by the charter school;

(*C*) The name and contact information for each member of the governing board of the charter school and a list of the management organization's officers, chief administrator, or other administrators, and any staff involved in approving or executing the management contract; and a description of any actual or perceived conflicts of interest, including financial interests, and how the applicant will resolve any actual or perceived conflicts of interest to ensure compliance with 2 CFR 200.318(c);

(*D*) A description of how the applicant will ensure that members of the governing board of the charter school are not selected, removed, controlled, or employed by the management organization and that the charter school's legal, accounting, and auditing services will be procured independently from the management organization;

(*E*) An explanation of how the applicant will ensure that the management contract is severable, severing the management contract will not cause the proposed charter school to close, the duration of the management contract will not extend beyond the expiration date of the school's charter, and renewal of the management contract will not occur without approval and affirmative action by the governing board of the charter school; and

(*F*) A description of the steps the applicant will take to ensure that it maintains control over all student records and has a process in place to provide those records to another public school or school district in a timely manner upon the transfer of a student from the charter school to another public school, including due to closure of the charter school, in accordance with section 4308 of the ESEA (2022 NFP).

(B) A description of the quality controls agreed to between the eligible applicant and the authorized public chartering agency involved, such as a contract or performance agreement, how a school's performance in the State's accountability system and impact on student achievement (which may include student academic growth) will be one of the most important factors for renewal or revocation of the school's charter, and how the State entity and the authorized public chartering agency involved will reserve the right to revoke or not renew a school's charter based on financial, structural, or operational factors involving the management of the school (4303(f));

(C) A description of how the autonomy and flexibility granted to a charter school is consistent with the definition of charter school in section 4310 of the ESEA (4303(f));

(D) A description of how the eligible applicant will solicit and consider input from parents and other members of the community on the implementation and operation of each charter school that will receive funds under the State entity's program (4303(f));

(E) A description of the eligible applicant's planned activities and expenditures of subgrant funds to support opening and preparing for the operation of new charter schools, opening and preparing for the operation of replicated high-quality charter schools, or expanding high-quality charter schools, and how the eligible applicant will maintain financial sustainability after the end of the subgrant period (4303(f));

(F) A description of how the eligible applicant will support the use of effective parent, family, and community engagement strategies to operate each charter school that will receive funds under the State entity's program (4303(f)); and

(G) A needs analysis and description of the need for the proposed project, including how the proposed project would serve the interests and meet the needs of students and families in the communities the charter school intends to serve. The needs analysis, which may consist of information and documents previously submitted to an authorized public chartering agency to address need, must include, but is not necessarily limited to, the following:

(*1*) Descriptions of the local community support, including information that demonstrates interest in, and need for, the charter school; benefits to the community; and other evidence of demand for the charter

school that demonstrates a strong likelihood the charter school will achieve and maintain its enrollment projections. Such information may include information on waiting lists for the proposed charter school or existing charter schools or traditional public schools; data on access to seats in high-quality public schools in the districts from which the charter school expects to draw students; and family interest in specialized instructional approaches proposed to be implemented at the charter school.

(*2*) Information on the proposed charter school's projected student enrollment, and evidence to support the projected enrollment based on the needs analysis and other relevant data and factors, such as the methodology and calculations used.

(*3*) An analysis of the proposed charter school's projected student demographics and a description of the demographics of students attending public schools in the local community in which the charter school would be located and the school districts from which the students are, or would be, drawn to attend the charter school; a description of how the applicant plans to establish and maintain a racially and socio-economically diverse student body, including proposed strategies (that are consistent with applicable legal requirements) to recruit, admit, enroll, and retain a diverse student body. An applicant that is unlikely to establish and maintain a racially and socio-economically diverse student body at the proposed charter school because the charter school would be located in a racially or socio-economically segregated or isolated community, or due to the charter school's specific education mission, must describe—

(*A*) Why it is unlikely to be able to establish and maintain a racially and socio-economically diverse student body at the proposed charter school;

(*B*) How the anticipated racial and socio-economic makeup of the student body would promote the purposes of the CSP to provide high-quality educational opportunities to all students, which may include a specialized educational program or mission; and

(*C*) The anticipated impact of the proposed charter school on the racial and socio-economic diversity of the public schools and school districts from which students would be drawn to attend the charter school.

(*4*) A robust family and community engagement plan designed to ensure the active participation of families and the community that includes the following:

(*A*) How families and the community were, are, or will be engaged in determining the vision and design for the charter school, including specific examples of how families' and the community's input was, is, or is expected to be incorporated into the vision and design for the charter school.

(*B*) How the charter school will meaningfully engage with both families and the community to create strong and ongoing partnerships.

(*C*) How the charter school will foster a collaborative culture that involves the families of all students, including underserved students, in ensuring their ongoing input in school decision-making.

(*D*) How the charter school's recruitment, admissions, enrollment, and retention processes will engage and accommodate families from various backgrounds, including English learners, students with disabilities, and students of color, including by holding enrollment and recruitment events on weekends or during non-standard work hours, making interpreters available, and providing enrollment and recruitment information in widely accessible formats (*e.g.,* hard copy and online in multiple languages; as appropriate, large print or braille for visually-impaired individuals) through widely available and transparent means (*e.g.,* online and at community locations).

(*E*) How the charter school has engaged or will engage families and the community to develop an instructional model to best serve the targeted student population and their families, including students with disabilities and English learners.

(*5*) How the plans for the operation of the charter school will support and reflect the needs of students and families in the community, including consideration of district or community assets and how the school's location, or anticipated location if a facility has not been secured, will facilitate access for the targeted student population (*e.g.,* access to public transportation or other transportation options, the demographics of neighborhoods within walking distance of the school, and transportation plans and costs for students who are not able to walk or use public transportation to access the school).

(*6*) A description of the steps the applicant has taken or will take to ensure that the proposed charter school (*A)* would not hamper, delay, or negatively affect any desegregation efforts in the community in which the charter school would be located and the public school districts from which students are, or would be, drawn to attend the charter school, including efforts to comply with a court order, statutory obligation, or voluntary efforts to create and maintain desegregated public schools; and (*B*) to ensure that the proposed charter school would not otherwise increase racial or socio-economic segregation or isolation in the schools from which the students are, or would be, drawn to attend the charter school. (2022 NFP).

(iii)(A) A description of how the State entity, in awarding subgrants to eligible applicants, will give priority to eligible applicants that propose projects that include the creation, replication, or expansion of a high-quality charter school that is developed and implemented—

(*1*) With meaningful and ongoing engagement with current or former teachers and other educators; and

(*2*) Using a community-centered approach that includes an assessment of community assets, informs the development of the charter school, and includes the implementation of protocols and practices designed to ensure that the charter school will use and interact with community assets on an ongoing basis to create and maintain strong community ties.

(B) In its application, an applicant must provide a high-quality plan that demonstrates how its proposed project would meet the requirements in paragraph (iii)(A) of the Promoting High-Quality Educator- and Community-Centered Charter Schools to Support Underserved Students priority, accompanied by a timeline for key milestones that span the course of planning, development, and implementation of the charter school.

(4) In the case of a State entity that partners with an outside organization to carry out the State entity's quality charter school program, in whole or in part, a description of the roles and responsibilities of the partner (4303(f));

(5) A description of how the State entity will ensure that each charter school receiving funds under the State entity's program has considered and planned for the transportation needs of the school's students (4303(f));

(6) A description of how the State in which the State entity is located addresses charter schools in the State's open meetings and open records laws (4303(f));

(7) A description of how the State entity will support diverse charter school models, including models that serve rural communities (4303(f));

(8) Evidence to support the requested funds and projected enrollment, such as explanations regarding the methodology and calculations (2022 NFP); and

(9) A description, including a timeline, of how the State entity will monitor and report on subgrant performance in accordance with 2 CFR 200.329, and address and mitigate subgrantee risk, including—

(i) How subgrantees will be selected for in-depth monitoring, including factors that indicate higher risk (*e.g.,* charter schools that have management contracts with for-profit EMOs, virtual charter schools, and charter schools with a history of poor performance);

(ii) How identified subgrantee risk will be addressed;

(iii) How subgrantee expenditures will be monitored;

(iv) How monitors will be trained;

(v) How monitoring findings will be shared with subgrantees;

(vi) How corrective action plans will be used to resolve monitoring findings;

(vii) How the State entity will ensure transparency so that monitoring findings and corrective action plans are available to families and the public; and

(viii) How the State entity will work with authorized public chartering agencies to share information regarding the monitoring of subgrantees, including in areas related to fiscal protocols and organizational governance, for the purpose of reducing the reporting burden on charter schools (2022 NFP).

(b) Assurances—Assurances by the State entity that—

(1) Each charter school receiving funds through the State entity's program will have a high degree of autonomy over budget and operations, including autonomy over personnel decisions (4303(f));

(2) The State entity will support charter schools in meeting the educational needs of their students, including children with disabilities and English learners (4303(f));

(3) The State entity will ensure that the authorized public chartering agency of any charter school that receives funds under the State entity's program adequately monitors each charter school under the authority of such agency in recruiting, enrolling, retaining, and meeting the needs of all students, including children with disabilities and English learners (4303(f));

(4) The State entity will provide adequate technical assistance to eligible applicants to meet the objectives described in application requirement (a)(1)(8) (4303(f));

(5) The State entity will promote quality authorizing, consistent with State law, such as through providing technical assistance to support each authorized public chartering agency in the State to improve such agency's ability to monitor the charter schools authorized by the agency, including by—

(i) Assessing annual performance data of the schools, including, as appropriate, graduation rates, student academic growth, and rates of student attrition;

(ii) Reviewing the schools' independent, annual audits of financial statements prepared in accordance with generally accepted accounting principles and ensuring that any such audits are publicly reported; and

(iii) Holding charter schools accountable to the academic, financial, and operational quality controls agreed to between the charter school and the authorized public chartering agency involved, such as renewal, non-renewal, or revocation of the school's charter (4303(f));

(6) The State entity will work to ensure that charter schools are included with the traditional public schools in decision-making about the public school system in the State (4303(f));

(7) The State entity will ensure that each charter school receiving funds under the State entity's program makes publicly available, consistent with the dissemination requirements of the annual State report card under section 1111(h) of the ESEA, including on the website of the school, information to help parents make informed decisions about the education options available to their children, including—

(i) Information on the educational program;

(ii) Student support services;

(iii) Parent contract requirements (as applicable), including any financial obligations or fees;

(iv) Enrollment criteria (as applicable); and

(v) Annual performance and enrollment data for each of the subgroups of students, as defined in section 1111(c)(2) of the ESEA, except that such disaggregation of performance and enrollment data shall not be required in a case in which the number of students in a group is insufficient to yield statistically reliable information or the results would reveal personally identifiable information about an individual student (4303(f)).

(8) The State Entity will ensure that each charter school receiving CSP funding has not and will not enter into a contract with a for-profit management organization, including a nonprofit management organization operated by or on behalf of a for-profit entity, under which the management organization, or its related entities, exercises full or substantial administrative control over the charter school and, thereby, the CSP project (2022 NFP).

(9) Each charter school receiving CSP funding will provide an assurance that any management contract between the charter school and a for-profit management organization, including a nonprofit CMO operated by or on behalf of a for-profit entity, guarantees or will guarantee that—

(i) The charter school maintains control over all CSP funds, makes all programmatic decisions, and directly administers or supervises the administration of the subgrant;

(ii) The management organization does not exercise full or substantial administrative control over the charter school (and, thereby, the CSP project), except that this does not limit the ability of a charter school to enter into a contract with a management organization for the provision of services that do not constitute full or substantial control of the charter school project funded under the CSP (*e.g.,* food services or payroll services) and that otherwise comply with statutory and regulatory requirements;

(iii) The charter school's governing board has access to financial and other data pertaining to the charter school, the management organization, and any related entities; and

(iv) The charter school is in compliance with applicable Federal and State laws and regulations governing conflicts of interest, and there are no actual or perceived conflicts of interest between the charter school and the management organization (2022 NFP).

(10) Each charter school receiving CSP funding will post on its website, on an annual basis, a copy of any management contract between the charter school and a for-profit management organization, including a nonprofit management organization operated by or on behalf of a for-profit entity, and report information on such contract to the State entity, including—

(i) A copy of the existing contract with the for-profit organization or a detailed description of the terms of the contract, including the name and contact information of the management organization, the cost (*i.e.,* fixed costs and estimates of any ongoing cost), including the amount of CSP funds proposed to be used toward such cost, and the percentage such cost represents of the charter school's total funding, the duration, roles and responsibilities of the management organization, and the steps the charter school is taking to ensure that it makes all programmatic decisions, maintains control over all CSP funds, and directly administers or supervises the administration of the grant or subgrant in accordance with 34 CFR 76.701;

(ii) A description of any business or financial relationship between the charter school developer or CMO and the management organization, including payments, contract terms, and any property owned, operated, or controlled by the management organization or related individuals or entities to be used by the charter school;

(iii) The names and contact information for each member of the governing boards of the charter school and a list of management organization's officers, chief administrator, and other administrators, and any staff involved in approving or executing the management contract; and a description of any actual or perceived conflicts of interest, including financial interests, and how the applicant resolved or will resolve any actual or perceived conflicts of interest to ensure compliance with 2 CFR 200.318(c); and

(iv) A description of how the charter school ensured that such contract is severable and that a change in management companies will not cause the proposed charter school to close (2022 NFP).

(11) Each charter school receiving CSP funding will disclose, as part of the enrollment process, any policies and requirements (*e.g.,* purchasing and wearing specific uniforms and other fees, or requirements for family participation), and any services that are or are not provided, that could impact a family's ability to enroll or remain enrolled in the school (*e.g.,* transportation services or participation in the National School Lunch Program) (2022 NFP).

(12) Each charter school receiving CSP funding will hold or participate in a public hearing in the local community in which the proposed charter school would be located to obtain information and feedback regarding the potential benefit of the charter school, which shall at least include information about how the proposed charter school will increase the availability of high-quality public school options for underserved students, promote racial and socio-economic diversity in such community or have an educational mission to serve primarily underserved students, and not increase racial or socio-economic segregation or isolation in the school districts from which students would be drawn to attend the charter school (consistent with applicable laws). Applicants must ensure that the hearing (and notice thereof) is accessible to individuals with disabilities and limited English proficient individuals as required by law, actively solicit participation in the hearing (*i.e.,* provide widespread and timely notice of the hearing), make good faith efforts to accommodate as many people as possible (*e.g.,* hold the hearing at a convenient time for families or provide virtual participation options), and submit a summary of the comments received as part of the application. The hearing may be conducted as part of the charter authorizing process, provided that it meets the requirements above. (2022 NFP)

(13) No eligible applicant receiving funds under the State entity's program will use implementation funds for a charter school until after the charter school has received a charter from an authorized public chartering agency and has a contract, lease, mortgage, or other documentation indicating that it has a facility in which to operate. Consistent with sections 4303(b)(1), 4303(h)(1)(B), and 4310(6) of the ESEA, an eligible applicant may use CSP planning funds for post-award planning and design of the educational program of a proposed new or replicated high-quality charter school that has not yet opened, which may include hiring and compensating teachers, school leaders, and specialized instructional support personnel; providing training and professional development to staff; and other critical planning activities that need to occur prior to the charter school opening when such costs cannot be met from other sources. (2022 NFP)

Note: The Department recognizes that the charter approval process may exceed the 18-month planning period for CSP grants and subgrants, as prescribed under section 4303(d)(1)(B) of the ESEA. In such a case, applicants may request approval from the State entity to amend their application to request an extension of the 18-month planning period. Under section 4303(d)(5) of the ESEA, the Secretary, in his discretion, may waive any statutory or regulatory requirement over which he exercises administrative authority, except the requirements related to the definition of ''charter school'' in section 4310(2), provided that the waiver is requested in an approved application and the Secretary determines that granting the waiver will promote the purposes of the CSP. It is also worth noting that a subgrantee may request approval from the State entity to amend its approved application and budget to cover additional planning costs that it may incur due to an unexpected delay in the charter approval process.

(14) Within 120 days of the date of any subgrant award notifications, the grantee will post on its website:

(i) A list of the charter schools slated to receive CSP funds, including the following for each school:

(A) The name, address, and grades served.

(B) A description of the education model.

(C) If the charter school has contracted with a for-profit management organization, the name of the management organization, the amount of CSP funding the management organization will receive from the school, and a description of the services to be provided.

(D) The award amount, including any funding that has been approved for the current year and any additional years of the CSP grant for which the school will receive support.

(E) The grant or subgrant application (redacted as necessary).

(F) The peer review materials, including reviewer comments and scores (redacted as necessary) from the subgrant competition (2022 NFP).

(c) Waivers—Requests for information about waivers, including—

(1) A request and justification for waivers of any Federal statutory or regulatory provisions that the State entity believes are necessary for the successful operation of the charter schools that will receive funds under the State entity's program under section 4303 of the ESEA or, in the case of a State entity that is a charter school support organization, a description of how the State entity will work with the State to request such necessary waivers, where applicable; and

(2) A description of any State or local rules, generally applicable to public schools, that will be waived or otherwise not apply to such schools.

Definitions:

The following definitions are from sections 4303(a), 4310, and 8101 of the ESEA (20 U.S.C. 7221b(a), 7221i, and 7801); 34 CFR 77.1; and the 2022 NFP.

Ambitious means promoting continued, meaningful improvement for program participants or for other individuals or entities affected by the grant, or representing a significant advancement in the field of education research, practices, or methodologies. When used to describe a performance target, whether a performance target is ambitious depends upon the context of the relevant performance measure and the baseline for that measure (34 CFR 77.1).

Authorized public chartering agency means an SEA, LEA, or other public entity that has the authority pursuant to State law and approved by the Secretary to authorize or approve a charter school (section 4310(1) of the ESEA).

Baseline means the starting point from which performance is measured and targets are set (34 CFR 77.1).

Charter management organization means a nonprofit organization that operates or manages a network of charter schools linked by centralized support, operations, and oversight (section 4310(3) of the ESEA).

Charter school means a public school that—

(1) In accordance with a specific State statute authorizing the granting of charters to schools, is exempt from significant State or local rules that inhibit the flexible operation and management of public schools, but not from any rules relating to the other requirements of this definition;

(2) Is created by a developer as a public school, or is adapted by a developer from an existing public school, and is operated under public supervision and direction;

(3) Operates in pursuit of a specific set of educational objectives determined by the school's developer and agreed to by the authorized public chartering agency;

(4) Provides a program of elementary or secondary education, or both;

(5) Is nonsectarian in its programs, admissions policies, employment practices, and all other operations, and is not affiliated with a sectarian school or religious institution; [2]

(6) Does not charge tuition;

(7) Complies with the Age Discrimination Act of 1975, title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), section 444 of GEPA (20 U.S.C. 1232g) (commonly referred to as the ''Family Educational Rights and Privacy Act of 1974''), and part B of the Individuals with Disabilities Education Act (IDEA);

(8) Is a school to which parents choose to send their children, and that—

(i) Admits students on the basis of a lottery, consistent with section 4303(c)(3)(A) of the ESEA, if more students apply for admission than can be accommodated; or

(ii) In the case of a school that has an affiliated charter school (such as a school that is part of the same network of schools), automatically enrolls students who are enrolled in the immediate prior grade level of the affiliated charter school and, for any additional student openings or student openings created through regular attrition in student enrollment in the affiliated charter school and the enrolling school, admits students on the basis of a lottery as described in paragraph (i);

(9) Agrees to comply with the same Federal and State audit requirements as do other elementary schools and secondary schools in the State, unless such State audit requirements are waived by the State;

(10) Meets all applicable Federal, State, and local health and safety requirements;

(11) Operates in accordance with State law;

(12) Has a written performance contract with the authorized public chartering agency in the State that includes a description of how student performance will be measured in charter schools pursuant to State assessments that are required of other schools and pursuant to any other assessments mutually agreeable to the authorized public chartering agency and the charter school; and

(13) May serve students in early childhood education programs or postsecondary students (section 4310(2) of the ESEA).

Child with a disability means—

(1) A child (i) with intellectual disabilities, hearing impairments (including deafness), speech or language impairments, visual impairments (including blindness), serious emotional disturbance (referred to as ''emotional disturbance''), orthopedic impairments, autism, traumatic brain injury, other health impairments, or specific learning disabilities; and (ii) who, by reason thereof, needs special education and related services.

(2) For a child aged 3 through 9 (or any subset of that age range, including ages 3 through 5), may, at the discretion of the State and the LEA, include a child (i) experiencing developmental delays, as defined by the State and as measured by appropriate diagnostic instruments and procedures, in one or more of the following areas: physical development; cognitive development; communication development; social or emotional development; or adaptive development; and (ii) who, by reason thereof, needs special education and related services (section 8101(4) of the ESEA).

Community assets means resources that can be identified and mobilized to improve conditions in the charter school and community. These assets may include—

(1) Human assets, including capacities, skills, knowledge base, and abilities of individuals within a community; and

(2) Social assets, including networks, organizations, businesses, and institutions that exist among and within groups and communities (2022 NFP).

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 (34 CFR 77.1).

Developer means an individual or group of individuals (including a public or private nonprofit organization), which may include teachers, administrators and other school staff, parents, or other members of the local community in which a charter school project will be carried out (section 4310(5) of the ESEA).

Disconnected youth means an individual, between the ages 14 and 24, who may be from a low-income background, experiences homelessness, is in foster care, is involved in the justice system, or is not working or not enrolled in (or at risk of dropping out of) an educational institution (2022 NFP).

Early childhood education program means—

(1) A Head Start program or an Early Head Start program carried out under the Head Start Act (42 U.S.C. 9831 *et seq.*), including a migrant or seasonal Head Start program, an Indian Head Start program, or a Head Start program or an Early Head Start program that also receives State funding;

(2) A State licensed or regulated child care program; or

(3) a program that (i) serves children from birth through age 6 that addresses the children's cognitive (including language, early literacy, and early mathematics), social, emotional, and physical development; and (ii) is (A) a State prekindergarten program; (B) a program authorized under section 619 (20 U.S.C. 1419) or part C of the IDEA; or (C) a program operated by an LEA (section 8101(16) of the ESEA).

Educator means an individual who is an early learning educator, teacher, principal or other school or district leader, specialized instructional support personnel (*e.g.,* school psychologist, counselor, school social worker, early intervention service personnel), paraprofessional, or faculty (2022 NFP).

Educationally disadvantaged student means a student in one or more of the categories described in section 1115(c)(2) of the ESEA, which include children who are economically disadvantaged, children with disabilities, migrant students, English learners, neglected or delinquent students, homeless students, and

[2] The Department will apply this element of the definition of ''charter school'' consistent with applicable U.S. Supreme Court precedent, including *Trinity Lutheran Church of Columbia, Inc.* v. *Comer,* 137 S.Ct. 2012 (2017), *Espinoza* v. *Montana Department of Revenue,* 140 S.Ct. 2246 (2020), and *Carson* v. *Makin,* 596 U.S. __(2022).

students who are in foster care (2022 NFP).

Eligible applicant means a developer that has—

(1) Applied to an authorized public chartering authority to operate a charter school; and

(2) Provided adequate and timely notice to that authority (section 4310(6) of the ESEA).

English learner, when used with respect to an individual, means an individual—

(1) Who is aged 3 through 21;

(2) Who is enrolled or preparing to enroll in an elementary school or secondary school;

(3)(i) Who was not born in the United States or whose native language is a language other than English;

(ii)(A) Who is a Native American or Alaska Native, or a native resident of the outlying areas; and

(B) Who comes from an environment where a language other than English has had a significant impact on the individual's level of English language proficiency; or

(iii) Who is migratory, whose native language is a language other than English, and who comes from an environment where a language other than English is dominant; and

(4) Whose difficulties in speaking, reading, writing, or understanding the English language may be sufficient to deny the individual—

(i) The ability to meet the challenging State academic standards;

(ii) The ability to successfully achieve in classrooms where the language of instruction is English; or

(iii) The opportunity to participate fully in society (section 8101(20) of the ESEA).

Expand, when used with respect to a high-quality charter school, means to significantly increase enrollment or add one or more grades to the high-quality charter school (section 4310(7) of the ESEA).

High-quality charter school means a charter school that—

(1) Shows evidence of strong academic results, which may include strong student academic growth, as determined by a State;

(2) Has no significant issues in the areas of student safety, financial and operational management, or statutory or regulatory compliance;

(3) Has demonstrated success in significantly increasing student academic achievement, including graduation rates where applicable, for all students served by the charter school; and

(4) Has demonstrated success in increasing student academic achievement, including graduation rates where applicable, for each of the subgroups of students, as defined in section 1111(c)(2) of the ESEA, except that such demonstration is not required in a case in which the number of students in a group is insufficient to yield statistically reliable information or the results would reveal personally identifiable information about an individual student (section 4310(8) of the ESEA).

Logic model (also referred to as 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 (34 CFR 77.1).

Parent includes a legal guardian or other person standing in loco parentis (such as a grandparent or stepparent with whom the child lives, or a person who is legally responsible for the child's welfare) (section 8101(38) of the ESEA).

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance (34 CFR 77.1).

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project (34 CFR 77.1).

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

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

Replicate, when used with respect to a high-quality charter school, means to open a new charter school, or a new campus of a high-quality charter school, based on the educational model of an existing high-quality charter school, under an existing charter or an additional charter, if permitted or required by State law (section 4310(9) of the ESEA).

State means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, and each of the outlying areas (section 8101(48)of the ESEA).

State educational agency means the agency primarily responsible for the State supervision of public elementary schools and secondary schools (section 8101(49) of the ESEA).

State entity means—

(1) A State educational agency;

(2) A State charter school board;

(3) A Governor of a State; or

(4) A charter school support organization (section 4303(a) of the ESEA).

Underserved student means a student in one or more of the following subgroups:

(1) A student who is living in poverty or is served by schools with high concentrations of students living in poverty.

(2) A student of color.

(3) A student who is a member of a federally recognized Indian Tribe.

(4) An English learner (as defined in section 8101 of the ESEA).

(5) A child or student with a disability (as defined in section 8101 of the ESEA).

(6) A disconnected youth.

(7) A migrant student.

(8) A student experiencing homelessness or housing insecurity.

(9) A student who is in foster care.

(10) A pregnant, parenting, or caregiving student.

(11) A student impacted by the justice system, including a formerly incarcerated student.

(12) A student performing significantly below grade level (2022 NFP).

Program Authority: Title IV, part C of the ESEA (20 U.S.C. 7221–7221j).

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, 76, 77, 79, 81, 82, 84, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The 2022 NFP.

II. Award Information

Type of Award: Discretionary grant.

Estimated Available Funds: $73,000,000.

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: $2,000,000 to $25,000,000 per year.

Estimated Average Size of Awards: $10,000,000 per year.

Maximum Award: See section III.4(a) of this notice, *Reasonable and Necessary Costs,* for information regarding the maximum amount of funds that State Entities may award for each charter school receiving subgrant funds.

Estimated Number of Awards: 8.

Note: The Department is not bound by any estimates in this notice. The estimated range and average size of awards are based on a single 12-month budget period. We may use FY 2022 funds to support multiple 12-month budget periods for one or more grantees.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Entities:* State entities in States with a specific State statute authorizing the granting of charters to schools.

Under section 4303(e)(1) of the ESEA, no State entity may receive a grant under this competition for use in a State in which a State entity is currently using a CSP State Entity grant. Accordingly, State entities in States in which a State entity has a current CSP State Entity grant that is not in its final budget period (nor operating under a no-cost extension in accordance with 34 CFR 75.261 [3]) (*i.e.,* Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Idaho, Indiana, Maryland, Michigan, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Texas, Washington, and Wisconsin) are ineligible to apply for a CSP State Entity grant under this competition. State entities in States in which a State entity has a current CSP State Entity grant that is operating under a no-cost extension (*i.e.,* Mississippi), or that is not operating under a no-cost extension but is in its final budget period and has notified the Department that it does not intend to request a no-cost extension (*i.e.,* no current grantees), however, are eligible to apply for a CSP State Entity grant under this competition.

Consistent with section 4303(e)(1), if a State entity is approved for a new CSP State Entity grant under this competition for use in a State in which a State entity has a current CSP State Entity grant that is operating under a no-cost extension (or that is in its final budget period and does not request a no-cost extension at least 10 calendar days before the end of the performance period specified in the Federal award in accordance with 2 CFR 200.308(e)(2)), the current State entity grantee must obligate all grant funds prior to the end of the current budget period. In other words, the current State entity grantee must complete all grant activities and begin the grant closeout process (*i.e.,* liquidating the grant and not incurring new costs) prior to the expiration date of the no-cost extension (or the end of the performance period for a grantee that is in its final budget period and did not request a no-cost extension). Likewise, if multiple State entities in a State submit applications that receive high enough scores to be recommended for funding under this competition, only the highest scoring application among such State entities would be funded.

State entities in States in which an SEA has a current CSP Grant for SEAs that was awarded under the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001 (*i.e.,* prior to FY 2017) are eligible to apply for a CSP State Entity grant under this competition, so long as no other State entity in the State has a current CSP State Entity grant that is not in its final budget period nor operating under a no-cost extension.

2.a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* A State Entity receiving a grant under this section shall not reserve more than 3 percent of funds for administrative costs, which may include technical assistance.

3. *Subgrantees:* (a) Under section 4303(b) and (c)(2) of the ESEA, a State entity may award subgrants to eligible applicants and technical assistance providers.

(b) Under section 4303(d)(2) of the ESEA, when awarding subgrants to eligible applicants, a State Entity must use a peer review process to review applications.

Note: An eligible applicant (*i.e.,* charter school developer or charter school) in a State in which no State Entity has an approved grant application under section 4303 of the ESEA may apply for funding directly from the Department under the CSP Grants to Charter School Developers for the Opening of New Charter Schools and for the Replication and Expansion of High-Quality Charter Schools (Developer) (ALN number 84.282B or 84.282E) program. Additional information about the CSP Developer program and the competition that is currently underway is available at *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/charter-school-programs/charter-schools-program-non-state-educational-agencies-non-sea-planning-program-design-and-initial-implementation-grant/.*

4. *Other:* (a) *Reasonable and Necessary Costs:* The Secretary may elect to impose maximum limits on the amount of subgrant funds that a State Entity may award to an eligible applicant per new charter school created or replicated, per charter school expanded, or per new school seat created.

For this competition, the maximum amount of subgrant funds a State Entity may award to a subgrantee per new charter school, replicated high-quality charter school, or expanded high-quality charter school over a five-year subgrant period is $1,500,000.

Note: Applicants must ensure that all costs included in the proposed budget are necessary and reasonable to meet the goals and objectives of the proposed project. Any costs determined by the Secretary to be unreasonable or unnecessary will be removed from the final approved budget.

(b) *Audits:* (i) A non-Federal entity that expends $750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions of 2 CFR part 200. (2 CFR 200.501(a)).

(ii) A non-Federal entity that expends less than $750,000 during the non-Federal entity's fiscal year in Federal awards is exempt from Federal audit requirements for that year, except as noted in 2 CFR 200.503 (Relation to other audit requirements), but records must be available for review or audit by appropriate officials of the Federal agency, pass-through entity, and Government Accountability Office. (2 CFR 200.501(d)).

[3] Under 34 CFR 75.261, a grantee may extend the project period of an award one time for up to 12 months without the prior approval of the Department if the grantee meets the requirements for extension in 2 CFR 200.308(d)(2), and Department statutes, regulations, and the terms of the award do not prohibit the extension.

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 December 27, 2021 (86 FR 73264), and available at *www.federalregister.gov/d/2021-27979,* which contain requirements and information on how to submit an application. Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a DUNS number to the implementation of the UEI. More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the CSP State Entity grant competition, your application may include business information that you consider proprietary. In 34 CFR 5.11, we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information, please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition. Please note that, under 34 CFR 79.8(a), we have shortened the standard 60-day intergovernmental review period in order to make an awards by the end of FY 2022.

4. *Funding Restrictions:* In accordance with section 4303(c) of the ESEA, a State entity receiving a grant under this program shall: (a) use not less than 90 percent of the grant funds to award subgrants to eligible applicants, in accordance with the quality charter school program described in the State entity's application pursuant to section 4303(f), for activities related to opening and preparing for the operation of new charter schools and replicated high-quality charter schools, or expanding high-quality charter schools; (b) reserve not less than 7 percent of the grant funds to provide technical assistance to eligible applicants and authorized public chartering agencies in carrying out such activities, and to work with authorized public chartering agencies in the State to improve authorizing quality, including developing capacity for, and conducting, fiscal oversight and auditing of charter schools; and (c) reserve not more than 3 percent of the grant funds for administrative costs, which may include technical assistance. A State entity may use a grant received under this program to provide technical assistance and to work with authorized public chartering agencies to improve authorizing quality under section 4303(b)(2) of the ESEA directly or through grants, contracts, or cooperative agreements.

Limitation on Grants and Subgrants: Under section 4303(d) of the ESEA, a grant awarded by the Secretary to a State entity under this competition shall be for a period of not more than 5 years.

A subgrant awarded by a State entity under this program shall be for a period of not more than 5 years, of which an eligible applicant may use not more than 18 months for planning and program design. An eligible applicant may not receive more than one subgrant under this program for each individual charter school for a 5-year period, unless the eligible applicant demonstrates to the State entity that such individual charter school has at least 3 years of improved educational results for students enrolled in such charter school, with respect to the elements described in section 4310(8)(A) and (D) of the ESEA.[4]

Other CSP Grants: A charter school that previously received funds for opening or preparing to operate a new charter school, or replicating or expanding a high-quality charter school, under the CSP State Entity program (ALN number 84.282A), the CSP Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools (CMO) program (ALN number 84.282M), or the CSP Developer program (ALN numbers 84.282B and 84.282E) may not use funds under this program to carry out the same or substantially similar activities. However, such charter school may be eligible to receive funds under this competition to expand the charter school beyond the existing grade levels or student count.

Likewise, a charter school that previously was awarded a subgrant from a State entity under this program (or the former CSP Grants for State Educational Agencies program) is ineligible to receive funds to carry out the same activities under the CMO program (ALN number 84.282M) or Developer program (ALN numbers 84.282B and 84.282E), including for opening or preparing to operate a new charter school, or for replication or expansion.

Uses of Subgrant Funds: Under section 4303(b) of the ESEA, State entities awarded grants under this competition shall award subgrants to eligible applicants to enable such eligible applicants to—

(a) Open and prepare for the operation of new charter schools;

(b) Open and prepare for the operation of replicated high-quality charter schools; or

(c) Expand high-quality charter schools.

Under section 4303(h) of the ESEA, an eligible applicant receiving a subgrant under this program shall use such funds to support activities related to opening and preparing for the operation of new charter schools or replicating or expanding high-quality charter schools, which shall include one or more of the following:

(a) Preparing teachers, school leaders, and specialized instructional support personnel, including through paying costs associated with—

(i) Providing professional development; and

(ii) Hiring and compensating, during the eligible applicant's planning period specified in the application for subgrant funds, one or more of the following:

(A) Teachers.

(B) School leaders.

(C) Specialized instructional support personnel.

(b) Acquiring supplies, training, equipment (including technology), and educational materials (including developing and acquiring instructional materials).

(c) Carrying out necessary renovations to ensure that a new school building complies with applicable statutes and

[4] Section 4303(e)(2) of the ESEA prescribes the circumstances under which an *eligible applicant* may be eligible to apply to a *State entity* for a second subgrant for an individual *charter school* for a 5-year period. The *eligible applicant* still would have to meet all program requirements, including the requirements for *replicating* or *expanding* a *high-quality charter school.*

regulations, and minor facilities repairs (excluding construction).

(d) Providing one-time, startup costs associated with providing transportation to students to and from the charter school.

(e) Carrying out community engagement activities, which may include paying the cost of student and staff recruitment.

(f) Providing for other appropriate, non-sustained costs related to opening, replicating, or expanding high-quality charter schools when such costs cannot be met from other sources.

Diversity of Projects: Per section 4303(d)(4) of the ESEA, each State entity awarding subgrants under this competition shall award subgrants in a manner that, to the extent practicable and applicable, ensures that such subgrants—

(a) Are distributed throughout different areas, including urban, suburban, and rural areas; and

(b) Will assist charter schools representing a variety of educational approaches.

Award Basis: In determining whether to approve a grant award and the amount of such award, the Department will consider, among other things, the applicant's performance and use of funds under a previous or existing award under any Department program (34 CFR 75.217(d)(3)(ii) and 233(b)). In assessing the applicant's performance and use of funds under a previous or existing award, the Secretary will consider, among other things, the outcomes the applicant has achieved and the results of any Departmental grant monitoring, including the applicant's progress in remedying any deficiencies identified in such monitoring.

We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit and English Language Requirement:* The application narrative (Part III of the application) is where you, the applicant, address the priorities, selection criteria, and application requirements that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 60 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

Applications must be in English, and peer reviewers will only consider supporting documents submitted with the application that are in English.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Pre-Application Webinar Information:* The Department will hold a pre-application meeting via webinar designed to provide technical assistance to interested applicants. Detailed information regarding this webinar will be provided at *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/charter-school-programs/state-entities/application-info-and-eligibility/*. There is no registration fee for attending this meeting.

For further information about the pre-application meeting, contact Jill Gaitens, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–5970. Telephone: (202) 205–1224. Email: *fy2022_se_competition@ed.gov.*

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from section 4303(g)(1) of the ESEA (20 U.S.C. 7221b(g)(1)), the 2022 NFP, and 34 CFR 75.210. The maximum possible total score an application can receive for addressing the criteria is 100 points. The maximum possible score for addressing each criterion is indicated in parentheses following the criterion.

(a) *Quality of the Project Design (up to 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:

(1) The extent to which the proposed project demonstrates a rationale (34 CFR 75.210(c)(2)(xxix)) (up to 5 points);

(2) 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 both quantitative and qualitative data to the extent possible (34 CFR 75.210(h)(2)(iv)) (up to 5 points);

(3) The ambitiousness of the State entity's objectives for the quality charter school program carried out under the CSP State Entity program (section 4303(g)(1)(B) of the ESEA (20 U.S.C. 7221b(g)(1)(B)) (up to 5 points);

(4) The extent to which the projected number of subgrant awards for each grant project year is supported by evidence of demand and need; and the extent to which the proposed average subgrant award amount is supported by evidence of the need of applicants (2022 NFP) (up to 20 points).

(b) *Quality of Eligible Applicants Receiving Subgrants (up to 15 points):* The likelihood that the eligible applicants receiving subgrants under the program will meet the State entity's objectives for the quality charter school program and improve educational results for students (section 4303(g)(1)(C) (20 U.S.C. 7221b(g)(1)(C))).

(c) *State Plan (up to 35 points):* The State entity's plan to—

(1) Adequately monitor the eligible applicants receiving subgrants under the State entity's program (section 4303(g)(1)(D)(i) (20 U.S.C. 7221b(g)(1)(D)(i))) (up to 10 points);

(2) Work with the authorized public chartering agencies involved to avoid duplication of work for the charter schools and authorized public chartering agencies (section 4303(g)(1)(D)(ii) (20 U.S.C. 7221b(g)(1)(D)(ii))) (up to 5 points);

(3) Provide technical assistance and support for—

(i) The eligible applicants receiving subgrants under the State entity's program; and

(ii) Quality authorizing efforts in the State (section 4303(g)(1)(D)(iii) of ESEA (20 U.S.C. 7221b(g)(1)(D)(iii))) (up to 10 points);

(4) The State entity's plan to solicit and consider input from parents and other members of the community on the implementation and operation of charter schools in the State (section 4303(g)(1)(E) of ESEA (20 U.S.C. 7221b(g)(1)(E))) (up to 5 points); and

(5) The degree of flexibility afforded by the State's charter school law and how the State entity will work to maximize the flexibility provided to charter schools under such law (section 4303(g)(1)(A) of ESEA (20 U.S.C. 7221b(g)(1)(A))) (up to 5 points).

(d) *Quality of the Management Plan (up to 15 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:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (34 CFR 75.210(g)(2)(i)) (up to 10 points);

(2) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project (34 CFR 75.210(g)(2)(ii)) (up to 3 points); and

(3) 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 (34 CFR 75.210(g)(2)(iv)) (up to 2 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).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

If the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115—232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements, please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) In accordance with section 4303(i) of the ESEA, each State entity receiving a grant under this section must submit to the Secretary, at the end of the third

year of the 5-year grant period (or at the end of the second year if the grant period is less than 5 years), and at the end of such grant period, a report that includes the following:

(1) The number of students served by each subgrant awarded under this section and, if applicable, the number of new students served during each year of the period of the subgrant.

(2) A description of how the State entity met the objectives of the quality charter school program described in the State entity's application, including—

(A) How the State entity met the objective of sharing best and promising practices as outlined in section 4303(f)(1)(A)(ix) of the ESEA in areas such as instruction, professional development, curricula development, and operations between charter schools and other public schools; and

(B) If known, the extent to which such practices were adopted and implemented by such other public schools.

(3) The number and amount of subgrants awarded under this program to carry out activities described in section 4303(b)(1)(A) through (C) of the ESEA.

(4) A description of—

(A) How the State entity complied with, and ensured that eligible applicants complied with, the assurances included in the State entity's application; and

(B) How the State entity worked with authorized public chartering agencies, and how the agencies worked with the management company or leadership of the schools that received subgrant funds under this program, if applicable.

(d) 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 the purposes of the Department reporting under 34 CFR 75.110: (a) The Secretary has established two performance indicators to measure annual progress toward achieving the purposes of the program, which are discussed elsewhere in this notice. The performance indicators are: (1) the number of *charter schools* in operation around the Nation; and (2) the percentage of fourth- and eighth-grade *charter school* students who are achieving at or above the proficient level on State assessments in mathematics and reading/language arts. Additionally, the Secretary has established the following measure to examine the efficiency of the CSP: the Federal cost per student in implementing a successful school (defined as a school in operation for three or more consecutive years).

(b) *Project-Specific Performance Measures.* Applicants must propose project-specific performance measures and performance targets consistent with the objectives of the proposed project. Applications must provide the following information as directed under 34 CFR 75.110(b) and (c).

(1) *Performance measures.* How each proposed performance measure would accurately measure the performance of the project and how the proposed performance measure would be consistent with the performance measures established for the program funding the competition.

(2) *Baseline data.* (i) Why each proposed baseline is valid; or (ii) if the applicant has determined that there are no established baseline data for a particular performance measure, an explanation of why there is no established baseline and of how and when, during the project period, the applicant would establish a valid baseline for the performance measure.

(3) *Performance targets.* Why each proposed performance target is ambitious yet achievable compared to the baseline for the performance measure and when, during the project period, the applicant would meet the performance target(s).

(4) *Data collection and reporting.* (i) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and (ii) the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things, whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

7. *Project Directors' Meeting:* Applicants approved for funding under this competition must attend a meeting for project directors either virtually or at a location to be determined in the continental United States during each year of the project. Applicants may include, if applicable, the cost of attending this meeting in their proposed budgets as allowable administrative costs.

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.

Ruth E. Ryder,

Deputy Assistant Secretary for Policy and Programs Office of Elementary and Secondary Education.

[FR Doc. 2022–14442 Filed 7–5–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0093]

Agency Information Collection Activities; Comment Request; Impact Aid Program—Application for Section 7002 Assistance

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before September 6, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0093. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Faatimah Muhammad, (202) 453–6827.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Impact Aid Program—Application for Section 7002 Assistance.

OMB Control Number: 1810–0036.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 215.

Total Estimated Number of Annual Burden Hours: 323.

Abstract: Extension without change of a currently approved collection.

Dated: June 30, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–14333 Filed 7–5–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Expanding Opportunity Through Quality Charter Schools Program (CSP)—Grants to Charter School Developers for the Opening of New Charter Schools and for the Replication and Expansion of High-Quality Charter Schools (Developer Grants)

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

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2022 for two types of grants: CSP Developer Grants, Assistance Listing Numbers 84.282B (for the opening of new charter schools) and 84.282E (for the replication and expansion of high-quality charter schools).

DATES:

Applications Available: July 6, 2022.

Notice of Intent to Apply: Applicants are strongly encouraged, but not required to submit a notice of intent to apply by July 21, 2022. Applicants who do not meet this deadline may still apply.

Deadline for Transmittal of Applications: August 5, 2022.

Deadline for Intergovernmental Review: September 6, 2022.

Pre-Application Webinar Information: The CSP intends to hold a webinar designed to provide technical assistance to interested applicants. Detailed information regarding this webinar will be provided at *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/charter-school-programs/charter-schools-program-non-state-educational-agencies-non-sea-planning-program-design-and-initial-implementation-grant/applicant-info-and-eligibility/.*

Note: For new potential grantees unfamiliar with grantmaking at the Department, please consult our funding basics resource at *www2.ed.gov/documents/funding-101/funding-101-basics.pdf* or a more detailed resource at *www2.ed.gov/documents/funding-101/funding-101.pdf.*

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 December 27, 2021 (86 FR 73264), and available at *www.federalregister.gov/d/2021–27979.* Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in SAM.gov, a Data Universal Numbering System (DUNS) number, to the implementation of the Unique Entity Identifier (UEI). More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

FOR FURTHER INFORMATION CONTACT: Porscheoy Brice, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E209, Washington, DC 20202–5970. Telephone: (202) 987–1769.

Email: *DeveloperCompetition2022@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The major purposes of the CSP are to expand opportunities for all students, particularly underserved students, to attend charter schools and meet challenging State academic standards; provide financial assistance for the planning, program design, and initial implementation of charter schools; increase the number of high-quality charter schools available to students across the United States; evaluate the impact of charter schools on student achievement, families, and communities; share best practices between charter schools and other public schools; aid States in providing facilities support to charter schools; and support efforts to strengthen the charter school authorizing process.

Through CSP Developer Grants, the Department provides financial assistance to charter school developers to enable them to open and prepare for the operation of new or replicated charter schools or to expand high-quality charter schools in States that do not currently have a CSP State Entity grant under the Elementary and Secondary Act of 1965 (ESEA). Charter schools that receive financial assistance through Developer Grants provide programs of elementary or secondary education, or both, and may also serve students in early childhood education programs or postsecondary students.

Background: This notice invites applications from eligible applicants for two types of grants: (1) Grants to Charter School Developers for the Opening of New Charter Schools (Assistance Listing Number 84.282B) and (2) Grants to Charter School Developers for the Replication and Expansion of High-Quality Charter Schools (Assistance Listing Number 84.282E). Under this competition, each Assistance Listing Number constitutes its own funding category. The Secretary intends to award grants under each Assistance Listing Number for applications that are sufficiently high quality.

We have published elsewhere in this issue of the **Federal Register** a notice of final priorities, requirements, definitions, and selection criteria for this program (2022 NFP), which supplements the notice of final priorities, requirements, definitions, and selection criteria for Developer Grants published in the **Federal Register** on July 3, 2019 (84 FR 31726) (2019 NFP).

Priorities: This competition includes one competitive preference priority from the 2022 NFP.

This competition also includes an invitational priority to encourage collaborations between charter and traditional public schools or districts that benefit students and families across schools. Some of the most successful charter schools have collaborated with traditional school districts, and there is evidence that these types of collaborations can improve outcomes for students in both charter schools and traditional public schools, including by sharing instructional materials, creating joint professional learning opportunities, and developing principal pipeline programs.

Competitive Preference Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority.

For Assistance Listing Numbers 84.282B and 84.282E, under 34 CFR 75.105(c)(2)(i), we will award up to an additional 5 points to an application that meets the competitive preference priority.

The priority is:

Promoting High-Quality Educator- and Community-Centered Charter Schools to Support Underserved Students (Up to 5 points).

(a) Under this priority, an applicant must propose to open a new charter school, or to replicate or expand a high-quality charter school, that is developed and implemented—

(1) With meaningful and ongoing engagement with current or former teachers and other educators (0 or 1 point); and

(2) Using a community-centered approach that includes an assessment of community assets, informs the development of the charter school, and includes the implementation of protocols and practices designed to ensure that the charter school will use and interact with community assets on an ongoing basis to create and maintain strong community ties. (Up to 2 points).

(b) In its application, an applicant must provide a high-quality plan that demonstrates how its proposed project would meet the requirements in paragraph (a) of this priority, accompanied by a timeline for key milestones that span the course of planning, development, and implementation of the charter school. (Up to 2 points).

Invitational Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Collaborations between Charter Schools and Traditional Public Schools or Districts that Benefit Students and Families across Schools.

(a) Under this priority, an applicant must propose a new collaboration, or the continuation of an existing collaboration, with at least one traditional public school or traditional school district that is designed to benefit students or families served by at least one member of the collaboration, is designed to lead to increased or improved educational opportunities for students served by at least one member of the collaboration, and includes implementation of one or more of the following—

(1) Co-developed or shared curricular and instructional resources or academic course offerings.

(2) Professional development opportunities for teachers and other educators, which may include professional learning communities, opportunities for teachers to earn additional certifications, such as in a high-need area or national board certification, and partnerships with educator preparation programs to support teaching residencies.

(3) Evidence-based (as defined in section 8101 of the ESEA) practices to improve academic performance for underserved students.

(4) Policies and practices to create safe, supportive, and inclusive learning environments, such as systems of positive behavioral intervention and support.

(5) Transparent enrollment and retention practices and processes that include clear and consistent disclosure to families of policies and requirements (*e.g.,* discipline policies, purchasing and wearing specific uniforms and other fees, or family participation), and any services that are or are not provided, that could impact a family's ability to enroll or remain enrolled in the school (*e.g.,* transportation services or participation in the National School Lunch Program).

(6) A shared transportation plan and system that reduces transportation costs for at least one member of the collaboration and takes into consideration various transportation

options, including public transportation and district-provided or shared transportation options, cost-sharing or free or reduced-cost fare options, and any distance considerations for prioritized bus services.

(7) A shared special education collaborative designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in improving academic and developmental outcomes and services for students with disabilities (as defined in section 8101 of the ESEA).

(8) A shared English learner (as defined in section 8101 of the ESEA) collaborative designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in providing educational programs to improve academic outcomes for English learners.

(9) Other collaborations, such as the sharing of innovative and best practices, designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in providing educational programs to improve academic outcomes for all students served by members of the collaboration.

(b) In its application, an applicant must provide a description of the collaboration that—

(1) Describes each member of the collaboration and whether the collaboration would be a new or existing commitment;

(2) States the purpose and duration of the collaboration;

(3) Describes the anticipated roles and responsibilities of each member of the collaboration;

(4) Describes how the collaboration will benefit one or more members of the collaboration, including how it will benefit students or families affiliated with such member and lead to increased educational opportunities for students, and meet specific and measurable, if applicable, goals;

(5) Describes the resources members of the collaboration will contribute; and

(6) Contains any other relevant information.

(c) Within 120 days of receiving a grant award or within 120 days of the date the collaboration is scheduled to begin, whichever is later, provide evidence of participation in the collaboration (which may include, but is not required to include, a memorandum of understanding (MOU)).

Definitions:

The following definitions are from sections 4310 (20 U.S.C. 7221i) and 8101 (20 U.S.C. 7801) of the ESEA, 34 CFR 77.1, and the 2019 and 2022 NFPs.

Ambitious means promoting continued, meaningful improvement for program participants or for other individuals or entities affected by the grant or representing a significant advancement in the field of education research, practices, or methodologies. When used to describe a performance target, whether a performance target is ambitious depends upon the context of the relevant performance measure and the baseline for that measure. (34 CFR 77.1)

Authorized public chartering agency means a State educational agency, local educational agency, or other public entity that has the authority pursuant to State law and approved by the Secretary to authorize or approve a charter school. (Section 4310(1) of the ESEA)

Baseline means the starting point from which performance is measured and targets are set. (34 CFR 77.1)

Charter management organization means a nonprofit organization that operates or manages a network of charter schools linked by centralized support, operations, and oversight. (Section 4310(3) of the ESEA)

Charter school means a public school that—

(1) In accordance with a specific State statute authorizing the granting of charters to schools, is exempt from significant State or local rules that inhibit the flexible operation and management of public schools, but not from any rules relating to the other requirements of this definition;

(2) Is created by a developer as a public school, or is adapted by a developer from an existing public school, and is operated under public supervision and direction;

(3) Operates in pursuit of a specific set of educational objectives determined by the school's developer and agreed to by the authorized public chartering agency;

(4) Provides a program of elementary or secondary education, or both;

(5) Is nonsectarian in its programs, admissions policies, employment practices, and all other operations, and is not affiliated with a sectarian school or religious institution; [1]

(6) Does not charge tuition;

(7) Complies with the Age Discrimination Act of 1975, title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), section 444 of GEPA (20 U.S.C. 1232g) (commonly referred to as the ''Family Educational Rights and Privacy Act of 1974''), and part B of the Individuals with Disabilities Education Act (IDEA);

(8) Is a school to which parents choose to send their children, and that—

(i) Admits students on the basis of a lottery, consistent with section 4303(c)(3)(A) of the ESEA, if more students apply for admission than can be accommodated; or

(ii) In the case of a school that has an affiliated charter school (such as a school that is part of the same network of schools), automatically enrolls students who are enrolled in the immediate prior grade level of the affiliated charter school and, for any additional student openings or student openings created through regular attrition in student enrollment in the affiliated charter school and the enrolling school, admits students on the basis of a lottery as described in clause (i);

(9) Agrees to comply with the same Federal and State audit requirements as do other elementary schools and secondary schools in the State, unless such State audit requirements are waived by the State;

(10) Meets all applicable Federal, State, and local health and safety requirements;

(11) Operates in accordance with State law;

(12) Has a written performance contract with the authorized public chartering agency in the State that includes a description of how student performance will be measured in charter schools pursuant to State assessments that are required of other schools and pursuant to any other assessments mutually agreeable to the authorized public chartering agency and the charter school; and

(13) May serve students in early childhood education programs or postsecondary students. (Section 4310(2) of the ESEA)

Community assets means resources that can be identified and mobilized to improve conditions in the charter school and community. These assets may include—

(1) Human assets, including capacities, skills, knowledge base, and abilities of individuals within a community; and

(2) Social assets, including networks, organizations, businesses, and institutions that exist among and within groups and communities. (2022 NFP)

[1] The Department will apply this element of the definition of ''charter school'' consistent with applicable U.S. Supreme Court precedent, including *Trinity Lutheran Church of Columbia, Inc.* v. *Comer,* 137 S.Ct. 2012 (2017), *Espinoza* v. *Montana Department of Revenue,* 140 S.Ct. 2246 (2020), and *Carson* v. *Makin,* 596 U.S. __(2022).

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. (34 CFR 77.1)

Developer means an individual or group of individuals (including a public or private nonprofit organization), which may include teachers, administrators and other school staff, parents, or other members of the local community in which a charter school project will be carried out. (Section 4310(5) of the ESEA)

Disconnected youth means an individual, between the ages of 14 and 24, who may be from a low-income background, experiences homelessness, is in foster care, is involved in the justice system, or is not working or not enrolled in (or at risk of dropping out of) an educational institution. (2022 NFP)

Early childhood education program means—

(1) A Head Start program or an Early Head Start program carried out under the Head Start Act (42 U.S.C. 9831 *et seq.*), including a migrant or seasonal Head Start program, an Indian Head Start program, or a Head Start program or an Early Head Start program that also receives State funding;

(2) A State licensed or regulated childcare program;

(3) A program that—

(i) Serves children from birth through age 6 that addresses the children's cognitive (including language, early literacy, and early mathematics), social, emotional, and physical development; and

(ii) Is (A) a State prekindergarten program; (B) a program authorized under section 619 (20 U.S.C. 1419) or part C of the IDEA; or (C) a program operated by an LEA. (ESEA section 8101(16))

Educationally disadvantaged student means a student in one or more of the categories described in section 1115(c)(2) of the ESEA, which include children who are economically disadvantaged, children with disabilities, migrant students, English learners, neglected or delinquent students, homeless students, and students who are in foster care. (2019 NFP)

Educator means an individual who is an early learning educator, teacher, principal or other school or district leader, specialized instructional support personnel (*e.g.,* school psychologist, counselor, school social worker, early intervention service personnel), paraprofessional, or faculty. (2022 NFP)

English learner, when used with respect to an individual, means an individual—

(1) Who is aged 3 through 21;

(2) Who is enrolled or preparing to enroll in an elementary school or secondary school;

(3)(i) Who was not born in the United States or whose native language is a language other than English;

(ii)(A) Who is a Native American or Alaska Native, or a native resident of the outlying areas; and

(B) Who comes from an environment where a language other than English has had a significant impact on the individual's level of English language proficiency; or

(iii) Who is migratory, whose native language is a language other than English, and who comes from an environment where a language other than English is dominant; and

(4) Whose difficulties in speaking, reading, writing, or understanding the English language may be sufficient to deny the individual—

(i) The ability to meet the challenging State academic standards;

(ii) The ability to successfully achieve in classrooms where the language of instruction is English; or

(iii) The opportunity to participate fully in society. (Section 8101(20) of the ESEA)

Expand, when used with respect to a high-quality charter school, means to significantly increase enrollment or add one or more grades to the high-quality charter school. (Section 4310(7) of the ESEA)

High-quality charter school means a charter school that—

(1) Shows evidence of strong academic results, which may include strong student academic growth, as determined by a State;

(2) Has no significant issues in the areas of student safety, financial and operational management, or statutory or regulatory compliance;

(3) Has demonstrated success in significantly increasing student academic achievement, including graduation rates where applicable, for all students served by the charter school; and

(4) Has demonstrated success in increasing student academic achievement, including graduation rates where applicable, for each of the subgroups of students, as defined in section 1111(c)(2) of the ESEA, except that such demonstration is not required in a case in which the number of students in a group is insufficient to yield statistically reliable information or the results would reveal personally identifiable information about an individual student. (Section 4310(8) of the ESEA)

Logic model (also referred to as 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. (34 CFR 77.1)

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance. (34 CFR 77.1)

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project. (34 CFR 77.1)

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

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

Replicate, when used with respect to a high-quality charter school, means to open a new charter school, or a new campus of a high-quality charter school, based on the educational model of an existing high-quality charter school, under an existing charter or an additional charter, if permitted or required by State law. (Section 4310(9) of the ESEA)

Underserved student means a student in one or more of the following subgroups:

(1) A student who is living in poverty or is served by schools with high concentrations of students living in poverty.

(2) A student of color.

(3) A student who is a member of a federally recognized Indian Tribe.

(4) An English learner (as defined in section 8101 of the ESEA).

(5) A child or student with a disability (as defined in section 8101 of the ESEA).

(6) A disconnected youth.

(7) A migrant student.

(8) A student experiencing homelessness or housing insecurity.

(9) A student who is in foster care.

(10) A pregnant, parenting, or caregiving student.

(11) A student impacted by the justice system, including a formerly incarcerated student.

(12) A student performing significantly below grade level. (2022 NFP)

Application Requirements:

Applications for CSP Developer Grant funds must address the following application requirements. These requirements are from section 4303(f) [2] of the ESEA (20 U.S.C. 7221b) and the 2019 and 2022 NFPs. The source of each requirement is provided in parentheses following each requirement. Except as otherwise provided, an applicant may choose to respond to each requirement separately or in the context of the applicant's responses to the selection criteria in section V.1 of this notice.

Grants to Charter School Developers for the Opening of New Charter Schools (Assistance Listing Number 84.282B) and for the Replication and Expansion of High-Quality Charter Schools (Assistance Listing Number 84.282E).

Applicants for grants under Assistance Listing Numbers 84.282B or 84.282E must address the following application requirements. An applicant must respond to the requirements in paragraph (a) in a stand-alone section of the application or in an appendix.

(a) Describe the eligible applicant's objectives in running a quality charter school program and how the objectives of the program will be carried out, including—

(1) How the eligible applicant will ensure that charter schools receiving funds under this program meet the educational needs of their students, including children with disabilities and English learners (Section 4303(f)(1)(A)(x) of the ESEA);

(2) The roles and responsibilities of eligible applicants, partner organizations, and charter management organizations, including the administrative and contractual roles and responsibilities of such partners (Section 4303(f)(1)(C)(i)(I) of the ESEA);

(3) The quality controls agreed to between the eligible applicant and the authorized public chartering agency involved, such as a contract or performance agreement, how a school's performance in the State's accountability system and impact on student achievement (which may include student academic growth) will be one of the most important factors for renewal or revocation of the school's charter, and how the authorized public chartering agency involved will reserve the right to revoke or not renew a school's charter based on financial, structural, or operational factors involving the management of the school (Section 4303(f)(1)(C)(i)(II) of the ESEA);

(4) How the autonomy and flexibility granted to a charter school is consistent with the definition of a charter school in section 4310 of the ESEA (Section 4303(f)(1)(C)(i)(III) of the ESEA);

(5) How the eligible applicant will solicit and consider input from parents and other members of the community on the implementation and operation of each charter school that will receive funds under the grant (Section 4303(f)(1)(C)(i)(IV) of the ESEA);

(6) The eligible applicant's planned activities and expenditures of grant funds to support the activities described in section 4303(b)(1) of the ESEA, and how the eligible applicant will maintain financial sustainability after the end of the grant period (Section 4303(f)(1)(C)(i)(V) of the ESEA);

(7) How the eligible applicant will support the use of effective parent, family, and community engagement strategies to operate each charter school that will receive funds under the grant (Section 4303(f)(1)(C)(i)(VI) of the ESEA); and

(8) How the eligible applicant will ensure that each charter school receiving funds under this program has considered and planned for the transportation needs of the school's students (Section 4303(f)(1)(E) of the ESEA).

(b) Describe the educational program that the applicant will implement in the charter school receiving funding under this program, including—

(1) Information on how the program will enable all students to meet the challenging State academic standards;

(2) The grade levels or ages of students who will be served; and

(3) The instructional practices that will be used. (2019 NFP)

(c) Describe how the applicant will ensure that the charter school that will receive funds will recruit, enroll, and retain students, including educationally disadvantaged students, which include children with disabilities and English learners. (2019 NFP)

(d) Describe the lottery and enrollment procedures that the applicant will use for the charter school if more students apply for admission than can be accommodated and, if the applicant proposes to use a weighted lottery, how the weighted lottery complies with section 4303(c)(3)(A) of the ESEA. (2019 NFP)

(e) Provide a complete logic model (as defined in 34 CFR 77.1) for the grant project. The logic model must include the applicant's objectives for implementing a new charter school or replicating or expanding a high-quality charter school with funding under this competition. (2019 NFP)

(f) Provide a budget narrative, aligned with the activities, target grant project outputs, and outcomes described in the logic model, that outlines how grant funds will be expended to carry out planned activities. (2019 NFP)

(g) If the applicant proposes to open a new charter school (Assistance Listing Number 84.282B) or proposes to replicate or expand a high-quality charter school (Assistance Listing Number 84.282E) that provides a single-sex educational program, demonstrate that the proposed single-sex educational programs are in compliance with the title IX of the Education Amendments of 1972 (20 U.S.C. 1681, *et seq.*) (''Title IX'') and its implementing regulations, including 34 CFR 106.34. (2019 NFP)

(h) Provide the applicant's most recent available independently audited financial statements prepared in accordance with generally accepted accounting principles. (2019 NFP)

(i) Provide—

(1) A request and justification for waivers of any Federal statutory or regulatory provisions that the eligible entity believes are necessary for the successful operation of the charter school to be opened or to be replicated or expanded; and

(2) A description of any State or local rules, generally applicable to public schools, that will be waived or otherwise not apply to the school that will receive funds. (2019 NFP)

(j) Describe how each school that will receive funds meets the definition of charter school under section 4310(2) of the ESEA. (2019 NFP)

(k) For any existing or proposed contract with a for-profit management organization (including a nonprofit management organization operated by or on behalf of a for-profit entity), without regard to whether the management organization or its related entities exercise full or substantial administrative control over the charter school or the CSP project, the applicant must provide the following information or equivalent information that the applicant has submitted to the authorized public chartering agency—

(1) A copy of the existing contract with the for-profit management organization or a description of the terms of the contract, including the name and contact information of the management organization; the cost (*i.e.,*

[2] Under section 4305(c) of the ESEA, Developer Grants must have the same terms and conditions as grants awarded to State entities under section 4303. For clarity, with respect to requirements that derive from section 4303, the Department has, as applicable, omitted the term ''State entity'' or replaced it with ''eligible applicant.'' In addition, the Department has replaced ''State entity's program'' and ''subgrant,'' respectively, with ''program'' and ''grant.''

fixed costs and estimates of any ongoing costs), including the amount of CSP funds proposed to be used toward such cost, and the percentage such cost represents of the school's total funding; the duration; roles and responsibilities of the management organization; and steps the applicant will take to ensure that it pays fair market value for any services or other items purchased or leased from the management organization, makes all programmatic decisions, maintains control over all CSP funds, and directly administers or supervises the administration of the grant in accordance with 34 CFR 75.701;

(2) A description of any business or financial relationship between the charter school developer and the management organization, including payments, contract terms, and any property owned, operated, or controlled by the management organization or related individuals or entities that will be used by the charter school;

(3) The name and contact information for each member of the governing board of the charter school and list of the management organization's officers, chief administrator, and other administrators, and any staff involved in approving or executing the management contract; and a description of any actual or perceived conflicts of interest, including financial interests, and how the applicant resolved or will resolve any actual or perceived conflicts of interest to ensure compliance with 2 CFR 200.318(c);

(4) A description of how the applicant will ensure that members of the governing board of the charter school are not selected, removed, controlled, or employed by the for-profit management organization and that the charter school's legal, accounting, and auditing services will be procured independently from the for-profit management organization);

(5) An explanation of how the applicant will ensure that the management contract is severable, severing the management contract will not cause the proposed charter school to close, the duration of the management contract will not extend beyond the expiration date of the school's charter, and renewal of the management contract will not occur without approval and affirmative action by the governing board of the charter school; and

(6) A description of the steps the applicant will take to ensure that it maintains control over all student records and has a process in place to provide those records to another public school or school district in a timely manner upon the transfer of a student from the charter school to another public school, including due to closure of the charter school, in accordance with section 4308 of the ESEA. (2022 NFP)

(l) Each applicant must provide—

(1) The name and address of the authorized public chartering agency that issued the applicant's approved charter or, in the case of an applicant that has not yet received an approved charter, the authorized public chartering agency to which the applicant has applied;

(2) A copy of the approved charter or, in the case of an applicant that has not yet received an approved charter, a copy of the charter application that was submitted to the authorized public chartering agency, including the date the application was submitted, and an estimated date by which the authorized public chartering agency will issue its final decision on the charter application;

(3) Documentation that the applicant has provided notice to the authorized public chartering agency that it has applied for a CSP grant; and

(4) A proposed budget, including a detailed description of any post-award planning costs and, for an applicant that does not yet have an approved charter, any planning costs expected to be incurred prior to the date the authorized public chartering agency issues a decision on the charter application. (2022 NFP)

Grants for the Replication and Expansion of High-Quality Charter Schools (Assistance Listing Number 84.282E).

In addition to the preceding application requirements, applicants for grants under Assistance Listing Number 84.282E must—

(a) For each charter school currently operated or managed by the applicant, provide—

(1) Information that demonstrates that the school is treated as a separate school by its authorized public chartering agency and the State, including for purposes of accountability and reporting under title I, part A of the ESEA;

(2) Student assessment results for all students and for each subgroup of students described in section 1111(c)(2) of the ESEA;

(3) Attendance and student retention rates for the most recently completed school year and, if applicable, the most recent available 4-year adjusted cohort graduation rates and extended year adjusted cohort graduation rates; and

(4) Information on any significant compliance and management issues encountered within the last three school years by the existing charter school being operated or managed by the eligible entity, including in the areas of student safety and finance. (2019 NFP)

Assurances:

Applicants for CSP Developer Grants must provide the following assurances. These assurances are from section 4303(f) of the ESEA and the 2022 NFP. The source of each assurance is provided in parentheses following each assurance.

Applicants for funds under this program must provide assurances that—

(a) Each charter school receiving funds through this program will have a high degree of autonomy over budget and operations, including autonomy over personnel decisions (Section 4303(f)(2)(A) of the ESEA);

(b) The eligible applicant will support charter schools in meeting the educational needs of their students, as described in section 4303(f)(1)(A)(x) of the ESEA (Section 4303(f)(2)(B) of the ESEA); and

(c) The eligible applicant will ensure that each charter school receiving funds under this program makes publicly available, consistent with the dissemination requirements of the annual State report card under section 1111(h) of the ESEA, including on the website of the school, information to help parents make informed decisions about the education options available to their children, including—

(i) Information on the educational program;

(ii) Student support services;

(iii) Parent contract requirements (as applicable), including any financial obligations or fees;

(iv) Enrollment criteria (as applicable); and

(v) Annual performance and enrollment data for each of the subgroups of students, as defined in section 1111(c)(2) of the ESEA, except that such disaggregation of performance and enrollment data shall not be required in a case in which the number of students in a group is insufficient to yield statistically reliable information or the results would reveal personally identifiable information about an individual student. (Section 4303(f)(2)(G) of the ESEA)

(d) Each applicant must provide an assurance that it has not and will not enter into a contract with a for-profit management organization, including a nonprofit management organization operated by or on behalf of a for-profit entity, under which the management organization or its related entities exercises full or substantial administrative control over the charter school and, thereby, the CSP project. (2022 NFP)

(e) Each applicant must provide an assurance that any management contract between the charter school and a for-profit management organization, including a nonprofit CMO operated by or on behalf of a for-profit entity, guarantees or will guarantee that—

(1) The charter school maintains control over all CSP funds, makes all programmatic decisions, and directly administers or supervises the administration of the grant or subgrant;

(2) The management organization does not exercise full or substantial administrative control over the charter school (and, thereby, the CSP project), except that this does not limit the ability of a charter school to enter into a contract with a management organization for the provision of services that do not constitute full or substantial control of the charter school project funded under the CSP (*e.g.,* food or payroll services) and that otherwise comply with statutory and regulatory requirements;

(3) The charter school's governing board has access to financial and other data pertaining to the charter school, the management organization, and any related entities; and

(4) The charter school is in compliance with applicable Federal and State laws and regulations governing conflicts of interest, and there are no actual or perceived conflicts of interest between the charter school and the management organization. (2022 NFP)

(f) Each applicant must provide an assurance that it will post on its website, on an annual basis, a copy of any management contract between the charter school and a for-profit management organization, including a nonprofit management organization operated by or on behalf of a for-profit entity, and report information on such contract to the Department, including—

(1) A copy of the existing contract with the for-profit management organization or description of the terms of the contract, including the name and contact information of the management organization, the cost (*i.e.,* fixed costs and estimates of any ongoing costs), including the amount of CSP funds proposed to be used toward such costs, and the percentage such cost represents of the charter school's total funding, the duration, roles and responsibilities of the management organization, the steps the charter will take to ensure that it pays fair market value for any services or other items purchased or leased from the management organization, and the steps the charter school is taking to ensure that it makes all programmatic decisions, maintains control over all CSP funds, and directly administers or supervises the administration of the grant or subgrant in accordance with 34 CFR 75.701 and 76.701;

(2) A description of any business or financial relationship between the charter school developer or CMO and the management organization, including payments, contract terms, and any property owned, operated, or controlled by the management organization or related individuals or entities to be used by the charter school;

(3) The names and contact information for each member of the governing boards of the charter school and a list of management organization's officers, chief administrator, and other administrators, and any staff involved in approving or executing the management contract; and a description of any actual or perceived conflicts of interest, including financial interests, and how the applicant resolved or will resolve any actual or perceived conflicts of interest to ensure compliance with 2 CFR 200.318(c); and

(4) A description of how the charter school ensured that such contract is severable and that a change in management companies will not cause the proposed charter school to close. (2022 NFP)

(g) Each applicant must provide an assurance that it will disclose, as part of the enrollment process, any policies or requirements (*e.g.,* purchasing and wearing specific uniforms and other fees, or requirements for family participation), and any services that are or are not provided, that could impact a family's ability to enroll or remain enrolled in the school (*e.g.,* transportation services or participation in the National School Lunch Program). (2022 NFP)

(h) Each applicant must provide an assurance that it will hold or participate in a public hearing in the local community in which the proposed charter school would be located to obtain information and feedback regarding the potential benefit of the charter school, which shall at least include how the proposed charter school will increase the availability of high-quality public school options for underserved students, promote racial and socio-economic diversity in such community or have an educational mission to serve primarily underserved students, and not increase racial or socio-economic segregation or isolation in the school districts from which students would be drawn to attend the charter school (consistent with applicable laws). Applicants must ensure that the hearing (and notice thereof) is accessible to individuals with disabilities and limited English proficient individuals as required by law, actively solicit participation in the hearing (*i.e.,* provide widespread and timely notice of the hearing), make good faith efforts to accommodate as many people as possible (*e.g.,* hold the hearing at a convenient time for families or provide virtual participation options), and submit a summary of the comments received as part of the application. The hearing may be conducted as part of the charter authorizing process, provided it meets the requirements above. (2022 NFP)

(i) Each applicant must provide an assurance that it will not use any implementation funds for a charter school until after the charter school has received a charter from an authorized public chartering agency and has a contract, lease, mortgage, or other documentation indicating that it has a facility in which to operate. Consistent with sections 4303(b)(1), 4303(h)(1)(B), and 4310(6) of the ESEA, an eligible applicant may use CSP planning funds for post-award planning and design of the educational program of a proposed new or replicated high-quality charter school that has not yet opened, which may include hiring and compensating teachers, school leaders, and specialized instructional support personnel; providing training and professional development to staff; and other critical planning activities that need to occur prior to the charter school opening when such costs cannot be met from other sources. (2022 NFP)

Note: The Department recognizes that the charter approval process may exceed the 18-month planning period for CSP grants, as prescribed under section 4303(d)(1)(B) of the ESEA. In such a case, applicants may request approval from the Department to amend their application to request an extension of the 18-month planning period. Under section 4303(d)(5) of the ESEA, the Secretary, in his discretion, may waive any statutory or regulatory requirement over which he exercises administrative authority, except the requirements related to the definition of ''charter school'' in section 4310(2), provided that the waiver is requested in an approved application and the Secretary determines that granting the waiver will promote the purposes of the CSP. It is also worth noting that a grantee may request approval from the Department, as appropriate, to amend its approved application and budget to cover additional planning costs that it may incur due to an unexpected delay in the charter approval process.

Program Authority: Title IV, part C of the ESEA, as amended.

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, 76, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The 2019 and 2022 NFPs.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $4,000,000.

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: $150,000–$300,000 per year.

Estimated Average Size of Awards: $225,000 per year.

Maximum Award: See Reasonable and Necessary Costs in section III.4. for information regarding the maximum amount of funds that may be awarded per new school.

Estimated Number of Awards: 8–10.

Note: The Department is not bound by any estimates in this notice. The estimated range and average size of awards are based on a single 12-month budget period. We may use available funds to support multiple 12-month budget periods for one or more grantees.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:*

Eligible applicants are developers that have—

(a) Applied to an authorized public chartering authority to operate a charter school; and

(b) Provided adequate and timely notice to that authority. (Section 4310(6) of the ESEA).

Additionally, the charter school must be located in a State with a State statute specifically authorizing the establishment of charter schools (as defined in section 4310(2) of the ESEA) and in which a State entity currently does not have a CSP State Entity grant (Assistance Listing Number 84.282A) under section 4303 of the ESEA.[3] (Section 4305(a)(2) of the ESEA) Eligibility in a State with a CSP SEA grant (Assistance Listing Number 84.282A) under the ESEA, as amended by the No Child Left Behind Act of 2001 (NCLB), is limited to grants for replication and expansion [4] (Assistance Listing Number 84.282E) and only if the Department has not approved an amendment to the SEA's approved grant application authorizing the SEA to make subgrants for replication and expansion.[5]

As a general matter, the Secretary considers charter schools that have been in operation for more than five years to be past the initial implementation phase and, therefore, ineligible to receive CSP funds under Assistance Listing Number 84.282B to support the opening of a new charter school or under Assistance Listing Number 84.282E for the replication of a high-quality charter school; however, such schools may receive CSP funds under Assistance Listing Number 84.282E for the expansion of a high-quality charter school.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing (1) proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate; or (5) for an entity that holds a sincerely held religious belief that it cannot apply for a determination as an entity that is tax-exempt under section 501(c)(3) of the Internal Revenue Code, evidence sufficient to establish that the entity would otherwise qualify as a nonprofit organization under (1) through (4) above.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Supplement-Not-Supplant:* This competition does not involve supplement-not-supplant funding requirements.

c. *Indirect Cost Rate Information:* 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.

4. *Reasonable and Necessary Costs:* The Secretary may elect to impose maximum limits on the amount of grant funds that may be awarded for a new charter school, or replicated, or expanded, high-quality charter school.

For this competition, the maximum limit of grant funds that may be awarded for a new, replicated, or expanded charter school is $1,500,000.

In accordance with 2 CFR 200.404, applicants must ensure that all costs included in the proposed budget are reasonable and necessary in light of the goals and objectives of the proposed project. Any costs determined by the Secretary to be unreasonable or unnecessary will be removed from the final approved budget.

[3] States in which a State entity currently has an approved CSP State Entity grant application under section 4303 of the ESEA that is actively running subgrant competitions are Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Idaho, Indiana, Maryland, Michigan, Minnesota, Mississippi, Nevada, New Hampshire, New Mexico, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, Texas, Washington, and Wisconsin. We will not consider applications from applicants in these States under either Assistance Listing Numbers 84.282B or 84.282E.

[4] States in which the SEA currently has an approved CSP SEA grant application under the ESEA, as amended by NCLB (*i.e.,* a grant award made in fiscal year 2016 or earlier), are Georgia and Ohio. We will not consider applications from applicants in these States for grants for the opening of new *charter schools* submitted under Assistance Listing Number 84.282B.

[5] States in which the SEA currently has an approved CSP SEA grant application under the ESEA, as amended by NCLB (*i.e.,* a grant award made in fiscal year 2016 or earlier), and have approved amendment requests that authorize the SEA to make subgrants for replication and expansion, is Ohio. We will not consider applications from applicants in this State for grants for the replication or expansion of *high-quality charter schools* under Assistance Listing Number 84.282E either.

A charter school that previously has received CSP funds for replication or expansion or for planning or initial implementation of a charter school under Assistance Listing Numbers 84.282A or 84.282M (under the ESEA) may not use funds under this grant for the same purpose. However, such charter school may be eligible to receive funds under this competition to expand the charter school beyond the existing grade levels or student count and beyond the grade levels or projected student count provided in the previous CSP award. Likewise, a charter school that receives funds under this competition is ineligible to receive funds for the same purpose under section 4303(b)(1) or 4305(b) of the ESEA, including opening and preparing for the operation of a new charter school, opening and preparing for the operation of a replicated high-quality charter school, or expanding a high-quality charter school (*i.e.,* Assistance Listing Numbers 84.282A or 84.282M).

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 December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/2021-27979,* which contain requirements and information on how to submit an application. Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a DUNS number to the implementation of the UEI. More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for this competition, your application may include business information that you consider proprietary. In 34 CFR 5.11, we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition. Please note that, under 34 CFR 79.8(a), we have shortened the standard 60-day intergovernmental review period in order to make an award by the end of FY 2022.

4. *Funding Restrictions:* Grantees must use the grant funds to open and prepare for the operation of a new charter school, to open and prepare for the operation of a replicated high-quality charter school, or to expand a high-quality charter school, as applicable. Grant funds must be used to carry out allowable activities, described in section 4303(h) of the ESEA, which include the following:

(a) Preparing teachers, school leaders, and specialized instructional support personnel, including through paying the costs associated with—

(1) Providing professional development; and

(2) Hiring and compensating, during the eligible applicant's planning period specified in the application for funds, one or more of the following:

(i) Teachers.

(ii) School leaders.

(iii) Specialized instructional support personnel.

(b) Acquiring supplies, training, equipment (including technology), and educational materials (including developing and acquiring instructional materials).

(c) Carrying out necessary renovations to ensure that a new school building complies with applicable statutes and regulations, and minor facilities repairs (excluding construction).

(d) Providing one-time, startup costs associated with providing transportation to students to and from the charter school.

(e) Carrying out community engagement activities, which may include paying the cost of student and staff recruitment.

(f) Providing for other appropriate, non-sustained costs related to the opening of new charter schools, or the replication or expansion of high-quality charter schools, as applicable, when such costs cannot be met from other sources.

A grant awarded by the Secretary under this competition may be for a period of not more than five years, of which the grantee may use not more than 18 months for planning and program design. (Section 4303(d)(1)(B) of the ESEA). Applicants may propose to support only one charter school per grant application.

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 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 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, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants 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, a contact person's name and email address, and the Assistance Listing Number. Applicants that do not submit a notice of intent to apply may still apply for funding.

V. Application Review Information

1. *Selection Criteria.* The selection criteria for applicants submitting applications under Assistance Listing Numbers 84.282B and 84.282E are listed in paragraphs (a) and (b) of this section, respectively. The maximum possible score for addressing all of the selection criteria is 100 points. The maximum possible score for addressing each criterion is indicated in parentheses following the criterion. These selection criteria are from the 2019 and 2022 NFPs and 34 CFR 75.210.

In evaluating an application for a Developer Grant, the Secretary considers the following criteria:

(a) *Selection Criteria for Grants for the Opening of New Charter Schools (Assistance Listing Number 84.282B).*

(1) *Quality of the Charter School's Management Plan (up to 40 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 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). (34 CFR 75.210(g)(2)(i))

(ii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project (up to 5 points). (34 CFR 75.210(f)(2)(iv))

(iii) 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 5 points). (34 CFR 75.210(g)(2)(iv))

(iv) The qualifications, including relevant training and experience, of key project personnel (up to 5 points). (34 CFR 75.210(e)(3)(ii))

(v) The adequacy of the applicant's plan to maintain control over all CSP grant funds (up to 5 points). (2022 NFP)

(vi) The adequacy of the applicant's plan to make all programmatic decisions (up to 5 points). (2022 NFP)

(vii) The adequacy of the applicant's plan to administer or supervise the administration of the grant, including maintaining management and oversight responsibilities over the grant (up to 5 points). (2022 NFP)

(2) *Quality of the Continuation Plan (up to 20 points).*

In determining the quality of the continuation plan, the Secretary considers the extent to which the eligible applicant is prepared to continue to operate the charter school that would receive grant funds in a manner consistent with the eligible applicant's application once the grant funds under this program are no longer available. (2019 NFP)

(3) *Quality of the Project Design (up to 10 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 demonstrates a rationale (as defined in 34 CFR 77.1(c)) (up to 5 points). (34 CFR 75.210(c)(2)(xxix))

(ii) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable (up to 5 points). (34 CFR 75.210(c)(2)(i))

(4) *Need for the Project (up to 30 points).*

The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers one or more of the following factors:

(i) The magnitude or severity of the problem to be addressed by the proposed project (up to 15 points). (34 CFR 75.210(a)(2)(i))

(ii) The magnitude of the need for the services to be provided or the activities to be carried out by the proposed project (up to 15 points). (34 CFR 75.210(a)(2)(ii))

(b) *Selection Criteria for Grants for the Replication and Expansion of High-Quality Charter Schools (Assistance Listing Number 84.282E).*

(1) *Quality of the Eligible Applicant (up to 20 points).*

In determining the quality of the eligible applicant, the Secretary considers the following factors:

(i) The extent to which the academic achievement results (including annual student performance on statewide assessments and annual student attendance and retention rates and where applicable and available, student academic growth, high school graduation rates, postsecondary enrollment and persistence rates, including in college or career training programs, employment rates, earnings and other academic outcomes) for educationally disadvantaged students served by the charter schools operated or managed by the applicant have exceeded the average academic achievement results for such students served by other public schools in the State (up to 5 points). (2019 NFP)

(ii) The extent to which one or more charter schools operated or managed by the applicant have closed; have had a charter revoked due to noncompliance with statutory or regulatory requirements; or have had their affiliation with the applicant revoked or terminated, including through voluntary disaffiliation (up to 5 points). (2019 NFP)

(iii) The extent to which one or more charter schools operated or managed by the applicant have had any significant issues in the area of financial or operational management or student safety, or have otherwise experienced significant problems with statutory or regulatory compliance that could lead to revocation of the school's charter (up to 5 points). (2019 NFP)

(iv) The extent to which the schools operated or managed by the applicant demonstrate strong results on measurable outcomes in non-academic areas such as, but not limited to, parent satisfaction, school climate, student mental health, civic engagement, and crime prevention and reduction (up to 5 points). (2019 NFP)

(2) *Quality of the Charter School's Management Plan (up to 35 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 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 5 points). (34 CFR 75.210(g)(2)(i))

(ii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project (up to 5 points). (34 CFR 75.210(f)(2)(iv))

(iii) 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 5 points). (34 CFR 75.210(g)(2)(iv))

(iv) The qualifications, including relevant training and experience, of key project personnel (up to 5 points). (34 CFR 75.210(e)(3)(ii))

(v) The adequacy of the applicant's plan to maintain control over all CSP grant funds (up to 5 points). (2022 NFP)

(vi) The adequacy of the applicant's plan to make all programmatic decisions (up to 5 points). (2022 NFP)

(vii) The adequacy of the applicant's plan to administer or supervise the

administration of the grant, including maintaining management and oversight responsibilities over the grant (up to 5 points). (2022 NFP)

(3) *Quality of the Continuation Plan (up to 10 points).*

In determining the quality of the continuation plan, the Secretary considers the extent to which the eligible applicant is prepared to continue to operate the charter school that would receive grant funds in a manner consistent with the eligible applicant's application once the grant funds under this program are no longer available. (2019 NFP)

(4) *Quality of the Project Design (up to 10 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 demonstrates a rationale (as defined in 34 CFR 77.1(c)) (up to 5 points). (34 CFR 75.210(c)(2)(xxix))

(ii) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable (up to 5 points). (34 CFR 75.210(c)(2)(i))

(5) *Need for the Project (up to 25 points).*

The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers one or more of the following factors:

(i) The magnitude or severity of the problem to be addressed by the proposed project (up to 15 points). (34 CFR 75.210(a)(2)(i))

(ii) 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). (34 CFR 75.210(a)(2)(ii))

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the Applicable Regulations section of this notice.

We reference the regulations outlining the terms and conditions of an award in the Applicable Regulations section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* For the purposes of the Department reporting under 34 CFR 75.110: (a) The Secretary has two performance indicators to measure progress toward achieving the purposes of the program, which are discussed elsewhere in this notice. The performance indicators are: (1) the number of charter schools in operation around the Nation and (2) the percentage of fourth- and eighth-grade charter school students who are achieving at or above the proficient level on State assessments in mathematics and reading/language arts. Additionally, the Secretary has established the following measure to examine the efficiency of the CSP: The Federal cost per student in implementing a successful school (defined as a school in operation for three or more consecutive years).

(b) *Project-Specific Performance Measures.* Applicants must propose project-specific performance measures and performance targets consistent with the objectives of the proposed project. Applications must provide the following information as directed under 34 CFR 75.110(b) and (c):

(1) *Performance measures.* How each proposed performance measure would accurately measure the performance of the project and how the proposed performance measure would be consistent with the performance measures established for the program funding the competition.

(2) *Baseline data.* (i) Why each proposed baseline is valid; or (ii) if the applicant has determined that there are no established baseline data for a particular performance measure, an explanation of why there is no established baseline and how and when, during the project period, the applicant would establish a valid baseline for the performance measure.

(3) *Performance targets.* Why each proposed performance target is ambitious yet achievable compared to the baseline for the performance measure and when, during the project period, the applicant would meet the performance target(s).

(4) *Data collection and reporting.* (i) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and (ii) the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things, whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

7. *Project Directors' Meeting:* Applicants approved for funding under this competition must attend a meeting for project directors at a location to be determined in the continental United States during each year of the project. Applicants may include the cost of attending this meeting as an administrative cost in their proposed budgets.

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.

Ruth E. Ryder,

Deputy Assistant Secretary for Policy and Programs Office of Elementary and Secondary Education.

[FR Doc. 2022–14448 Filed 7–5–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–2657–012; ER19–2214–001; ER20–479–002; ER20–481–002; ER20–482–002; ER20–484–002; ER20–1650–003; ER22–1523–001; ER22–1549–001.

Applicants: Sun Streams PVS, LLC, Sun Streams 2, LLC, Little Bear Master Tenant, LLC, Little Bear Solar 5, LLC, Little Bear Solar 4, LLC, Little Bear Solar 3, LLC, Little Bear Solar 1, LLC, Milford Wind Corridor Phase I, LLC, Milford Wind Corridor Phase II, LLC.

Description: Triennial Market Power Analysis for Southwest Region of

Milford Wind Corridor Phase II, LLC, et al.

Filed Date: 6/28/22.

Accession Number: 20220628–5175.

Comment Date: 5 p.m. ET 8/29/22.

Docket Numbers: ER18–2511–004.

Applicants: North Western Corporation.

Description: Market: Triennial Market Power Analysis for the Northwest Region to be effective N/A.

Filed Date: 6/29/22.

Accession Number: 20220629–5152.

Comment Date: 5 p.m. ET 8/29/22.

Docket Numbers: ER22–895–002.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 3908 T.

Filed Date: 6/29/22.

Accession Number: 20220629–5097.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–1470–001.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing: City Utilities of Springfield submits tariff filing per 35: City Utilities of Springfield, Missouri Compliance filing in ER22–1470 to be effective 6/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5109.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–1990–000.

Applicants: DTE Electric Company.

Description: Supplement to May 31, 2022 DTE Electric Company tariff filing.

Filed Date: 6/28/22.

Accession Number: 20220628–5056.

Comment Date: 5 p.m. ET 7/19/22.

Docket Numbers: ER22–2015–000.

Applicants: Tampa Electric Company.

Description: Supplemental Motion for Waiver of OATT Formula Rate Implementation Protocols Provision of Tampa Electric Company.

Filed Date: 6/27/22.

Accession Number: 20220627–5163.

Comment Date: 5 p.m. ET 7/7/22.

Docket Numbers: ER22–2190–001; ER13–1816–017; ER14–1594–005; ER14–1596–005; ER14–1934–006; ER14–1935–006; ER15–1020–004; ER20–242–003; ER20–245–003; ER20–246–003; ER22–2191–001; ER22–2192–001.

Applicants: EDPR Scarlet I LLC, EDPR CA Solar Park II LLC, Windhub Solar A, LLC, Sun Streams, LLC, Sunshine Valley Solar, LLC, Rising Tree Wind Farm III LLC, Rising Tree Wind Farm II LLC, Rising Tree Wind Farm LLC, Lone Valley Solar Park II LLC, Lone Valley Solar Park I LLC, Sustaining Power Solutions LLC, EDPR CA Solar Park LLC.

Description: Triennial Market Power Analysis for Southwest Region and Notice of Non-Material Change in Status of EDPR CA Solar Park LLC, et al.

Filed Date: 6/28/22.

Accession Number: 20220628–5174.

Comment Date: 5 p.m. ET 8/29/22.

Docket Numbers: ER22–2209–000.

Applicants: New York State Electric & Gas Corporation.

Description: § 205(d) Rate Filing: Rate Schedule FERC No. 87 Supplement to be effective 9/1/2022.

Filed Date: 6/28/22.

Accession Number: 20220628–5137.

Comment Date: 5 p.m. ET 7/19/22.

Docket Numbers: ER22–2210–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2022–06–28–PSCo-CSU–WACM–666–0.0.0 to be effective 6/29/2022.

Filed Date: 6/28/22.

Accession Number: 20220628–5144.

Comment Date: 5 p.m. ET 7/19/22.

Docket Numbers: ER22–2211–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2045R11 Evergy Kansas Central, Inc. NITSA NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5002.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2212–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2900R18 KMEA NITSA NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5006.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2213–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2562R11 Kansas Municipal Energy Agency NITSA and NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5012.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2214–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1891R11 Evergy Kansas Central, Inc. NITSA NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5017.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2215–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1892R11 Evergy Kansas Central, Inc. NITSA NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5018.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2216–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Modify the Timing of the Day-Ahead Supply Adequacy Study to be effective 12/31/9998.

Filed Date: 6/29/22.

Accession Number: 20220629–5020.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2217–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1978R11 Evergy Kansas Central, Inc. NITSA NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5028.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2218–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1894R11 Evergy Kansas Central, Inc. NITSA NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5029.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2219–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2198R32 Kansas Power Pool NITSA NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5034.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2220–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2415R17 Kansas Municipal Energy Agency NITSA and NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5039.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2222–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1893R12 Evergy Kansas Central, Inc. NITSA NOA to be effective 9/1/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5046.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2223–000.

Applicants: Lowell Cogeneration Company Limited Partnership.

Description: Tariff Amendment: Cancellation entire tariff to be effective 6/30/2022.

Filed Date: 6/29/22.

Accession Number: 20220629–5067.

Comment Date: 5 p.m. ET 7/20/22.

Docket Numbers: ER22–2224–000.
Applicants: Upper Missouri G. & T. Electric Cooperative, Inc.
Description: § 205(d) Rate Filing: Revised FERC Electric Tariff Vol. No. 1 to be effective 7/1/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5075.
Comment Date: 5 p.m. ET 7/20/22.
Docket Numbers: ER22–2225–000.
Applicants: Duke Energy Florida, LLC.
Description: § 205(d) Rate Filing: DEF–SECI RS No. 226 to be effective 9/1/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5089.
Comment Date: 5 p.m. ET 7/20/22.
Docket Numbers: ER22–2226–000.
Applicants: ISO New England Inc., New England Power Pool Participants Committee.
Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: ISO–NE/NEPOOL; Rev. to Modify Process for Interconnection of New DER to be effective 8/28/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5090.
Comment Date: 5 p.m. ET 7/20/22.
Docket Numbers: ER22–2227–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2022–06–29 EIM Entity Agreement—Avangrid to be effective 8/29/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5105.
Comment Date: 5 p.m. ET 7/20/22.
Docket Numbers: ER22–2228–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 2491R10 Evergy Kansas Central, Inc. NITSA NOA to be effective 9/1/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5116.
Comment Date: 5 p.m. ET 7/20/22.
Docket Numbers: ER22–2229–00.0
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 2066R11 Evergy Kansas Central, Inc. NITSA NOA to be effective 9/1/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5125.
Comment Date: 5 p.m. ET 7/20/22.
Docket Numbers: ER22–2230–000.
Applicants: BigBeau Solar, LLC.
Description: Market: Triennial Market Power Update BigBeau Solar to be effective 8/29/2022.
Filed Date: 6/29/22
Accession Number: 20220629–5128.
Comment Date: 5 p.m. ET 8/29/22
Docket Numbers: ER22–2231–000.
Applicants: Maverick Solar 6, LLC.
Description: Market: Triennial Market Power Update Maverick Solar 6 to be effective 8/29/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5133.
Comment Date: 5 p.m. ET 8/29/22.
Docket Numbers: ER22–2232–000.
Applicants: Maverick Solar 7, LLC
Description: Market: Triennial Market Power Update Maverick Solar 7 to be effective 8/29/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5134.
Comment Date: 5 p.m. ET 8/29/22.
Docket Numbers: ER22–2233–000.
Applicants: Desert Harvest, LLC.
Description: Market: Triennial Market Power Update Desert Harvest to be effective 8/29/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5136.
Comment Date: 5 p.m. ET 8/29/22.
Docket Numbers: ER22–2234–000.
Applicants: Desert Harvest II LLC.
Description: Market: Triennial Market Power Update Desert Harvest II to be effective 8/29/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5141.
Comment Date: 5 p.m. ET 8/29/22.
Docket Numbers: ER22–2235–000.
Applicants: Maverick Solar, LLC.
Description: Market: Triennial Market Power Update Maverick Solar to be effective 8/29/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5146.
Comment Date: 5 p.m. ET 8/29/22.
Docket Numbers: ER22–2236–000.
Applicants: Maverick Solar 4, LLC.
Description: Market: Triennial Market Power Update Maverick Solar 4 to be effective 8/29/2022.
Filed Date: 6/29/22.
Accession Number: 20220629–5150.
Comment Date: 5 p.m. ET 8/29/22.

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: June 29, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–14327 Filed 7–5–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: RP22–872–001.
Applicants: East Cheyenne Gas Storage, LLC.
Description: Compliance filing: ECGS 2022–06–28 Docket No. RP22–872 Compliance to be effective N/A.
Filed Date: 6/28/22.
Accession Number: 20220628–5111.
Comment Date: 5 p.m. ET 7/11/22.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 29, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–14323 Filed 7–5–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RC11–6–013]

North American Electric Reliability Corporation; Notice of Staff Review of Enforcement Programs

Commission staff coordinated with the staff of the North American Electric

Reliability Corporation (NERC) to conduct the annual oversight of the Find, Fix, Track and Report (FFT) program, as outlined in the March 15, 2012 Order,[1] and the Compliance Exception (CE) Program, as proposed by NERC's September 18, 2015 annual Compliance Filing and accepted by delegated letter order.[2]

Commission staff reviewed a sample of 29 FFT noncompliances out of 191 FFT noncompliances posted by NERC between October 2020 and September 2021 and a sample of 32 CE noncompliances out of 1,050 CE noncompliances posted by NERC between October 2020 and September 2021.

Commission staff found that the FFT and CE programs are meeting expectations, with limited exceptions. Specifically, Commission staff identified one instance where the CE would be more appropriate as an FFT with a moderate risk. Staff also noted in two instances of FFT that the originally posted description of the noncompliances were incomplete. The Regional Entities appropriately included 60 of the 61 samples in the FFT and CE programs, and all 61 FFTs and CEs have been adequately remediated and the root cause of each noncompliance was clearly identified. Commission staff also reviewed the supporting information for these FFTs or CEs and agreed with the final risk determinations for 60 of the 61 noncompliances, which clearly identified the factors affecting the risk prior to mitigation (such as potential and actual risk) and actual harm.

Finally, Commission staff noted that the FFTs and CEs sampled did not contain any material misrepresentations by the registered entities.

Dated: June 29, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–14331 Filed 7–5–22; 8:45 am]

BILLING CODE 6717–01–P

[1] *North American Electric Reliability Corp.,* 138 FERC ¶ 61,193, at P 73 (2012) (discussing Commission plans to survey a random sample of FFTs submitted each year to gather information on how the FFT program is working).

[2] *North American Electric Reliability Corp.,* Docket No. RC11–6–004, at 1 (Nov. 13, 2015) (delegated letter order) (accepting NERC's proposal to combine the evaluation of CEs with the annual sampling of FFTs).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP16–10–000; CP21–57–000; CP19–477–000]

Mountain Valley Pipeline, LLC; Notice of Request for Extension of Time

Take notice that on June 24, 2022, Mountain Valley Pipeline, LLC (Mountain Valley) requested that the Federal Energy Regulatory Commission (Commission) grant an extension of time, until October 13, 2026, to complete construction of the Mountain Valley Pipeline Project (Project) and place the Project facilities into service, as authorized in the October 13, 2017 Order Issuing Certificate.[1] On October 9, 2020, the Commission issued an order granting a two-year extension of time, until October 13, 2022, for Mountain Valley to complete construction of the Project and place the Project facilities into service.[2] On April 8, 2022, the Commission issued an order amending the Project certificate to permit Mountain Valley to: (1) change the crossing method for 183 waterbodies and wetlands; (2) slightly shift the permanent right-of-way at mileposts 0.70 and 230.8 to avoid one wetland and one waterbody, respectively; and (3) conduct 24-hour construction activities at eight trenchless crossings. The Commission conditioned the Amendment Order on Mountain Valley completing construction by the October 13, 2022 construction deadline.

Mountain Valley states that its request for an extension of time is due to the ongoing litigation and remand proceedings related to several permits and authorizations in the above identified dockets.

Mountain Valley states that it has shown good cause for the extension as Project construction is substantially complete and Mountain Valley is actively working to reinstate all required permits so that it can complete construction as expeditiously as possible. Mountain Valley avers it is currently obtaining all necessary permits, including updated environmental findings where applicable, that will be in place before Mountain Valley is permitted to complete construction of the Project. Mountain Valley states it has expended approximately $5.5 billion on the Project to date and the Project's total cost is targeted to be approximately $6.6 billion. Mountain Valley states its extension of time request is necessary to maintain its erosion and sedimentation control program. Finally, Mountain Valley states that the Project remains fully subscribed under binding long-term agreements. Accordingly, Mountain Valley requests an extension of the October 13, 2022 deadline until October 13, 2026, to complete construction of the Mountain Valley Pipeline Project and place the Project facilities into service.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on Mountain Valley'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 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).

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

[1] *Mountain Valley Pipeline, LLC,* 161 FERC ¶ 61,043 (2017), *order on reh'g,* 163 FERC ¶ 61,197 (2018) (''Certificate Order''), *aff'd sub. nom., Appalachian Voices* v. *FERC,* No. 17–1271, 2019 WL 847199 (D.C. Cir. Feb. 19, 2019). The Order required Mountain Valley to construct and place the facilities in service within three years of the date of the Order or October 13, 2020.

[2] *Mountain Valley Pipeline, LLC,* 173 FERC ¶ 61,026 (2020), *petition for review pending sub nom. Sierra Club* v. *FERC,* No. 20–1512 (D.C. Cir.) (oral argument held Apr. 7, 2022). On September 29, 2021, Mountain Valley filed a request for extension of time in Docket No. CP19–477–000 to align the in-service deadline for its already-constructed Greene Interconnect with that for the mainline Project. The Commission has not yet acted on that uncontested request. As part of the instant request, Mountain Valley is modifying the pending request in that docket for consistency.

[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.

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 July 14, 2022.

Dated: June 29, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–14332 Filed 7–5–22; 8:45 am]

BILLING CODE 6717–01–P

[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).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2022–0511; FRL–9986–01–OGC]

Proposed Consent Decree, Unreasonable Delay Claim Regarding Petition Concerning Treated Seeds and Treated Article Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Environmental Protection Agency (EPA) Administrator's March 18, 2022, Memorandum entitled Consent Decrees and Settlement Agreements to Resolve Environmental Claims Against the Agency, notice is hereby given of a proposed consent decree that resolves *Center for Food Safety, et al.* v. *U.S. Environmental Protection Agency,* a case in the United States District Court for the Northern District of California (3:21–cv–09640–JSC) that alleges EPA unreasonably delayed responding to a petition for rulemaking, submitted to EPA on or around April 26, 2017, relating to the regulatory exemption of pesticide treated seed.

DATES: Written comments on the proposed consent decree must be received by August 5, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2022–0511 online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments, see the ''Additional Information about Commenting on the Proposed Consent Decree'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Amber Aranda, Pesticides and Toxic Substances Law Office; telephone (202) 564–3186; email address *aranda.amber@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2022–0511) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains a copy of the proposed consent decree and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Consent Decree

Prior to this lawsuit being filed, EPA received a petition on or around April 26, 2017, requesting that EPA (1) amend 40 CFR 152.25(a) to exclude seeds for planting coated with systemic pesticides intended to kill pests of the plant, or, (2) in the alternative, publish a formal agency interpretation in the **Federal Register** stating that 40 CFR 152.25(a) does not apply to seeds for planting coated with systemic pesticides intended to kill pests of the plant, and (3) aggressively enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic insecticidal chemical (hereinafter, this petition will be referred to as the ''2017 Petition'' and the three requests enumerated in this paragraph will be referred to as the ''2017 Petition Requests''). EPA sought public comment on the 2017 Petition. *See* ''Pesticides; Petition Seeking Rulemaking or a Formal Agency Interpretation for Planted Seeds Treated with Systemic Insecticides; Request for Comment,'' 83 FR 66260 (December 26, 2018) (the ''Request for Comment''). EPA received approximately 100 substantive comments. Plaintiffs filed a Complaint on December 14, 2021, alleging that EPA's failure to respond to the petition constitutes an unreasonable delay under Section 706(1) of the Administrative Procedure Act, 5 U.S.C. 706(1).

This proposed consent decree states that no later than September 30, 2022, the appropriate EPA official shall, by

letter, either grant, deny, or grant in part and deny in part each of the 2017 Petition Requests. Court approval of this proposed consent decree would resolve all claims in this case except for the claim for the costs of litigation, including reasonable attorneys' fees.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who are not named as parties to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the APA or FIFRA. Unless EPA or the Department of Justice determines that consent should be withdrawn, the terms of the proposed consent decree will be affirmed and entered with the Court.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2022–0511 via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, 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.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Dated: June 30, 2022.

Randolph L. Hill,

Associate General Counsel.

[FR Doc. 2022–14338 Filed 7–5–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, July 12, 2022 at 10:00 a.m. and its continuation at the conclusion of the open meeting on July 14, 2022.

PLACE: 1050 First Street NE, Washington, DC and virtual (this meeting will be a hybrid meeting).

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2022–14436 Filed 7–1–22; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice

TIME AND DATE: 10:00 a.m., Thursday, July 14, 2022.

PLACE: The Richard V. Backley Hearing Room, Room 511, 1331 Pennsylvania Avenue NW, Suite 504 North, Washington, DC 20004 (enter from F Street entrance).

Note that workplace policies instituted to address the COVID–19 pandemic may restrict the ability of some participants to take part in the argument in-person. Those participants will join the argument through a videoconference involving all other participants who are appearing in-person.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument in the matter *Peabody Midwest Mining, LLC and Butler employed by Peabody Midwest Mining, LLC,* Docket Nos. LAKE 2019–0023, 2019–0122, 2019–0361. (Issues include whether the Judge erred in concluding that the operator violated standards when it failed to immediately de-energize equipment and stop work when it encountered high methane levels, whether the violations were significant and substantial, and whether a supervisor was liable for individual penalties.)

Pursuant to the Commission's COVID–19 Workplace Safety Plan, in-person attendance shall be limited to persons participating in the oral argument process (*e.g.,* Chair and Commissioners, parties and their representatives, Commission employees providing support for the meeting). Non-participating individuals may listen to the meeting by calling the phone number listed below in this notice.

Any person attending this oral argument who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202)

708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO MEETING: 1–(866) 236–7472, Passcode: 678–100.

Authority: 5 U.S.C. 552b.

Dated: July 1, 2022.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2022–14451 Filed 7–1–22; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice

TIME AND DATE: 10:00 a.m., Friday, July 15, 2022.

PLACE: The Richard V. Backley Hearing Room, Room 511, 1331 Pennsylvania Avenue NW, Suite 504 North, Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Peabody Midwest Mining, LLC and Butler employed by Peabody Midwest Mining, LLC,* Docket Nos. LAKE 2019–0023, 2019–0122, 2019–0361. (Issues include whether the Judge erred in concluding that the operator violated standards when it failed to immediately de-energize equipment and stop work when it encountered high methane levels, whether the violations were significant and substantial, and whether a supervisor was liable for individual penalties.)

Pursuant to the Commission's COVID–19 Workplace Safety Plan, in-person attendance shall be limited to persons participating in the decisional process (*e.g.,* Chair and Commissioners, Commission employees providing support for the meeting). Non-participating individuals may listen to the meeting by calling the phone number listed below in this notice.

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO MEETING: 1–(866) 236–7472, Passcode: 678–100.

Authority: 5 U.S.C. 552b.

Dated: July 1, 2022.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2022–14454 Filed 7–1–22; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Systemic Risk Report (FR Y–15; OMB No. 7100–0352).

DATES: Comments must be submitted on or before September 6, 2022.

ADDRESSES: You may submit comments, identified by FR Y–15, 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 the OMB number or FR number in the subject line of the message.
- Fax: (202) 452–3819 or (202) 452–3102.
- *Mail:* Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M–4775, 2001 C St NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M–4365A, 2001 C St NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Collection title: Systemic Risk Report.
Collection identifier: FR Y–15.
OMB control number: 7100–0352.
Frequency: Quarterly.
Respondents: The FR Y–15 panel is comprised of top-tier U.S. bank holding companies (BHCs) and covered savings and loan holding companies (SLHCs) with $100 billion or more in total consolidated assets,[1] foreign banking organizations (FBOs) with $100 billion or more in total combined U.S. assets, and any U.S. BHC designated as a global systemically important bank (GSIB) based on its method 1 score calculated under 12 CFR 217.404 as of December 31 of the previous calendar year.[2]
Estimated number of respondents: 52.
Estimated average hours per response: Reporting, 404; Recordkeeping, 1.
Estimated annual burden hours: Reporting, 84,032; Recordkeeping, 208.
General description of collection: The FR Y–15 quarterly report collects systemic risk data from the respondents listed above. The Board uses the FR Y–15 data to monitor, on an ongoing basis, the systemic risk profile of certain financial institutions that are subject to enhanced prudential standards under section 165 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).[3] In addition, the FR Y–15 is used to (i) facilitate the implementation of the surcharge for GSIBs, (ii) identify other financial institutions which may present significant systemic risk, and (iii) analyze the systemic risk implications of proposed mergers and acquisitions.
Legal authorization and confidentiality: Sections 163 and 165 of the Dodd-Frank Act, as amended by the Economic Growth, Regulatory Relief, and Consumer Protection Act, authorize the Board to consider risk to U.S. financial stability in regulating and examining BHCs with $100 billion or more in consolidated assets and nonbank financial companies that are under the Board's supervision.[4] The Board is further authorized to impose prudential standards for such entities and to differentiate among companies on an individual basis or by category, taking into consideration their capital structure, complexity, financial activities, size, and any other risk-related factors that the Board deems appropriate.[5] This authorization also covers certain foreign banks with U.S. operations under the International Banking Act (IBA).[6] Sections 165(b)(1)(B) and 165(f) of the Dodd-Frank Act authorize the Board to establish enhanced public disclosures for companies subject to prudential standards under section 165.[7]

In addition, the reporting requirements associated with the FR Y–15 are authorized for BHCs pursuant to section 5 of the BHC Act;[8] for SLHCs pursuant to sections 10(b)(2) and 10(g) of the Home Owners' Loan Act;[9] and for IHCs pursuant to section 5 of the BHC Act and sections 8(a) and 13(a) of the IBA.[10]

The FR Y–15 report is mandatory. Most information provided on the FR Y–15 is made public unless a reporting entity submits a specific request for confidentiality, either on the FR Y–15 or on the form from which the data item is obtained.[11] Such information may be kept confidential under exemption 4 of the Freedom of Information Act (FOIA) if the submitter substantiates that it is confidential commercial or financial information that is both customarily and actually treated as private.[12] In addition, items 1 through 4 of Schedule G, which contain sensitive information regarding the reporting entity's liquidity position, may be accorded confidential treatment under exemption 4 until the first reporting date after the final liquidity coverage ratio disclosure standard has been implemented. Information collected on the FR Y–15 may also be considered confidential under FOIA exemption 8 if it is obtained as part of an examination or supervision of a financial institution.[13]

Board of Governors of the Federal Reserve System, June 30, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–14374 Filed 7–5–22; 8:45 am]

BILLING CODE 6210–01–P

[1] Covered SLHCs are those that are not substantially engaged in insurance or commercial activities. *See* 12 CFR 217.2.

[2] *See* 12 CFR 217.402.

[3] Public Law 111–203 (2010); 12 U.S.C. 5365.

[4] 12 U.S.C. 5363; 5365.

[5] 12 U.S.C. 5365(a)(2)(C). The Board is required to establish prudential standards for BHCs with assets equal to or greater than $250 billion and nonbank financial companies supervised by the Board that (A) are more stringent than the standards and requirements applicable to nonbank financial companies and bank holding companies that do not present similar risks to the financial stability of the United States; and (B) increase in stringency based on the considerations enumerated in section 165(b)(3). 12 U.S.C. 5365(a)(1).

[6] 12 U.S.C. 3106(a). Section 8(a)provides that certain foreign banks with U.S. operations will be treated as BHCs for purposes of the Bank Holding Company Act (BHC Act), and sections 163 and 165 of the Dodd-Frank Act amend the BHC Act.

[7] 12 U.S.C. 5365(b)(1)(B) and (f).

[8] 12 U.S.C. 1844.

[9] 12 U.S.C. 1467a(b)(2); 1467a(g).

[10] 12 U.S.C. 3106(a); 3108(a).

[11] Several data items in the FR Y–15 are retrieved from the FR Y–9C and other items may be retrieved from the FFIEC 101. Confidential treatment will also extend to any automatically calculated items on the FR Y–15 that have been derived from confidential data items and that, if released, would reveal the underlying confidential data.

[12] 5 U.S.C. 552(b)(4).

[13] 5 U.S.C. 552(b)(8).

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Transfer Agent Registration and Amendment Form and Transfer Agent Deregistration Form (Form TA–1 and Form TA–W); OMB No. 7100–0099).

DATES: Comments must be submitted on or before September 6, 2022.

ADDRESSES: You may submit comments, identified by Form TA–1 or Form TA–W, 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 the OMB number or FR number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M–4775, 2001 C St NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless

modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M–4365A, 2001 C St NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

Collection title: Transfer Agent Registration and Amendment Form and Transfer Agent Deregistration Form.

Collection identifier: Form TA–1 and Form TA–W.

OMB control number: 7100–0099.

Frequency: As needed.

Respondents: The respondent panel for this collection of information consists of current and former transfer agents that are a state member bank (SMB) or a subsidiary thereof, a bank holding company (BHC), a savings and loan holding company (SLHC), or a subsidiary of a BHC that is a bank within the meaning of the Securities Exchange Act of 1934 (Exchange Act) and that is not required to register with the Office of the Comptroller of the Currency (OCC) or the Federal Deposit Insurance Corporation (FDIC).

Estimated number of respondents: Registrations, 1; Amendments, 1; Deregistrations, 1.

Estimated average hours per response: Registrations, 1.25; Amendments, 0.16; Deregistrations, 0.5.

Estimated annual burden hours: Registrations, 1; Amendments, 0.16; Deregistrations, 1.

General description of collection: The Exchange Act requires any person acting as a transfer agent [1] to register as such with the appropriate regulatory agency (ARA). The Board is the ARA for transfer agents listed in the respondents section above. Transfer agents for which the Board is the ARA must register with the Board using Form TA–1. Additionally, registered transfer agents for which the Board is their ARA may deregister by submitting Form TA–W.

Proposed revisions: The Board proposes to utilize its own Form TA–W for respondents to deregister rather than asking respondents to use a Securities and Exchange Commission (SEC) form or submit a separate letter, as has been done in the past. This would allow the Board to have its OMB control number on the form and make changes in the future if necessary. The draft Form TA–W asks the same type of information that is on the SEC deregistration form.

Legal authorization and confidentiality: This information collection is authorized under section 17A(c) of the Exchange Act.[2] The collection is also authorized under sections 2, 17(a)(3), and 23(a) of the Exchange Act [3] and under the Board's general authority to require reports from SMBs,[4] BHCs,[5] and SLHCs.[6] The collection is mandatory for transfer agents for which the Board is the ARA. Information collected on the forms is available to the public upon request and is not considered confidential.

Consultation outside the agency: The SEC, Board, FDIC, and OCC jointly developed the Form TA–1 and associated instructions, and the Board has consulted with the FDIC and OCC to determine whether revisions to that form are necessary.

[1] Transfer agents are persons that provide securities transfer, registration, monitoring, and other specified services on behalf of securities issuers. See 15 U.S.C. 78c(25) (defining ''transfer agent'').

[2] 15 U.S.C. 78q–1(c) (requiring all transfer agents for securities registered under section 12 of the Exchange Act to register with the ARA by filing ''an application for registration in such form and containing such information'' as the ARA may prescribe).

[3] 12 U.S.C. 78b, 78q(a)(3) and 78w(a) (authorizing the Board to promulgate regulations and establish recordkeeping and reporting requirements with respect to Board-registered Transfer Agents).

[4] 12 U.S.C. 248(a) and 324.

[5] 12 U.S.C. 1844(c).

[6] 12 U.S.C. 1467a(b) and (g).

Board of Governors of the Federal Reserve System, June 30, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–14364 Filed 7–5–22; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Notice of Proposed Stock Redemption (FR 4008; OMB No. 7100–0131).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Notice of Proposed Stock Redemption.

Collection identifier: FR 4008.

OMB control number: 7100–0131.

Frequency: On occasion.

Respondents: Bank holding companies (BHCs).

Estimated number of respondents: 6.

Estimated average hours per response: 15.5.

Estimated annual burden hours: 93.

General description of collection: The Bank Holding Company Act of 1956 (BHC Act) and Board's Regulation Y—Bank Holding Companies and Change in Bank Control (12 CFR 225) require a BHC to seek the prior approval of the Board before purchasing or redeeming its equity securities in certain circumstances. Due to the limited information that a BHC must provide in connection with any such request, there is no required reporting form (the FR 4008 designation is for internal purposes only), and each request for prior approval is generally filed 30 days before the proposed stock purchase or redemption as a notification with the Reserve Bank that has direct supervisory responsibility for the requesting BHC. The Federal Reserve uses the information provided in the redemption notices to supervise BHCs.

Legal authorization and confidentiality: The FR 4008 is authorized pursuant to sections 5(b) and (c) of the BHC Act.[1] Section 5(b) of the BHC Act, as amended by section 616 of the Dodd-Frank Wall Street Reform and Consumer Protection Act,[2] authorizes the Board to ''issue such regulations and orders, including regulations and orders relating to the capital requirements for bank holding companies, as may be necessary to enable it to administer and carry out the purposes of this chapter and prevent evasions thereof.'' Section 5(c) of the BHC Act generally authorizes the Board to, among other things, require reports from BHCs on a range of issues. The FR 4008 is required for certain BHCs to obtain the benefit of being able to purchase or redeem their equity securities.

Individual respondents may request that data submitted be kept confidential. If a respondent requests confidential treatment, the Board will determine whether the information is entitled to confidential treatment on an ad hoc basis. Requests may include information related to the BHC's business operations, such as terms and sources of the funding for the redemption and pro forma balance sheets. To the extent that this information constitutes nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, it may be kept confidential under exemption 4 of the Freedom of Information Act, which exempts ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.'' [3]

Current actions: On March 2, 2022, the Board published a notice in the **Federal Register** (87 FR 11706) requesting public comment for 60 days on the extension, without revision, of the FR 4008. The comment period for this notice expired on May 2, 2022. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, June 30, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–14376 Filed 7–5–22; 8:45 am]

BILLING CODE 6210–01–P

[1] 12 U.S.C. 1844(b) and (c).

[2] Public Law 111–203, 124 Stat. 1376 (2010).

[3] 5 U.S.C. 552(b)(4).

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

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 question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the 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 July 21, 2022.

A. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Jonesboro Bancshares, Inc., Jonesboro, Louisiana;* to engage de novo in extending credit and servicing loans pursuant to section 225.28(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–14366 Filed 7–5–22; 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 July 21, 2022.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291, or electronically to *MA@mpls.frb.org*:

1. *The Alix E. Behm Revocable Living Trust, Alix E. Behm, as trustee; and the Kenneth M. Behm Revocable Living Trust, Kenneth M. Behm, as trustee, all of Willmar, Minnesota;* to join the Behm Family Shareholder Group, a group acting in concert, to acquire voting shares of Kandiyohi Bancshares, Inc., Willmar, Minnesota, and thereby indirectly acquire voting shares of Home State Bank, Litchfield, Minnesota.

B. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Scotty Dan Allen and Johnny Brad Allen, both of Stephenville, Texas;* as a group acting in concert to acquire additional voting shares of F & M Bancshares, Inc., and thereby indirectly acquire voting shares of Farmers and Merchants Bank, both of De Leon, Texas. In addition, Scotty Dan Allen, individually, to retain voting shares of F & M Bancshares, Inc., and thereby indirectly retain voting shares of Farmers and Merchants Bank.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–14379 Filed 7–5–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Notice by Financial Institutions of Government Securities Broker or Government Securities Dealer Activities and Notice by Financial Institutions of Termination of Activities as a Government Securities Broker or Government Securities Dealer (Form G–FIN and Form G–FINW; OMB No. 7100–0224).

DATES: Comments must be submitted on or before September 6, 2022.

ADDRESSES: You may submit comments, identified by Form G–FIN or Form G–FINW, 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 the OMB number or FR number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M–4775, 2001 C St NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement, and other documentation, will be made available

on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at *https://www.reginfo.gov/public/do/PRAMain,* if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collections

Collection title: Notice by Financial Institutions of Government Securities Broker or Government Securities Dealer Activities and Notice by Financial Institutions of Termination of Activities as a Government Securities Broker or Government Securities Dealer.

Collection identifiers: Form G–FIN and Form G–FINW.

OMB control number: 7100–0224.

Frequency: Event-generated.

Respondents: State member banks, foreign banks, uninsured state branches or state agencies of foreign banks, commercial lending companies owned or controlled by foreign banks, and Edge Act corporations (collectively, Board-regulated financial institutions) that are required to register as government security brokers or government security dealers and those entities that have terminated such activities.

Estimated number of respondents:

Reporting
Form G–FIN: 39; Form G–FINW: 1
Recordkeeping
Form G–FIN: 39; Form G–FINW: 1

Estimated average hours per response:

Reporting
Form G–FIN: 1; Form G–FINW: 0.25
Recordkeeping
Form G–FIN: 0.25; Form G–FINW: 0.25

Estimated annual burden hours:

Reporting
Form G–FIN: 39; Form G–FINW: 10
Recordkeeping
Form G–FIN: 0; Form G–FINW: 0 [1]

General description of collection: The Securities Exchange Act of 1934, as amended (the Act), requires financial institutions to notify their appropriate regulatory agency (ARA) prior to using the mails or any means or instrumentality of interstate commerce to engage in government securities broker or dealer activities, and to notify their ARA upon terminating such activities. The Board is the ARA for Board-regulated financial institutions. A Board-regulated financial institution must use Form G–FIN to register as a government securities broker or dealer or to amend a previously submitted Form G–FIN and must use Form G–FINW to notify the Board of its termination of such activities.

Legal authorization and confidentiality: Form G–FIN and Form G–FINW are authorized under section 15C of the Act,[2] which requires a financial institution that is a broker or dealer of government securities to submit a written notice advising its ARA that it is a government securities broker or a government securities dealer or that it has ceased to act as such. The Act also directs the Board, in consultation with the other ARAs (the Federal Deposit Insurance Corporation (FDIC) and the Office of the Comptroller of the Currency (OCC)),[3] as well as with the Securities and Exchange Commission (SEC), to prescribe the form of and the information collected in these notices.[4] Further support for the creation and collection of these notices by the Board is found in Department of Treasury (Treasury) regulations, authorized by section 15 of the Act, which state that the Form G–FIN and Form G–FINW are promulgated by the Board and that such forms are to be used by non-exempt [5] financial institutions to notify their ARA of their status as government securities brokers or dealers or the termination of such status.[6]

Section 15C of the Act also instructs the Secretary of the Treasury to promulgate recordkeeping requirements regarding the forms and records to be retained by government securities brokers and dealers and to specify the time period for which such records shall be preserved. Accordingly, the recordkeeping requirement associated with these forms is contained in 17 CFR 404.4, which requires state member banks and uninsured state branches or state agencies of foreign banks, as well as other institutions, to retain these forms for three years after the financial institution notifies its ARA that it has ceased to function as a government securities broker or dealer. Although Treasury's recordkeeping requirement does not explicitly apply to foreign banks, to Edge corporations, or to commercial lending companies that are owned or controlled by foreign banks, the Board has the authority to ''issue such rules and regulations with respect to transactions in government securities as may be necessary to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade.'' [7] Imposing a recordkeeping requirement on foreign banks, Edge corporations, and commercial lending companies owned or controlled by foreign banks is necessary for the public interest and protection of investors in order to ensure that the proper notification has been provided when these institutions are transacting in government securities. In addition, the Board is authorized to impose recordkeeping requirements on foreign banks,[8] Edge corporations,[9] and on commercial lending companies that are owned or controlled by foreign

[1] Due to the mechanics of the RISC/OIRA Consolidated Information System (ROCIS), fractional amounts below 0.5 are rounded to 0.

[2] 15 U.S.C. 78o–5(a)(l)(B).

[3] These forms are also collected by the FDIC and the OCC, respectively, for government securities brokers and dealers under their supervision. A copy of the form filed with each ARA is also made available by the ARA to the SEC under the Act. 15 U.S.C. 78o–5(a)(1)(B)(iii).

[4] 15 U.S.C. 78o–5(a)(l)(B)(ii).

[5] The Act permits the Secretary of the Treasury to exempt certain government securities brokers or dealers, 15 U.S.C. 78o–5(a)(5), and the Secretary of the Treasury has promulgated regulations exempting certain types of firms. See 17 CFR part 401.

[6] See 17 CFR 400.1(d), 449.1, and 449.2; see also 17 CFR 400.5(b) (requiring that any amendments or corrections to the notice of status of government securities broker or dealer be filed by the financial institution on Form G–FIN within 30 days).

[7] 15 U.S.C. 78o–5(b)(3)(A). See 15 U.S.C. 78o–5(a)(1)(B).

[8] 12 U.S.C. 3107 and 3108.

[9] 12 U.S.C. 625.

banks.[10] The obligation to file the Form G–FIN and Form G–FINW with the Board, and the obligation for the government securities broker or dealer to retain a copy of the Form G–FIN and Form G–FINW, is mandatory for those financial institutions for which the Board serves as the ARA, unless the financial institution is exempt from the reporting requirement under Treasury's regulations. The filing of these forms and the records retention period is event-generated.

Under the Act, each ARA is instructed to make these forms available to the SEC, and the SEC is instructed to make the notices available to the public.[11] Thus, the information collected on Form G–FIN and Form G–FINW is ordinarily not treated as confidential.[12] However, given that Item 6 of Form G–FIN instructs the filer to attach copies of the confidential Form G–FIN–4, or if applicable, to attach copies of any previously filed confidential Form MSD–4 or confidential Form U–4, such attachments may be treated as confidential by the Board under exemptions 4 and/or 6 of the Freedom of Information Act.[13]

Consultation outside the agency: The Board consulted with the FDIC, OCC, and SEC in confirming that there were no changes needed to the collection as part of this clearance.

Board of Governors of the Federal Reserve System, June 30, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–14375 Filed 7–5–22; 8:45 am]

BILLING CODE 6210–01–P

[10] 12 U.S.C. 3106, as applied through 12 U.S.C. 1844(c).

[11] 15 U.S.C. 78o–5(a)(l)(B)(iii).

[12] The Board's Regulation H provides that any person filing any statement, report, or document under the Act may submit written objection to the public disclosure of the information when such information is filed in accordance with the procedures provided in 12 CFR 208.36(d). In addition, if a respondent believes that information disclosed on these forms constitutes nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, the respondent may request confidential treatment pursuant to exemption 4 of the Freedom of Information Act (FOIA) pursuant to the Board's Rules Regarding the Availability of Information, 12 CFR 261.15.

[13] Generally, information provided on Form MSD–4 and Form MSD–5 will be kept confidential from the public under exemption 6 of the FOIA, which protects information in ''personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.'' 5 U.S.C. 552(b)(6). In addition, other information on Form MSD–4 and Form MSD–5, such as the name of the municipal securities dealer that filed the form, may be withheld under exemption 4 of the FOIA, if it constitutes nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent (*e.g.,* if a municipal securities dealer recently hired or terminated a number of municipal securities employees, disclosing these forms could reveal competitively sensitive commercial information about that dealer). 5 U.S.C. 552(b)(4). We note that FINRA's Form U–4 collects the social security number and other personally identifiable information about an individual, which may be withheld under the Privacy Act, 5 U.S.C. 552b. In addition, Treasury's Form G–FIN–4 states ''[t]he Department of the Treasury and the appropriate regulatory agencies regard the information provided by each respondent on this form as confidential.''

FEDERAL TRADE COMMISSION

[File No. 222 3012]

MWE Investments, LLC; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis of Proposed Consent Order to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 5, 2022.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''MWE Investments, LLC; File No. 222 3012'' on your comment and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Melissa Dickey (202–326–2662), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 5, 2022. Write ''MWE Investments, LLC; File No. 222 3012'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''MWE Investments, LLC; File No. 222 3012'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form,

must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this document and the news release describing the proposed settlement. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 5, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (the ''Commission'') has accepted, subject to final approval, an agreement containing a consent order from MWE Investments, LLC, a manufacturer and licensor of the Westinghouse brand mark for use on outdoor power equipment (''Respondent'' or ''Westinghouse'').

The proposed consent order (''Proposed Order'') has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the agreement, along with any comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the Proposed Order.

This matter involves the warranty that Westinghouse offers to purchasers of its outdoor generators. According to the Commission's complaint, the warranty is conditioned on purchasers using authorized Westinghouse parts and accessories; otherwise, the warranty is void.

Based on the foregoing, the Commission alleges that Respondent violated the Magnuson-Moss Warranty Act and regulations promulgated thereunder and engaged in deceptive acts or practices in violation of Section 5(a) of the FTC Act.

The Proposed Order contains injunctive provisions addressing the alleged deceptive conduct. Section I prohibits Respondent from expressly or implicitly conditioning a warranty on a consumer's use of any article or service which is identified by brand, trade, or corporate name, unless the article or service is offered for free or the Commission has issued a waiver to the company, or from otherwise violating the Warranty Act or the Rules promulgated thereunder. Section II prohibits Respondent from representing to consumers, expressly or by implication, (a) that its warranties will be void if they use third-party parts or services or if they modify or alter the product without authorization, or (b) that consumers should only use branded parts or have their product repaired, altered or serviced by authorized service providers, but permits Respondent to represent that it will exclude warranty coverage and deny warranty claims if a generator is modified in a manner that results in increased carbon monoxide emissions, or that results in the removal of carbon monoxide sensors, safety warnings, guards, or other parts that affect the safe or intended performance or use of the generator. Section II also requires Respondent to include language in the warranty that affirmatively notifies consumers of their rights to use third-party services and parts under the Magnuson-Moss Warranty Act and enjoins Respondent from both misrepresenting any material facts to consumers about the warranty.

Sections III and IV require Respondent to inform its customers whose products are under warranty, as well as authorized dealers and repair shops, that its warranty has been updated, and that the updated warranty is not conditioned on the use of authorized parts or services. Respondent must clearly and conspicuously post and keep on its website the notice and its updated warranty terms, and it must submit reports regarding its notification program.

Sections V through VII of the Proposed Order are reporting and compliance provisions, which include recordkeeping requirements and provisions requiring Respondent to provide information or documents necessary for the Commission to monitor compliance with the Proposed Order. Section IX states that the Proposed Order will remain in effect for twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the Proposed Order. It is not intended to constitute an official interpretation of the complaint or Proposed Order, or to modify in any way the Proposed Order's terms.

By direction of the Commission.

April J. Tabor,

Secretary.

Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter

Today the Commission announced actions settling charges that Harley-Davidson, LLC and MWE Investments, LLC (''Westinghouse'') have engaged in unlawful repair restrictions. As stated in the complaints, the Commission charged Harley-Davidson, which manufactures motorcycles and related equipment, and Westinghouse, which makes and sells outdoor generators and related products, with unlawfully conditioning their warranties on the use of authorized parts in violation of both the Magnuson-Moss Warranty Act and the FTC Act. The Commission also alleged that Harley-Davidson failed to provide a clear description of warranty terms in a single document, a violation of the Disclosure Rule.

The consent orders obtained in these matters bar both manufacturers from continuing the unlawful tying of their warranties to the use of authorized service or parts and prohibit them from misrepresenting any material facts about the warranty. Importantly, the firms are also required to note clearly and conspicuously in public statements that using third-party parts or repair services will not void the warranty. They must also provide customers with clear notice alerting them of the change.

In July 2021, the Commission unanimously adopted a policy statement that committed the agency to prioritizing enforcement actions tackling unlawful repair restrictions.[1]

[1] Press Release, Fed. Trade Comm'n, FTC to Ramp Up Law Enforcement Against Illegal Repair Restrictions (July 21, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/07/ftc-ramp-law-enforcement-against-illegalrepair-restrictions.* This policy statement followed a July 2019 workshop that the FTC held on unlawful repair restrictions and a May 2021 report documenting the types of repair restrictions that firms frequently impose and the various arguments criticizing and defending them. See Nixing the Fix: A Workshop on Repair Restrictions, Fed. Trade Comm'n (July 16, 2019), *https://www.ftc.gov/news-events/events/2019/07/nixing-fix-workshop-repairrestrictions;* Press Release, Fed. Trad Comm'n, FTC Report to

Today's enforcement actions—the first addressing unlawful repair restrictions since we adopted the policy statement—mark an important step forward, demonstrating our commitment to vigorously protecting Americans' right to repair. We are grateful to the Bureau of Consumer Protection staff for their excellent work driving this effort forward.

Illegal repair restrictions can significantly raise costs for consumers, stifle innovation, close off business opportunity for independent repair shops, create unnecessary electronic waste, delay timely repairs, and undermine resiliency—harms that can have an outsized impact on low-income communities in particular.[2] It is critical that unlawful repair restrictions continue to be a key area of focus for the Commission and that we continue to use all of our tools and authorities to root out these illegal practices.

[FR Doc. 2022–14286 Filed 7–5–22; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice and request for comment.

SUMMARY: The FTC requests that the Office of Management and Budget (OMB) extend for three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the agency's Mail, internet, or Telephone Order Merchandise Rule (MITOR or Rule). That clearance expires on July 31, 2022.

DATES: Comments must be received by August 5, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. The *reginfo.gov* web link is a United States Government website produced by OMB and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

FOR FURTHER INFORMATION CONTACT: Jock Chung, 202–326–2984, Attorney, Enforcement Division, Bureau of Consumer Protection, 600 Pennsylvania Avenue NW, Mail Drop CC–9528, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Title: Mail, internet, or Telephone Order Merchandise Rule (MITOR or Rule), 16 CFR part 435.

OMB Control Number: 3084–0106.

Type of Review: Extension of a currently approved collection.

Abstract: Generally, the MITOR requires a seller (or merchant) to: (1) have a reasonable basis for any express or implied shipment representation made in soliciting the sale (if no express time period is promised, the implied shipment representation is 30 days); (2) notify the buyer (or consumer) and obtain the buyer's consent to any delay in shipment; and (3) make prompt and full refunds when the buyer exercises a cancellation option or the seller is unable to meet the Rule's other requirements.

On March 21, 2022, the FTC sought comment on the information collection requirements associated with the Rule. 87 FR 15995. The FTC received no germane comments during the public comment period. Pursuant to OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule. For more details about the Rule requirements and the basis for the calculations summarized below, see 87 FR 15995.

Likely Respondents: Businesses engaged in the sale of merchandise by mail, internet or telephone.

Estimated Annual Hours Burden: 3,117,410 hours.

Third Party Disclosure: [(53,300 established businesses × 50 hours) + (1,967 new entrants × 230 hours) = 3,117,410 hours.

Estimated Annual Cost Burden: $80,304,482, which is derived from 3,117,410 hours × $25.76/hour.[1]

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential'' —as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2022–14276 Filed 7–5–22; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0045; Docket No. 2022–0053; Sequence No. 14]

Submission for OMB Review; Bid Guarantees, Performance and Payment Bonds, and Alternative Payment Protection

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management

Congress Examines Anti-Competitive Repair Restrictions, Recommends Ways to Expand Consumers' Repair Options (May 6, 2021), *https://www.ftc.gov/newsevents/news/press-releases/2021/05/ftc-report-congress-examines-anti-competitive-repair-restrictions-recommendsways-expand-consumers.*

[2] Remarks of Chair Lina M. Khan Regarding the Proposed Policy Statement on Right to Repair, at 1 (July 21, 2021), *https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/remarks-chair-lina-m-khanregarding-proposed-policy-statement-right-repair;* Fed. Trade Comm'n, Nixing The Fix: An FTC Report To Congress On Repair Restrictions, at 4–5, 9–15 (2021).

[1] The hourly wage rates for sales and related workers are updated from the 60-Day **Federal Register** notice and are based on mean hourly wages found at *https://www.bls.gov/news.release/ocwage.htm* (''Occupational Employment and Wages–May 2021,'' U.S. Department of Labor, released March 2022, Table 1 (''National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2021'').

and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding bid guarantees, performance and payment bonds, and alternative payment protections.

DATES: Submit comments on or before August 5, 2022.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

Additionally, submit a copy to GSA through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite OMB Control No. 9000–0045, Bid Guarantees, Performance and Payment Bonds, and Alternative Payment Protection. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

FOR FURTHER INFORMATION CONTACT: Marissa Ryba, Procurement Analyst, at telephone 314–586–1280, or *marissa.ryba@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0045, Bid Guarantees, Performance and Payment Bonds, and Alternative Payment Protection, Standard Forms (SF) 24, 25, 25–A, 25–B, 34, 35, 273, 274, 275, 1414, 1415, 1416, and 1418.

B. Needs and Uses

This justification supports an extension of the expiration date of OMB Control No. 9000–0045. This clearance covers the information that offerors or contractors must submit to comply with the following Federal Acquisition Regulation (FAR) requirements:

FAR 52.228–1, Bid Guarantee. This provision (or clause) requires offerors or contractors to furnish a bid guarantee in the proper form and amount when a performance bond or a performance and payment bond is also required. (SF 24, Bid Bond; SF 34, Annual Bid Bond).

FAR 52.228–2, Additional Bond Security. This clause requires contractors to furnish additional bond security under certain circumstances. This clause is used both for construction and other than construction contracts. (SF 1414 Consent of Surety; SF 1415, Consent of Surety and Increase of Penalty).

FAR 52.228–13, Alternative Payment Protections. This clause requires contractors to submit one of the payment protections listed in the clause by the contracting officer, in construction contracts greater than $35,000 but not exceeding $150,000.

FAR 52.228–14, Irrevocable Letter of Credit. This clause requires offerors or contractors to provide certain information when they intend to use an irrevocable letter of credit (ILC) in lieu of a required bid bond, or to secure other types of required bonds such as performance and payment bonds. This clause is required in solicitations and contracts when a bid guarantee, or performance bond, or performance and payment bonds are required.

FAR 52.228–15, Performance and Payment Bonds-Construction. This clause requires contractors to provide performance and payment bonds in construction contracts exceeding $150,000 (SF 25, Performance Bond; SF 25–A, Payment Bond; SF 25–B, Continuation Sheet (for SF's 24, 25, and 25–A); SF 273, Reinsurance Agreement for a Bonds Statute Performance Bond; SF 274, Reinsurance Agreement for a Bonds Statute Payment Bond).

FAR 52.228–16, Performance and Payment Bonds-Other Than Construction. This clause requires contractors to furnish performance and payment bonds for other than construction contracts exceeding the simplified acquisition threshold only in certain circumstances. (SF 35, Annual Performance Bond; SF 275, Reinsurance Agreement in Favor of the United States; SF 1416, Payment Bond for Other Than Construction Contracts; SF 1418, Performance Bond for Other Than Construction Contracts).

The bid guarantees, bonds, or alternative payment protections are retained by the Government until the contractor's obligation is fulfilled.

C. Annual Burden

Respondents: 6,279.

Total Annual Responses: 6,279.

Total Burden Hours: 6,279.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 87 FR 25487, on April 29, 2022. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0045, Bid Guarantees, Performance and Payment Bonds, and Alternative Payment Protection.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2022–14319 Filed 7–5–22; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES'

Administration for Children and Families

Proposed Information Collection Activity; State Court Improvement Program (OMB # 0970–0307)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Court Improvement Program (CIP) Program Strategic Plan Template and Annual CIP Self-Assessment (Office of Management and Budget (OMB) #0970–0307, expiration November 30, 2022). There are minimal updates to the form to reflect new legislation as well as to support technical assistance. The collections are necessary to continue operating the program in compliance with congressional reauthorization.

DATES: *Comments are 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.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed collection is a continuation of the current

collection and comprised of two components. An application including a strategic plan and annual self-assessment. The self-assessment reflects what the state has done in the prior year focusing on its progress and status within the change management cycle. The strategic plan looks forward to those interventions and actions the state plans to undertake to address needs or buttress strengths they have discovered in their assessment activities. Additions from the prior approval include infrastructural questions around the Child and Family Services Reviews regarding efforts to engage legal and judicial staff and collaborate with the child welfare agency. They also include overall court structural questions which are responsive to requests from grantees to facilitate peer connections of similarly situated states. The next application will be due June 30, 2023.

Respondents: We anticipate the highest state court of every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands to respond. All 53 jurisdictions currently participate in the program.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Annual Self-Assessment	53	1	40	2,120
Strategic Plan	53	* .20	52	551.20
Estimated Total Annual Burden Hours:				2,671.20

* The full Strategic Plan is completed every 5 years. In years when the Strategic Plan is not completed, respondents may spend minimal time updating relevant sections of the Strategic Plan. This is accounted for in the estimate for the Annual Self-Assessment.

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: 42 U.S.C. 629h.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–14343 Filed 7–5–22; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Generic Program-Specific Performance Progress Report (0970–0490)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comments.

SUMMARY: This notice describes the proposal to extend data collection under the Administration for Children and Families (ACF) Generic Program-Specific Performance Progress Report (PPR) (0970–0490). This overarching generic allows ACF program offices to collect performance and progress data from recipients and sub-recipients who receive funding from ACF under a discretionary grant or cooperative agreement. This generic mechanism provides the opportunity for ACF program offices to tailor requests for performance and progress data to specific funding recipients. No changes are proposed to the purpose or use of the data collections under this generic, but ACF is requesting an increase in burden.

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.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF is primarily a grant-making agency that promotes the economic and social well-being of families, children, individuals and communities with partnerships, funding, guidance, training and technical assistance. Prior to the use of this generic program-specific PPR, a standard ACF PPR (#0970–0406) was used for all ACF discretionary grant and cooperative agreement awards for post award reporting. Historically, on the standard ACF PPR form, ACF required grantees to only respond to a common set of broad questions, which often solicited qualitative or incomplete information. This one-size-fits-all approach did not adequately collect the specific data needed for particular grant programs or allow program offices to assess continuous quality improvement. Different grant programs vary in purpose, target population, and activities. Therefore, a need for program offices to customize performance measurements was identified and the generic program-specific PPR was developed.

ACF program offices have benefited from the ability to create and use a program-specific PPR that is more effective and includes specific data elements that reflects a specific program's indicators, demographics, priorities and objectives.

A generic program-specific PPR that can be tailored for program-specific needs allows program offices to collect useful data in a uniform and systematic manner. The reporting format allows program offices to gather uniform program performance data from each grantee, allowing aggregation at the program level to calculate outputs and outcomes, providing a snapshot and allowing for longitudinal analysis.

Data from a tailored program-specific PPR that demonstrates a program's successes and challenges have been useful for accountability purposes, such as required reports to Congress. Moreover, it has been useful for program management and oversight, such as identifying grantees' technical assistance needs and ensuring

compliance with federal and programmatic regulations and policies. To review currently approved PPRs under this generic, see: *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202206-0970-004.*

Respondents: ACF funding recipients.

Annual Burden Estimates

ACF is requesting an increase in burden to reflect use over the past 3 years and anticipated use in the next 3 years.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Program Specific PPRs	800	2.3	5	9,200

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.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–14352 Filed 7–5–22; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; National Communication System for Runaway and Homeless Youth, Currently Operated by the National Runaway Safeline (NRS) Data Collection (New Collection)

AGENCY: Family and Youth Services Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Family and Youth Services Bureau's (FYSB) Runaway and Homeless Youth Division has a legislative requirement to fund a National Communication System, which is currently operated by the National Runaway Safeline (NRS). The NRS provides information, referral services, crisis intervention, and prevention resources to vulnerable youth at risk of running away and/or becoming homeless and their families or legal guardians at no cost. When necessary, the NRS refers runaway and homeless youth to shelters, counseling, medical assistance, and other vital services. The NRS collects information from all contacts with youth and adults connecting with the NRS (*i.e.,* parents, family members, legal guardians, service providers) on a voluntary basis to inform crisis services and develop an annual report on the information collected during calls, chats, emails, and forum posts from young people who reached out to the NRS's crisis services.

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.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The NRS is required to have a system for collecting and analyzing data to report on calls, emails, chat, texts, and online messages received as well as other information, such as prevention resources, referrals, demographics, and visitors to the NRS website. The NRS must submit monthly and semi-annual reports that includes the following:

- Number of calls received, answered, and missed.
- Number of chats, emails, and texts received; number of chats, emails, and texts answered; and number of chats, emails, and texts that were missed and did not receive a response, in which the users are youth in crisis, runaway youth, and youth experiencing homelessness.
- Number of parents, legal guardians, and service providers contacting the NRS and the type of resources, interventions, and technical support/assistance requested and provided.
- Number and type of prevention materials disseminated to communities, especially to underserved populations.
- Number and type of unique visitors to the NRS' website.
- Information on referrals provided and where youth were referred for services.
- Information on the callers' or users' demographics and where they were located when contacting the NRS.
- Information on the prevention materials developed and disseminated by the NRS.
- Information and analysis of the latest trends and their impact on runaway prevention.

The NRS will use two online forms, one form to collect relevant information disclosed during calls, emails, and forum posts and a second online form to collect information from chats. All data will be provided to FYSB in the aggregate and no personally identifiable data are collected.

The information collected will allow FYSB to better understand the types of services needed by youth contacting the NRS, as well as to identify outreach and prevention strategies to increase the visibility of the NRS services among youth experiencing housing instability, homelessness, youth who runaway, and youth in crisis. Additionally,

The findings from this data collection will be included in a required Report to Congress to provide accurate information on the status of youth in crisis and runaway and homeless youth nationwide.

Respondents: Youth and adults who contact the National Runaway Safeline during calls, chats, emails, and forum posts.

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
Youth in Crisis Form	47,175	1	.23	10,850	3,617
NRS Live Chat Form	29,679	1	.65	19,291	6,430

Estimated Total Annual Burden Hours: 10,047.

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 331 of the Runaway and Homeless Youth Act authorizes the award of grants for the National Communication System for Runaway and Homeless Youth (34 U.S.C. 11231).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–14341 Filed 7–5–22; 8:45 am]

BILLING CODE 4182–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Request for Nominations on Public Advisory Panels of the Medical Devices Advisory Committee

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on certain panels of the Medical Devices Advisory Committee (MDAC or Committee) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on certain device panels of the MDAC in the CDRH. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by August 5, 2022 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by August 5, 2022.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993, 301–796–5960, email: *margaret.ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for nonvoting industry representatives to the panels listed in the table in this document.

I. Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the FD&C Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988.

Panels	Function
Clinical Chemistry and Clinical Toxicology Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine, including clinical toxicology, clinical chemistry, endocrinology and oncology and makes appropriate recommendations to the Commissioner of Food and Drugs.
Immunology Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine, including oncology, immunology, and allergy and makes appropriate recommendations to the Commissioner of Food and Drugs.
Gastroenterology-Urology Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational gastroenterology, urology, and nephrology devices and makes appropriate recommendations to the Commissioner of Food and Drugs.
General Hospital and Personal Use Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general hospital, infection control and personal use devices and makes appropriate recommendations to the Commissioner of Food and Drugs.
Ophthalmic Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the eye and makes appropriate recommendations to the Commissioner of Food and Drugs.

II. Qualifications

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nomination must include a current, complete résumé or curriculum vitae for each nominee, including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory panel for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the particular device panels listed in the table. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14359 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2086]

Determination of Regulatory Review Period for Purposes of Patent Extension; VYEPTI

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VYEPTI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 6, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 3, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–E–2086 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; VYEPTI.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product VYEPTI (eptinezumab-jjmr). VYEPTI is indicated for the preventive treatment of migraine in adults. Subsequent to this approval, the USPTO received a patent term restoration application for VYEPTI (U.S. Patent No. 9,745,373) from AlderBio Holdings LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of VYEPTI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VYEPTI is 2,599 days. Of this time, 2,233 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* January 11, 2013. The applicant claims January 13, 2013, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 11, 2013, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* February 21, 2019. FDA has verified the applicant's claim that the

biologics license application (BLA) for VYEPTI (BLA 761119) was initially submitted on February 21, 2019.

3. *The date the application was approved:* February 21, 2020. FDA has verified the applicant's claim that BLA 761119 was approved on February 21, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 637 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14350 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1768]

Advisory Committee; Pharmacy Compounding Advisory Committee; Renewal

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

ACTION: Notice; renewal of federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pharmacy Compounding Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmacy Compounding Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the April 25, 2024, expiration date.

DATES: Authority for the Pharmacy Compounding Advisory Committee will expire on April 25, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–2507, *PCAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3, FDA is announcing the renewal of the Pharmacy Compounding Advisory Committee (the Committee). The Committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to compounding drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the U.S. Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one or more technically qualified members, selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one or more non-voting representative members who are identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/pharmacy-compounding-advisory-committee/pharmacy-compounding-advisory-committee-charter* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14346 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2262; FDA–2020–E–2263]

Determination of Regulatory Review Period for Purposes of Patent Extension; MONJUVI

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MONJUVI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 6, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 3, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2020–E–2262; FDA–2020–E–2263 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; MONJUVI.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological

product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product MONJUVI (tafasitamab-cxix). MONJUVI is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Subsequent to this approval, the USPTO received patent term restoration applications for MONJUVI (U.S. Patent Nos. 8,524,867; 9,803,020) from Xenocor, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 1, 2021, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of MONJUVI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MONJUVI is 3,806 days. Of this time, 3,590 days occurred during the testing phase of the regulatory review period, while 216 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* March 3, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 3, 2010.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 30, 2019. FDA has verified the applicant's claim that the biologics license application (BLA) for MONJUVI (BLA 761163) was initially submitted on December 30, 2019.

3. *The date the application was approved:* July 31, 2020. FDA has verified the applicant's claim that BLA 761163 was approved on July 31, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 610 days or 1,370 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14357 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0117]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Emergency Use Authorization of Medical Products

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 5, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0595. 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–45, 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.

Emergency Use Authorization of Medical Products

OMB Control Number 0910–0595—Extension

This information collection helps support implementation of Agency policies applicable to the authorization for medical products for use in emergencies under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b). For more information regarding emergency use authorization (EUA), visit our website at *https://www.fda.gov/*

emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. The FD&C Act permits the Commissioner of Food and Drugs (the Commissioner) to authorize the use of unapproved medical products, or unapproved uses of approved medical products, during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)).

Also under section 564 of the FD&C Act, the Commissioner may establish conditions on issuing an authorization that may be necessary or appropriate to protect the public health. These conditions can include: (1) requirements to disseminate or disclose information to healthcare providers or authorized dispensers and product recipients; (2) adverse event monitoring and reporting; (3) data collection and analysis; (4) specific recordkeeping and records access; (5) restrictions on product advertising, distribution, and administration; and (6) limitations on good manufacturing practice requirements. As governed by statute, some conditions are mandatory to the extent practicable for authorizations of unapproved products, and discretionary for authorizations of unapproved uses of approved products. Some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out an activity for which the authorization is issued. Sections 564A and 564B of the FD&C Act establish streamlined mechanisms intended to facilitate preparedness and response activities involving certain FDA approved products without requiring FDA to issue an EUA, and set forth emergency dispensing order and expiration date extension authority.

The guidance document entitled, ''Emergency Use Authorization of Medical Products and Related Authorities'' (January 2017), available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities,* discusses FDA issuance of Emergency Use Authorizations (EUAs) under section 564 of the FD&C Act; implementation of the emergency use authorities set forth in section 564A of the FD&C Act; reliance on the governmental pre-positioning authority set forth in section 564B of the FD&C Act; and related FDA regulations. As discussed in the guidance document, the specific type and amount of data needed to support an EUA will vary depending on the nature of the declared emergency and the nature of the candidate product. The guidance document encourages early engagement with FDA, explains mechanisms for communication, and makes content and format recommendations on submitting information to the Agency. The guidance document also recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

In the **Federal Register** of March 3, 2022 (87 FR 12175), we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received. One comment communicated that the information collection has proven useful in expediting the availability of vaccines during the pandemic, and also suggested potential modifications. The second comment was not responsive to the information collection topics solicited in our 60-day notice. Neither comment offered alternative burden estimates.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for a substantive amendment to an existing EUA	2724	2	5448	45	245,160
Pre-EUA submissions or amendments	2001	1	2001	34	68,034
Submitting information required under conditions of authorization	36	3	108	8	864
State and local public health authority submissions required under conditions of authorization for unapproved EUA product	1	1	1	2	2
State and local public health authority requests for Emergency Dispensing Order	1	1	1	2	2
State and local public health authority requests for expiration date extension	1	1	1	20	20
Total			7560		314,082

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

Although we have averaged burden across all respondents, we categorize reporting activity by the type of EUA-related submission: (1) those who file a request for FDA to issue an EUA and/or a substantive amendment to an EUA that has previously been issued; (2) those who submit a request for FDA to review information/data (*i.e.,* a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) those who must report on activities related to an unapproved EUA product (*e.g.,* administering product, disseminating information) who must report to FDA regarding such activity; (4) public health authorities (*e.g.,* State, local) who must report on certain activities (*e.g.,* administering product, disseminating information) related to an unapproved EUA, and public health authorities who submit an expiration date extension request for an approved product; (5) those who request an emergency dispensing order under section 564A; and (6) those who request

expiry dating extensions under section 564A of the FDC&C Act. We attribute greater burden to those requests for FDA to review pre-EUA packages submitted by product sponsors than burden we attribute to those submitted by Federal agencies (*e.g.,* Centers for Disease Control and Prevention, the Department of Defense), and have considered other factors that contribute to variability in burden for reporting, including the type of product and whether there is a previously reviewed pre-EUA package or investigational application.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Records associated with conditions of authorization	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
EUA Holders	648	2	1,296	25	32,400
State and local Public Health Authorities	1	1	1	3	3
Total			1,297		32,403

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

We provide a conservative estimate for respondent recordkeeping, recognizing that the Federal Government performs much of this activity in conjunction with submissions. We do not include burden for public health authorities who may need to submit emergency dispensing orders or expiration date extension requests, assuming covered entities already maintain these records for the products they stockpile.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Information collection activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Dissemination of required information by EUA Holder or Authorized Stakeholder	635	2	1270	5	6350

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

Our third-party disclosure estimate is based on the number of EUA holders and authorized stakeholders disseminating information, including fact sheets, advertising, and promotional materials.

We have increased our burden estimate for the information collection to reflect the increase in submissions we have received over the last 3 years.

Dated: June 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14347 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–1956]

Identifying Trading Partners Under the Drug Supply Chain Security Act; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act.'' FDA is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA). The revised draft guidance explains how to determine when certain statutory requirements will apply to entities that are considered trading partners in the drug supply chain. It also discusses the activities of private-label distributors, salvagers, and returns processors and reverse logistics providers. Additionally, the revised draft guidance discusses the distribution of drugs for emergency medical reasons, office use, non-human research purposes, and research purposes in humans under an investigational new drug application. This guidance revises the August 2017 draft guidance entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act.''

DATES: Submit either electronic or written comments on the draft guidance by September 6, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–1956 for ''Identifying Trading Partners Under the Drug Supply Chain Security Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *Aaron.Weisbuch@fda.hhs.gov* or *drugtrackandtrace@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act.'' The DSCSA (Title II of Pub. L. 113–54) establishes new requirements to develop and enhance drug distribution security by 2023. It does this, in part, by defining different types of entities in the drug supply chain as *trading partners* (manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers). Among other things, the DSCSA requires that trading partners of manufacturers, wholesale distributors, dispensers, and repackagers meet the applicable requirements for being ''authorized trading partners.''

In addition, the DSCSA outlines requirements for specific trading partners, including drug product tracing, verification, and licensure requirements (where applicable). This revised draft guidance describes the activities and requirements for entities that are considered to be a manufacturer, repackager, wholesale drug distributor, third-party logistics provider, and/or dispenser and therefore considered a trading partner under the DSCSA. This guidance revises the draft guidance entitled ''Identifying Trading Partners Under the Drug Supply Chain Security Act'' that was published on August 24, 2017 (82 FR 40159).

In response to public comments received and policy considerations, FDA has added or revised its current thinking on the status of some entities as trading partners, including private-label distributors, salvagers, and returns processors and reverse logistics providers. The Agency has also provided clarification on certain drug distribution scenarios, including distribution for emergency medical use, office use, non-human research purposes, and research in humans under an investigational new drug application. FDA also addresses the interpretation of section 582(a)(7) of the Federal Food, Drug, and Cosmetic Act, which discusses third-party logistics providers licensure status prior to the effective date of the forthcoming regulations establishing licensure standards.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on ''Identifying Trading Partners Under the Drug Supply Chain Security Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this revised draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-*

information-biologics/biologics-guidances, or https://www.regulations.gov.

Dated: June 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14345 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–0559; FDA–2018–N–4206; FDA–2017–D–5225; FDA–2018–N–3758; FDA–2018–D–4533]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
PHS Guideline on Infectious Disease Issues in Xenotransplantation	0910–0456	6/30/2025
MDUFMA Small Business Qualification Certification	0910–0508	6/30/2025
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	0910–0752	6/30/2025
Expanded Access to Investigational Drugs for Treatment Use	0910–0814	6/30/2025
Compounding Animal Drugs from Bulk Drug Substances	0910–0904	6/30/2025

Dated: June 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14348 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–E–0450]

Determination of Regulatory Review Period for Purposes of Patent Extension; MARGENZA

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MARGENZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 6, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 3, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–E–0450 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; MARGENZA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product MARGENZA (margetuximab-cmkb). MARGENZA is indicated in combination with chemotherapy for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. Subsequent to this approval, the USPTO received a patent term restoration application for MARGENZA (U.S. Patent No. 8,802,093) from MacroGenics, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 8, 2021, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of MARGENZA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MARGENZA is 3,950 days. Of this time, 3,585 days occurred during the testing phase of the regulatory review period, while 365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* February 24, 2010. The applicant claims February 27, 2010, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 24, 2010, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 18, 2019. FDA has verified the applicant's claim that the biologics license application (BLA) for MARGENZA (BLA 761150) was initially submitted on December 18, 2019.

3. *The date the application was approved:* December 16, 2020. FDA has verified the applicant's claim that BLA 761150 was approved on December 16, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,342 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14360 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–0280 and FDA–2021–N–0371]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Financial Disclosure by Clinical Investigators	0910–0396	5/31/2025
Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites	0910–0872	5/31/2025
Infant Formula Enforcement Discretion Policy	0910–0903	11/30/2022

Dated: June 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14358 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1981]

Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' This guidance identifies the standards necessary to facilitate adoption of secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain, and clarifies the trading partners, products, and transactions subject to such standards. This guidance is a revision of the draft guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information,'' issued in November 2014 as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by September 6, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–1981 for ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lysette Deshields, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' The Drug Supply Chain Security Act (DSCSA) outlines requirements for enhanced drug distribution security, which include the steps to achieve interoperable, electronic tracing of products at the package level. These requirements for enhanced drug distribution security go into effect on November 27, 2023. Section 582(g)(1) of the FD&C Act (21 U.S.C. 360eee–1(g)(1)) sets forth enhanced drug distribution security requirements for trading partners, including adherence to standards established by FDA for the exchange of transaction information and transaction statements in a secure, interoperable, electronic manner and the verification of product at the package level. Additionally, section 582(h)(4)(A) of the FD&C Act specifies that FDA issue a draft guidance, and revise the draft guidance as appropriate, to identify and make recommendations with respect to the standards necessary for adoption in order to support the secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization.

In this revised draft guidance, FDA considered the standards established pursuant to sections 505D of the FD&C Act (21 U.S.C. 355e) and 582(a)(2) of the FD&C Act in the November 2014 draft guidance entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information'' (available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-standards-interoperable-exchange-information-tracing-certain-human-finished-prescription-drugs*). The pilot projects conducted per section 582(j) of the FD&C Act also informed revisions made to this draft guidance.

This revised draft guidance updates the policy articulated in the November 2014 draft guidance to reflect the enhanced drug distribution security requirements that will go into effect on November 27, 2023, including that paper-based methods of product tracing will no longer be permitted and verification of product at the package level will be required, unless a waiver, exception, or exemption applies. This revised draft guidance is intended to facilitate the creation of a uniform methodology for product tracing while ensuring the protection of confidential commercial information and trade secrets. FDA also published other guidances describing recommendations for enhanced drug distribution security, including the attributes necessary for enhanced product tracing and verification, which should be read in conjunction with this draft guidance (see FDA's Drug Supply Chain Security Law and Policies web page at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies*).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will

represent the current thinking of FDA on ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously approved collections of information found in FDA regulations or guidance.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: June 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14342 Filed 7–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given for the meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention National Advisory Council (CSAP NAC) on August 8, 2022. The Council was established to advise the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and Director, CSAP concerning matters relating to the activities carried out by and through the Center and the policies respecting such activities.

The meeting will be open to the public and will consist of discussions of substance use prevention priorities and updates on CSAP program developments.

The meeting will be held via webcast and phone only. Attendance by the public on-site will not be available. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person on or before one week prior to the meeting. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations should notify the contact on or before one week prior to the meeting. A maximum of five minutes will be allotted for each presentation, as time permits.

To participate in the meeting, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA Committees' website: *https://snacregister.samhsa.gov,* or communicate with the CSAP Council's Designated Federal Officer (see contact information below).

Substantive program information may be obtained after the meeting by accessing the SAMHSA Committee website, *https://www.samhsa.gov/about-us/advisory-councils/csap-national-advisory-council,* or by contacting the Designated Federal Officer.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council.

Date/Time/Type: August 8, 2022, from 12:00 p.m. to 4:00 p.m. EDT: (Open).

Place: (Virtual). For Webcast information: please register at the SAMHSA Committees' website, listed above.

Contact: Michelle McVay, Designated Federal Officer, SAMHSA CSAP NAC, 5600 Fishers Lane, Rockville, MD 20852, Telephone: 240–276–0446, Email: *michelle.mcvay@samhsa.hhs.gov.*

Dated: June 29, 2022.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2022–14311 Filed 7–5–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency; Department of Homeland Security.

ACTION: Notice; correction.

SUMMARY: On June 1, 2022, FEMA published in the **Federal Register** a changes in flood hazard determination notice that contained an erroneous table. This notice provides corrections to that table to be used in lieu of the erroneous information. The table provided here represents the changes in flood hazard determinations and communities affected for the City of Margaret and Unincorporated Areas of St. Clair County, Alabama.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of June 1, 2022, in FR Doc. 2022–11679, in the table on page 33186, the entries for Alabama: St. Clair County are corrected to read as follows (after the signature):

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Alabama:					
St. Clair County (FEMA Docket No.: B–2136).	City of Margaret (20–04–4313P).	The Honorable Jeffery G. Wilson, Mayor, City of Margaret, P.O. Box 100, Margaret, AL 35953.	St. Clair County Flood Management Department, 165 5th Avenue, Suite 100, Ashville, AL 35953.	Aug. 20, 2021	010393
St. Clair County (FEMA Docket No.: B–2136).	Unincorporated areas of St. Clair County (20–04–4313P).	The Honorable Paul Manning, Chairman, St. Clair County Commission, 165 5th Avenue, Suite 100, Ashville, AL 35953.	St. Clair County Flood Management Department, 165 5th Avenue, Suite 100, Ashville, AL 35953.	Aug. 20, 2021	010290

[FR Doc. 2022–14271 Filed 7–5–22; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2022–0036]

Homeland Security Advisory Council

AGENCY: The Office of Partnership and Engagement (OPE), Department of Homeland Security (DHS).

ACTION: Notice of open Federal Advisory Committee meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will meet virtually on Monday, July 18, 2022. The meeting will be open to the public.

DATES: The meeting will take place from 12 p.m. ET to 1 p.m. ET on Monday, July 18, 2022. Please note that the meeting may end early if the Council has completed its business.

ADDRESSES: The HSAC meeting will be held via teleconference. Members of the public interested in participating may do so by following the process outlined below (see ''Public Participation''). At all other times during the meeting, the public will be in listen-only mode. Written comments can be submitted from July 7, 2022 to July 15, 2022. Comments must be identified by Docket No. DHS–2022–0036 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: HSAC@hq.dhs.gov.* Include Docket No. DHS–2022–0036 in the subject line of the message.
- *Mail:* Michael Miron, Deputy Executive Director of Homeland Security Advisory Council, Office of Partnership and Engagement, Mailstop 0385, Department of Homeland Security, 2707 Martin Luther King Jr. Ave. SE, Washington, DC 20528.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and ''DHS–2022–0036,'' the docket number for this action. Comments received will be posted without alteration at *https://www.regulations.gov,* including any personal information provided. You may wish to review the Privacy and Security Notice found via a link on the homepage of *www.regulations.gov*

Docket: For access to the docket to read comments received by the Council, go to *https://www.regulations.gov,* search ''DHS–2022–0036,'' ''Open Docket Folder'' and provide your comments.

FOR FURTHER INFORMATION CONTACT: Michael Miron at 202–891–2876 or *HSAC@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under Section 10(a) of the Federal Advisory Committee Act (FACA), Public Law 92–463 (5 U.S.C. Appendix), which requires each FACA committee meeting to be open to the public unless the President, or the head of the agency to which the advisory committee reports, determines that a portion of the meeting may be closed to the public in accordance with 5 U.S.C. 552b(c).

The HSAC provides organizationally independent, strategic, timely, specific, actionable advice, and recommendations to the Secretary of Homeland Security on matters related to homeland security. The Council consists of senior executives from government, the private sector, academia, law enforcement, and non-governmental organizations.

The agenda for the meeting is as follows: The Council will receive interim findings from the Disinformation Best Practices and Safeguards Study Group (an HSAC subcommittee) leadership. Following the interim findings briefing, there will be a break for members of the public who wish to provide comment. Members of the public will be in listen-only mode except during the public comment session. Members of the public may register to participate in this Council teleconference via the following procedures. Each individual must provide their full legal name and email address no later than 5 p.m. ET on Friday, July 15, 2022 to Michael Miron of the Council via email to *HSAC@hq.dhs.gov* or via phone at 202–891–2876. Members of the public who have registered to participate will be provided the conference call details after the closing of the public registration period and prior to the start of the meeting.

For information on services for individuals with disabilities, or to request special assistance, please email *HSAC@hq.dhs.gov* by 5 p.m. ET on July 15, 2022 or call 202–891–2876. The HSAC is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Michael Miron at 202–891–2876 or *HSAC@hq.dhs.gov* as soon as possible.

Dated: June 30, 2022.

Michael J. Miron,

Deputy Executive Director, Homeland Security Advisory Council, Department of Homeland Security.

[FR Doc. 2022–14385 Filed 6–30–22; 4:15 pm]

BILLING CODE 9112–FN–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–OSA–2022–0086; FF04S00000 223 FXSC14200400000; OMB Control Number 1018—New]

Agency Information Collection Activities; Southeast Conservation Adaptation Strategy (SECAS) Social Network Analysis Survey

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 6, 2022.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (reference

Office of Management and Budget (OMB) Control Number 1018–SECAS in the subject line of your comment):

- *Internet (preferred): https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R4–OSA–2022–0086.
- *Email: Info_Coll@fws.gov.*
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Fish and Wildlife Act of 1956 (16 U.S.C. 742d) designates the Department of the Interior as a key agency responsible for the conservation and protection of wildlife and fisheries resources in the United States. This responsibility dictates that we gather accurate data on conservation efforts through means such as research to improve the development, management, and advancement of efforts. The Service's Science Applications and Migratory Bird Program in the Southeast Region is seeking to conduct a social network analysis to collect information regarding regional conservation efforts, conservation partnership goals, structure, and focal geography, and the connectedness of these efforts and partnerships. The proposed survey collects information necessary to address this gap in understanding and will serve to advance the Southeast Conservation Adaptation Strategy's (SECAS) leadership role as a regional forum and decision-support hub.

The proposed survey collects the following information:

- Familiarity and engagement with SECAS, including satisfaction with SECAS aspects and importance of SECAS indicators (Section 2);
- Organizational conservation priorities, including level of importance and usefulness of and reliance on SECAS resources (Section 3);
- Conservation partnerships, including identification of partner organizations and collaboration types (Section 4); and
- Organizational information, including type of organization and scope of work (Section 5).

The information collected in this effort will be used to develop multiple products aimed at translating the data into information that can strengthen partnerships, identify gaps, and inform conservation decisions.

The public may request a copy of the proposed survey instrument by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**, above).

Title of Collection: Southeast Conservation Adaptation Strategy (SECAS) Social Network Analysis.

OMB Control Number: 1018–New.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Leaders and executives in the private sector and State, local, and Tribal governments in the Service's Southeast Region.

Total Estimated Number of Annual Respondents: 200 (100 private sector entities and 100 State/local/Tribal governments).

Total Estimated Number of Annual Responses: 200.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 50.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: There is no cost associated with the survey.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2022–14317 Filed 7–5–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCOSO00000.L11700000.DF0000. LXSGCO000000.223]

Notice of Intent to Amend Multiple Resource Management Plans Regarding Gunnison Sage-Grouse (*Centrocercus minimus*) Conservation and Prepare an Associated Environmental Impact Statement, Colorado and Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) Colorado and Utah State Directors intend to prepare a Gunnison Sage-Grouse Resource Management Plan (RMP) Amendment with an associated environmental impact statement (EIS), and by this notice are announcing the beginning of the public scoping period to solicit public comments and identify issues, providing the planning criteria for public review, and issuing a call for nominations for areas of critical environmental concern (ACECs). This notice terminates the previous Gunnison Sage-Grouse Rangewide Draft RMP Amendment and Draft EIS (DOI–BLM–CO–0000–2014–0001–RMP–EIS) initiative that began in July 2014.

DATES: The BLM requests the public submit comments concerning the scope of the analysis, potential alternatives, and identification of relevant information, studies, and ACEC nominations by August 22, 2022. To afford the BLM the opportunity to consider issues and ACEC nominations raised by commenters in preparing the draft RMP amendment/EIS, please ensure your comments are received prior to the close of the 45-day scoping period or 15 days after the last public meeting, whichever is later. The date(s) and location(s) of any public meetings associated with this land use planning initiative will be announced at least 15 days in advance through local news media, newspapers, and the BLM website at the web address located in **ADDRESSES** below.

ADDRESSES: You may submit comments issues and planning criteria related to these Gunnison sage-grouse RMP amendments and nominations of new ACECs by the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2019031/510.*
- *Mail:* Gunnison Sage-Grouse RMP Amendment/EIS, BLM Grand Junction Field Office, 2815 H Rd., Grand Junction, CO 81506.

Documents pertinent to this proposal may be examined online at *https://eplanning.blm.gov/eplanning-ui/project/2019031/510* and at the following Field Office and District Office locations:

- Rocky Mountain District Office; 3028 E Main St.; Canon City, CO 81212
  - San Luis Valley Field Office, 1313 E Highway 160; Monte Vista, CO 81144
- Southwest District Office; 2465 S Townsend Ave.; Montrose, CO 81401
  - Gunnison Field Office; 210 W Spencer Ave.; Gunnison, CO 81230
  - Tres Rios Field Office; 29211 Highway 184; Dolores, CO 81323
  - Uncompahgre Field Office; 2465 S Townsend Ave.; Montrose, CO 81401
- Upper Colorado River District Office; 2815 H Road, Grand Junction, CO 81506
  - Grand Junction Field Office; 2815 H Road; Grand Junction, CO 81506
- Canyon Country District Office; 82 East Dogwood; Moab, UT 84532
  - Moab Field Office; 82 East Dogwood; Moab, UT 84532
  - Monticello Field Office; 365 North Main, Monticello, UT 84535

FOR FURTHER INFORMATION CONTACT: Leah Waldner, Sage-Grouse Coordinator, BLM Colorado; telephone: 970–244–3045; or email: *BLM_CO_GUSG_RMPA@blm.gov*; address: BLM Grand Junction Field Office, 2815 H Rd, Grand Junction, CO 81506. Contact Ms. Waldner via email to have your name added to our mailing list. Persons in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM Colorado and Utah State Directors intend to prepare an RMP amendment with an associated EIS for the management of Gunnison sage-grouse and its habitat, announce the beginning of the scoping process, seek public input on issues and planning criteria, and invite the public to nominate ACECs. The BLM is considering amending the following RMPs to incorporate management actions with the potential to affect Gunnison sage-grouse populations or occupied and unoccupied habitat: Canyons of the Ancients National Monument RMP (2010), Dominguez-Escalante National Conservation Area RMP (2017), Grand Junction Field Office RMP (2015), Gunnison Gorge National Conservation Area RMP (2004), Gunnison Resource Area RMP (1993), McInnis Canyons National Conservation Area RMP (2004), San Luis Resource Area RMP (1991), Tres Rios Field Office RMP (2015), Uncompahgre Field Office RMP (2020), Moab Field Office RMP (2008), and Monticello Field Office RMP (2008).

The planning area is located in the following nineteen Colorado counties: Alamosa, Archuleta, Conejos, Costilla, Delta, Dolores, Garfield, Gunnison, Hinsdale, La Plata, Mesa, Mineral, Montezuma, Montrose, Ouray, Rio Grande, Saguache, San Juan, and San Miguel, and in the following two Utah counties: Grand and San Juan. The planning area encompasses approximately 7.6 million acres of BLM-managed surface land and approximately 17.1 million acres of Federal mineral estate. This acreage includes Federal minerals on Federal lands and ''split-estate'' Federal minerals located under surface lands with non-Federal ownership. The decision area includes approximately 1.5 million acres of split-estate Federal minerals (*e.g.,* privately owned surface and State lands). It does not include National Forest System land and other Federal land where the BLM does not make planning decisions. The BLM typically adopts the leasing requirements determined by other Federal surface-managing agencies when leasing the mineral estate (while within the planning area, those lands are outside the decision area).

In addition, this notice terminates the previous Gunnison Sage-Grouse Rangewide Draft RMP Amendment and Draft EIS (DOI–BLM–CO–0000–2014–0001–RMP–EIS) initiative that began in July 2014 and resulted in the release of a draft RMP amendment/draft EIS in August 2016. That planning effort was paused following notification in April 2018 that the U.S. Fish and Wildlife Service (USFWS) intended to formulate a recovery plan for the species. No final EIS or Record of Decision will be issued for BLM–CO–0000–2014–0001–RMP–EIS. The USFWS released the *Final Recovery Plan for Gunnison Sage-Grouse* in October 2020.

Purpose and Need

The preliminary purpose for the BLM action is to promote the recovery of the threatened Gunnison sage-grouse and maintain and enhance the occupied and unoccupied habitat upon which the species depends; ensure that management actions on BLM lands and sub-surface mineral estate support conservation goals for Gunnison sage-grouse and do not result in the adverse modification of occupied or unoccupied habitat for the species; and develop BLM management practices considering current science and data, relevant Federal, State, and local decisions supporting recovery, the *Department of the Interior Climate Action Plan* (2021), the USFWS *Final Recovery Plan for Gunnison Sage-Grouse* (2020), and the USFWS *Recovery Implementation*

Strategy for Gunnison sage-grouse (Centrocercus minimus) (2020).

The BLM's primary need is to address the rangewide downward population trend of the Gunnison sage-grouse and issues related to land management that may affect habitat; fulfill the Endangered Species Act (ESA) Section 7(a)(1) requirement that the BLM use its authority to further the purposes of the ESA by implementing management actions that conserve federally listed species and the ecosystems upon which they depend; and respond to changed ecological and climate conditions affecting BLM-managed lands (including drought, invasive plants, habitat loss and fragmentation, impaired riparian areas, and more frequent wildland fires).

Preliminary Alternatives

The BLM manages approximately 42 percent of the Gunnison sage-grouse occupied habitat across the entire range. The BLM manages approximately 50 percent of the occupied habitat within Gunnison Basin, Colorado, which is the largest population of Gunnison sage-grouse, containing approximately 85 percent of the species' adult individuals (November 21, 2014; 79 FR 69191). The USFWS identified threats to Gunnison sage-grouse in the *Final Recovery Plan for Gunnison Sage-Grouse* (2020), the *Recovery Implementation Strategy for Gunnison Sage-Grouse* (2020), and the *Species Status Assessment Report for the Gunnison Sage-Grouse* (2019). Some of the threats affecting the survival of Gunnison sage-grouse include habitat fragmentation and development, severe drought and climate change, invasive plants, juniper encroachment, improper grazing practices, predation, and recreation. The BLM will propose and analyze, with the best available scientific methods and information, alternatives for the recovery of Gunnison sage-grouse populations and conservation of sagebrush habitat. The BLM has found that existing BLM land use plans in Colorado and Utah may not fully take into account new data and science related to the management of Gunnison sage-grouse and sagebrush habitat.

The BLM will consider continuation of current management (No Action Alternative) under the existing BLM RMPs, as amended. To address the threat of fragmentation and development to Gunnison sage-grouse habitat, the BLM will consider limits on density and disturbance from development, including facility and route density limitations. The BLM will additionally consider whether to incorporate new or changed oil and gas leasing and management decisions that would incorporate conservation measures for important sagebrush habitat areas for Gunnison sage-grouse. The BLM may consider closure of areas to future oil and gas leasing in addition to stipulations such as timing limitations, controlled surface use restrictions, and no surface occupancy restrictions. The BLM will also consider changes that minimize or compensate for impacts from resource uses, such as recreation and grazing, and address habitat resiliency during periods of drought. The BLM will also consider designation of ACECs. The BLM welcomes comments on the preliminary alternatives as well as suggestions for additional alternatives.

Planning Criteria

The planning criteria guide the planning effort and lay the groundwork for the effects analysis by identifying the preliminary issues and their analytical frameworks. The BLM has identified the following preliminary planning criteria to guide development of the RMP amendment and is accepting public input during the scoping period consistent with 43 CFR 1610.4–2(c):

- The planning effort will be limited to land use planning decisions specific to conservation of the Gunnison sage-grouse and its habitat; existing land use plan decisions not affected by the amendments will remain in effect;
- The RMP amendment and associated EIS process will comply with FLPMA, NEPA, and other Federal statutes, regulations, executive orders, and management policies;
- The BLM will recognize valid existing rights;
- The BLM will adhere to adaptive management principles;
- The BLM will give priority to designating and protecting ACECs;
- The BLM will consider land use allocations and/or prescriptive standards to conserve Gunnison sage-grouse habitat, as well as objectives and management actions to restore, enhance, and improve Gunnison sage-grouse habitat;
- The BLM will consider a range of reasonable alternatives, including appropriate management prescriptions that focus on the relative values of resources while contributing to the conservation of the Gunnison sage-grouse and its habitat;
- The BLM will consider the socioeconomic impacts of alternatives; socioeconomic analyses will use an accepted input/output quantitative model such as the Impact Analysis for Planning or the Regional Input-Output Modeling System;
- The BLM will use current scientific information, research, technologies, inventory, monitoring, and coordination results, and approved BLM spatial data supported by current metadata to ascertain the extent and quality of Gunnison sage-grouse habitat and determine appropriate management strategies to enhance or restore habitat; data will be consistent with principles of the Information Quality Act of 2000;
- The BLM will ensure that activities on BLM-administered lands within Gunnison sage-grouse habitat do not negatively impact land health standards; standards and guidelines for livestock grazing and other applicable programs affecting BLM lands will be included in all alternatives;
- The BLM will coordinate and communicate with State, local, and Tribal governments to ensure that management direction and decisions are consistent with applicable State, local, and Tribal plans and policies to the extent consistent with the laws and policies governing the public lands; seek to resolve inconsistencies among plans; and provide ample opportunities for State, local, and Tribal governments to comment on the development of alternatives and the draft RMP amendment;
- The BLM will confer with the USFWS as the primary management agency for ESA-listed species and will consider conservation measures outlined in the *Final Recovery Plan for Gunnison sage-grouse* (2020) and the *Recovery Implementation Strategy for Gunnison sage-grouse (Centrocercus minimus)* (2020);
- The BLM recognizes the important role of State wildlife agencies and will confer and coordinate with these agencies as appropriate;
- The BLM will consider habitat requirements and best management practices outlined by the interagency Rangewide Steering Committee in the *Gunnison Sage-grouse Rangewide Conservation Plan* (2005) and other applicable resources;
- The BLM will evaluate any special management attention needed for the recognized relevant and important values of those areas nominated for ACEC designation and any new nominations, in accordance with BLM Manual 1613; and
- The BLM will consider the draft analysis and direction in the BLM Gunnison Sage-Grouse Rangewide Draft RMP Amendment/Draft EIS (2016).

Summary of Expected Impacts

The RMP amendment and draft EIS will evaluate existing RMPs within the planning area and address management

actions including, but not limited to, mineral leasing and development, recreation, livestock grazing management, realty actions, fire management, vegetation and habitat objectives, and restoration actions. The BLM will then consider, with the best available science, reasonable alternative approaches to its management strategies. Expected changes to RMP management decisions could include seasonal timing limitations, avoidance and mitigation measures, development restrictions within habitat areas, design features, controlled use or surface disturbance restrictions, seasonal closures of high-use areas, and grazing management guidelines.

The public is invited to comment on data relevant to the proposed action and relationship between land use management and Gunnison sage-grouse conservation, and the effects of the management actions under consideration on other public land resources and uses. This information will inform the scope of the impact analysis in the draft EIS. The BLM seeks information related to activities and public land uses that may cause disturbance to important Gunnison sage-grouse habitat and will consider that information as appropriate in describing the existing environment and reasonably foreseeable trends, or in the effects analysis.

Schedule for the Decision-Making Process

This amendment process is expected to be completed within 2 years. The BLM will provide additional opportunities for public participation consistent with the NEPA and land use planning processes, including a 90-day comment period on the Gunnison Sage-Grouse Draft RMP Amendment/EIS and a concurrent 30-day public protest period and a 60-day Governor's consistency review on the proposed RMP amendment. The draft RMP amendment/EIS is anticipated to be available for public review in the summer of 2023 and the proposed RMP amendment/final EIS is anticipated to be available for public protest in early 2024 with a Gunnison Sage-Grouse Approved RMP Amendment and Record of Decision in May 2024.

Public Scoping Process

This notice of intent initiates the scoping period and public review of the planning criteria, which guide the development of the draft RMP amendment/EIS and its analysis.

The BLM anticipates holding a minimum of two and up to four public scoping meetings, which may be conducted through online platforms, to explain project details and obtain feedback. BLM representatives will be available to answer questions. The specific date(s) of these scoping meetings, along with information about how to participate, will be announced at least 15 days in advance through local media, newspapers, and the BLM's project website (see **ADDRESSES**). All comments must be received by the date shown in the **DATES** section. It is important that reviewers provide timely comments in a manner that makes them useful to the agency's preparation of the draft RMP amendment/EIS. Therefore, comments should be provided prior to the close of the scoping period and should clearly articulate the reviewer's concerns and contentions. Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered.

ACECs

The following ACEC is currently designated in the planning area and within the scope of the draft RMP amendment/EIS: Gunnison Sage-Grouse ACEC/Important Bird Area (IBA) covering 22,200 acres of public surface. Gunnison sage-grouse and its habitat is emphasized for protection as an important and relevant value in the designated ACEC within the Gunnison Gorge National Conservation Area (NCA). The BLM will re-evaluate this designated ACEC/IBA for consideration in the draft RMP amendment/EIS.

The BLM will also evaluate these previously nominated ACECs for consideration in the draft RMP amendment/EIS:

- Dry Creek Basin (approximately 34,785 acres) and Northdale/Northdale Expansion (5,239 acres originally nominated; 6,936 additional acres nominated) areas deferred in the Tres Rios Field Office ACEC RMP Amendment (2020) pending issuance of the Gunnison Sage-Grouse RMP Amendment;
- All Gunnison Sage-Grouse Occupied and Unoccupied Habitat (approximately 623,000 acres) previously described as Alternative B in the Gunnison Sage-Grouse Rangewide Draft RMP Amendment/Draft EIS (2016) (DOI–BLM–CO–0000–2014–0001–RMP–EIS).

This notice invites the public to nominate additional areas for ACEC consideration. To assist the BLM in evaluating nominations for consideration in the draft RMP amendment/EIS, please provide supporting descriptive materials, maps, and evidence of the relevance and importance of resources or hazards by the close of the public comment period in order to facilitate timely evaluation. The BLM has identified the anticipated issues related to the consideration of ACECs in the planning criteria.

Lead and Cooperating Agencies

The BLM is the lead agency for the NEPA analysis associated with this planning effort. The BLM has invited other Federal agencies, State and local government agencies, and Tribes to be cooperating agencies. Other stakeholders that may be interested in or affected by the proposed action are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the EIS as a cooperating agency.

Responsible Official

The BLM Colorado State Director is the deciding official for the potential RMP amendments in the planning area in Colorado. The Utah State Director is the deciding official for the potential RMP amendments in the planning area in Utah.

Nature of Decision To Be Made

The nature of the decision to be made will be the State Directors' selection of land use planning decisions for managing BLM-administered lands under the principles of multiple use and sustained yield in a manner that best addresses the purpose and need.

Interdisciplinary Team

The BLM will use an interdisciplinary approach to develop the plan in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in this planning effort to consider the resource issues and concerns identified during development of the RMP amendment/EIS: wildlife biology, fluid minerals, geographic information systems, and land use planning.

Additional Information

The BLM will identify, analyze, and consider mitigation to address the reasonably foreseeable impacts to resources from the proposed plan amendment and all reasonable alternatives and, in accordance with 40 CFR 1502.14(f), include appropriate mitigation measures not already included in the proposed plan amendment or alternatives. Mitigation may include avoidance, minimization, rectification, reduction or elimination

over time, and compensation, and may be considered at multiple scales, including the landscape scale.

The BLM will utilize and coordinate the NEPA and land use planning processes for this effort to help support compliance with applicable procedural requirements of the ESA (16 U.S.C. 1536) and Section 106 of the National Historic Preservation Act (54 U.S.C. 306108) as implemented in 36 CFR 800.2(d)(3), including the public involvement requirements of Section 106. The information about historic and cultural resources and threatened and endangered species within the area potentially affected by the proposed plan amendment will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will consult with Indian Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM Manual Section 1780, and other Departmental policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with Indian Tribal Nations and other stakeholders that may be interested in or affected by the proposed plan amendment that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a cooperating agency.

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: 40 CFR 1501.9 and 43 CFR 1610.2)

Stephanie Connolly,

BLM Colorado Acting State Director.

[FR Doc. 2022–14361 Filed 7–5–22; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV952000 LF1000000.PN0000; 6100.241A; MO # 4500163655; TAS:22X]

Filing of Plats of Survey; NEVADA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public and interested State and local government officials of the filing of Plats of Survey in Nevada.

DATES: Filing is applicable at 10:00 a.m. on the dates indicated below.

FOR FURTHER INFORMATION CONTACT: Michael O. Harmening, Chief Cadastral Surveyor for Nevada, Bureau of Land Management, Nevada State Office, 1340 Financial Blvd., Reno, NV 89502–7147, phone: 775–861–6490. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: 1. The Plat of Survey of the following described land was officially filed at the Bureau of Land Management (BLM) Nevada State Office, Reno, Nevada, on August 3, 2012.

The plat, in three sheets, representing the dependent resurvey of the Fourth Standard Parallel South, through Range 53 East and a portion of Range 54 East, the south and east boundaries, a portion of the subdivisional lines, and Mineral Survey Nos. 2182A and 3800, and the subdivision of section 21, Township 17 South, Range 53 East, Mount Diablo Meridian, Nevada, under Group No. 912, was accepted July 30, 2012. This survey was executed to meet certain administration needs of the Bureau of Land Management and the USDA Forest Service.

2. The Plat of Survey of the following described lands was officially filed at the Bureau of Land Management (BLM) Nevada State Office, Reno, Nevada, on September 30, 2020.

The plat, in four sheets, representing the dependent resurvey of portions of the west and north boundaries, a portion of the subdivisional lines, and a portion of the subdivision-of- section lines of section 18, and the subdivision of sections 6 and 7, and a metes-and-bounds survey in sections 6, 7, and 18, Township 19 South, Range 62 East, Mount Diablo Meridian, Nevada, under Group No. 957, was accepted September 29, 2020. This survey was executed to meet certain administrative needs of the Bureau of Land Management.

3. The Plat of Survey of the following described land lands was officially filed at the Bureau of Land Management (BLM) Nevada State Office, Reno, Nevada, on November 23, 2020.

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines, and the subdivision of sections 23 and 34, Township 19 South, Range 59 East, Mount Diablo Meridian, Nevada, under Group No. 956, was accepted November 19, 2020. This survey was executed to meet certain administrative needs of the Bureau of Land Management.

4. The Plat of Survey of the following described lands was officially filed at the Bureau of Land Management (BLM) Nevada State Office, Reno, Nevada, on April 02, 2021.

The plat, in five sheets, representing the dependent resurvey of the Eighth Standard Parallel North, through Range 51 East and a portion of Range 52 East, the corrective dependent resurvey of a portion of the west boundary, and the dependent resurvey of a portion of the subdivisional lines and portions of certain mineral surveys, Township 40 North, Range 51 East, Mount Diablo Meridian, Nevada, under Group No. 876, was accepted March 29, 2021. This survey was executed to meet certain administrative needs of the Bureau of Land Management.

5. The Plat of Survey of the following described lands was officially filed at the Bureau of Land Management (BLM) Nevada State Office, Reno, Nevada, on July 08, 2021.

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines and H.E.S. No. 57, Township 47 North, Range 58 East, Mount Diablo Meridian, Nevada, under Group No. 996, was accepted July 06, 2021. This survey was executed to meet certain administrative needs of the Bureau of Land Management.

6. The Plat of Survey of the following described lands was officially filed at the Bureau of Land Management (BLM) Nevada State Office, Reno, Nevada, on September 16, 2021.

The plat, in one sheet, representing the dependent resurvey of a portion of the south boundary and a portion of the subdivisional lines, and the subdivision of certain sections. Township 22 North, Range 23 East, Mount Diablo Meridian, Nevada, under Group No. 989, was accepted August 27, 2021. This survey was executed to meet certain

administrative needs of the Bureau of Land Management and the Bureau of Indian Affairs.

The surveys, listed above, are now the basic record for describing the lands for all authorized purposes. These records have been placed in the open files in the BLM Nevada State Office and are available to the public as a matter of information.

Dated: June 30, 2022.

Michael O. Harmening,

Chief Cadastral Surveyor for Nevada.

[FR Doc. 2022–14363 Filed 7–5–22; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV9120000.L18200000.XX0000. LXSS006F0000.223.241A. MO:4500163075]

Notice of Public Meeting: Mojave-Southern Great Basin Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior's Bureau of Land Management (BLM) Mojave-Southern Great Basin Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Mojave-Southern Great Basin RAC will hold an in-person meeting with a virtual participation option on Tuesday, August 9, 2022. The meeting will be held from 1:00 to 4:30 p.m. and may end earlier or later depending on the needs of group members.

ADDRESSES: The meeting will be held at the BLM Southern Nevada District Office, 4701 North Torrey Pines, Las Vegas, NV. Individuals that prefer to participate virtually must register by visiting the RAC's web page no later than 1 week before the meeting at *https://www.blm.gov/get-involved/resource-advisory-council/near-me/nevada.*

Written comments can be mailed to: BLM Southern Nevada District Office, Attn: RAC Coordinator; 4701 North Torrey Pines, Las Vegas, Nevada 89130. Comments can also be submitted by email to *k1cannon@blm.gov* with the subject line: BLM Mojave-Southern Great Basin RAC.

FOR FURTHER INFORMATION CONTACT: Kirsten Cannon, RAC Coordinator, by telephone at (702) 515–5057, or by email at *k1cannon@blm.gov.*

SUPPLEMENTARY INFORMATION: The 15-member BLM Mojave-Southern Great Basin RAC serves in an advisory capacity concerning issues relating to land use planning and the management of the public land resources located within the BLM's Battle Mountain, Ely, and Southern Nevada Districts. Meetings are open to the public in their entirety and a public comment period will be held near the end of the meeting.

Agenda items include District Manager reports, a discussion on renewable energy applications and prioritization, a review of roles and responsibilities for new members and election of a RAC Chair, and a presentation on the Red Rock Canyon National Conservation Area (NCA) Business Plan and associated amenity recreation fee proposal for the Red Rock Canyon NCA for recommendation to the BLM. The final meeting agenda will be available two weeks in advance of the meeting on the RAC's web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-me/nevada.*

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the (see **FOR FURTHER INFORMATION CONTACT**) section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

Interested persons may make oral presentations to the RAC during the meeting or file written statements. Such requests should be made to RAC Coordinator Kirsten Cannon prior to the public comment period. Depending on the number of people who wish to speak, the time for individual comments may be limited. Individuals who need further information about the meetings, or special assistance such as sign language interpretation or other reasonable accommodations, may contact Kirsten Cannon (see **FOR FURTHER INFORMATION CONTACT**).

Before including your address, phone number, email address, or other personal identifying information in your comments, please 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: 43 CFR 1784.4–2)

Angelita S. Bulletts,

District Manager.

[FR Doc. 2022–14313 Filed 7–5–22; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

Notice of Approved Class III Tribal Gaming Ordinance

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of the approval of Stillaguamish Tribe of Indians' Class III gaming ordinance by the Chairman of the National Indian Gaming Commission.

DATES: This notice is applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Dena Wynn, Office of General Counsel at the National Indian Gaming Commission, 202–632–7003, or by facsimile at 202–632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) 25 U.S.C. 2701 *et seq.,* established the National Indian Gaming Commission (Commission). Section 2710 of IGRA authorizes the Chairman of the Commission to approve Class II and Class III tribal gaming ordinances. Section 2710(d)(2)(B) of IGRA, as implemented by NIGC regulations, 25 CFR 522.8, requires the Chairman to publish, in the **Federal Register**, approved Class III tribal gaming ordinances and the approvals thereof.

IGRA requires all tribal gaming ordinances to contain the same requirements concerning tribes' sole proprietary interest and responsibility for the gaming activity, use of net revenues, annual audits, health and safety, background investigations and licensing of key employees and primary management officials. The Commission, therefore, believes that publication of each ordinance in the **Federal Register**

would be redundant and result in unnecessary cost to the Commission.

Thus, the Commission believes that publishing a notice of approved Class III tribal gaming ordinances in the **Federal Register**, is sufficient to meet the requirements of 25 U.S.C. 2710(d)(2)(B). Every ordinance and approval thereof is posted on the Commission's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances within five (5) business days of approval.

On June 27, 2022, the Chairman of the National Indian Gaming Commission approved Stillaguamish Tribe of Indians' Class III Gaming Ordinance. A copy of the approval letter is posted with this notice and can be found with the approved ordinance on the NIGC's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances. A copy of the approved Class III ordinance will also be made available upon request. Requests can be made in writing to the Office of General Counsel, National Indian Gaming Commission, Attn: Dena Wynn, 1849 C Street NW, MS #1621, Washington, DC 20240 or at *info@nigc.gov.*

National Indian Gaming Commission.
Dated: June 28, 2022.

Michael Hoenig,

General Counsel.

June 27, 2022
VIA EMAIL
Eric White, Chairman
Stillaguamish Tribe of Indians
P.O. Box 277
3322 236th St. NE
Arlington, WA 98223
Re: Gaming Code Amendment
Dear Chairman White:

This letter responds to your request for the National Indian Gaming Commission Chairman to review and approve the Stillaguamish Gaming Code. On April 7, 2022, the Stillaguamish Tribe of Indians Board of Directors approved Resolution 2022/057, adopting the Revised Second Amendment to the Gaming Code.

Thank you for bringing the amendment to our attention and for providing us with a copy. The Gaming Code is approved as it is consistent with the Indian Gaming Regulatory Act and NIGC regulations.

If you have any questions, please contact Senior Attorney Esther Dittler at 202–853–7511.

Sincerely,
E. Sequoyah Simermeyer
Chairman

[FR Doc. 2022–14297 Filed 7–5–22; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

Notice of Approved Class III Tribal Gaming Ordinance

AGENCY: National Indian Gaming Commission.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of the approval of Tulalip Tribes of Washington's Class III gaming ordinance by the Chairman of the National Indian Gaming Commission.

DATES: This notice is applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Dena Wynn, Office of General Counsel at the National Indian Gaming Commission, 202–632–7003, or by facsimile at 202–632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) 25 U.S.C. 2701 *et seq.,* established the National Indian Gaming Commission (Commission). Section 2710 of IGRA authorizes the Chairman of the Commission to approve Class II and Class III tribal gaming ordinances. Section 2710(d)(2)(B) of IGRA, as implemented by NIGC regulations, 25 CFR 522.8, requires the Chairman to publish, in the **Federal Register**, approved Class III tribal gaming ordinances and the approvals thereof.

IGRA requires all tribal gaming ordinances to contain the same requirements concerning tribes' sole proprietary interest and responsibility for the gaming activity, use of net revenues, annual audits, health and safety, background investigations and licensing of key employees and primary management officials. The Commission, therefore, believes that publication of each ordinance in the **Federal Register** would be redundant and result in unnecessary cost to the Commission.

Thus, the Commission believes that publishing a notice of approved Class III tribal gaming ordinances in the **Federal Register**, is sufficient to meet the requirements of 25 U.S.C. 2710(d)(2)(B). Every ordinance and approval thereof is posted on the Commission's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances within five (5) business days of approval.

On May 9, 2022, the Chairman of the National Indian Gaming Commission approved Tulalip Tribes of Washington's Class III Gaming Ordinance. A copy of the approval letter is posted with this notice and can be found with the approved ordinance on the NIGC's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances. A copy of the approved Class III ordinance will also be made available upon request. Requests can be made in writing to the Office of General Counsel, National Indian Gaming Commission, Attn: Dena Wynn, 1849 C Street NW, MS #1621, Washington, DC 20240 or at *info@nigc.gov.*

National Indian Gaming Commission.
Dated: June 28, 2022.

Michael Hoenig,

General Counsel.

May 9, 2022
VIA EMAIL
Chair Teri Gobin
Board of Directors, Tulalip Tribes
6406 Marine Drive
Tulalip, WA 98271
Re: Tulalip Tribes Amended Gaming Ordinance
Dear Chair Gobin:

This letter responds to the March 14, 2022 email submission on behalf of the Tulalip Tribes (''Tribes'') informing the National Indian Gaming Commission that the Tribes had amended its gaming ordinance. The submission included two administrative amendments that clarified the definition of ''Tribal gaming operation'' and added an attendance requirement for the Tribes gaming commissioners.

Thank you for bringing these amendments to our attention and for providing us with a thorough submission of the Band's gaming laws and regulations. The amended ordinance is approved as it is consistent with the requirements of the Indian Gaming Regulatory Act and NIGC's regulations. If you have any questions or require anything further, please contact Josh Proper at (202) 632–0294.

Sincerely,
E. Sequoyah Simermeyer
Chairman

[FR Doc. 2022–14298 Filed 7–5–22; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

Notice of Approved Class III Tribal Gaming Ordinance

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of the approval of Paskenta Band of Nomlaki Indians' Class III gaming ordinance by the Chairman of the National Indian Gaming Commission.

DATES: This notice is applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Dena Wynn, Office of General Counsel

at the National Indian Gaming Commission, 202–632–7003, or by facsimile at 202–632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) 25 U.S.C. 2701 *et seq.,* established the National Indian Gaming Commission (Commission). Section 2710 of IGRA authorizes the Chairman of the Commission to approve Class II and Class III tribal gaming ordinances. Section 2710(d)(2)(B) of IGRA, as implemented by NIGC regulations, 25 CFR 522.8, requires the Chairman to publish, in the **Federal Register**, approved Class III tribal gaming ordinances and the approvals thereof.

IGRA requires all tribal gaming ordinances to contain the same requirements concerning tribes' sole proprietary interest and responsibility for the gaming activity, use of net revenues, annual audits, health and safety, background investigations and licensing of key employees and primary management officials. The Commission, therefore, believes that publication of each ordinance in the **Federal Register** would be redundant and result in unnecessary cost to the Commission.

Thus, the Commission believes that publishing a notice of approved Class III tribal gaming ordinances in the **Federal Register** is sufficient to meet the requirements of 25 U.S.C. 2710(d)(2)(B). Every ordinance and approval thereof is posted on the Commission's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances within five (5) business days of approval.

On May 24, 2022, the Chairman of the National Indian Gaming Commission approved Paskenta Band of Nomlaki Indians' Class III Gaming Ordinance. A copy of the approval letter is posted with this notice and can be found with the approved ordinance on the NIGC's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances. A copy of the approved Class III ordinance will also be made available upon request. Requests can be made in writing to the Office of General Counsel, National Indian Gaming Commission, Attn: Dena Wynn, 1849 C Street NW, MS #1621, Washington, DC 20240 or at *info@nigc.gov.*

National Indian Gaming Commission.
Dated: June 28, 2022.

Michael Hoenig,

General Counsel.

May 24, 2022
VIA EMAIL
Chairman Andrew Alejandra
Paskenta Band of Nomlaki Indians
P.O. Box 709
Coming, CA 96021

Re: Paskenta Band Amended Gaming Ordinance

Dear Chairman Alejandra:

This letter responds to the March 21, 2022 submission on behalf of the Paskenta Band of Nomlaki Indians (''Tribe'') informing the National Indian Gaming Commission that the Tribe amended its gaming ordinance. The amendments to the tribal gaming code were intended to update the ordinance to reflect changes in tribal law, ensure consistency with federal law and bring it in conformity with the Tribe's new gaming compact with the State of California that became effective on December 11, 2020.

25 CFR 522.2(t) requires a tribe to submit a description for resolving disputes between the gaming public and the tribe with any request for approval of a gaming ordinance. Previously, the dispute resolution process was described in the Tribe's ordinance. Resolution TC2022–5 amends the gaming ordinance to now require the gaming commission to promulgate dispute resolution regulations that meet the minimum standards set forth in the Tribe's gaming compact. Since the amended gaming ordinance specifies that any dispute resolution process must meet the minimum standards of the Tribe's gaming compact, it is my understanding that in the absence of an approved dispute resolution regulations, the dispute resolution process described in gaming compact will control.

Thank you for bringing these amendments to our attention. The amended ordinance, as noted above, is approved as it is consistent with the requirements of the Indian Gaming Regulatory Act and NIGC's regulations. If you have any questions or require anything further, please contact Josh Proper at (202) 632–0294.

Sincerely,
E. Sequoyah Simermeyer
Chairman

[FR Doc. 2022–14294 Filed 7–5–22; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

Notice of Approved Class III Tribal Gaming Ordinance

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of the approval of Kalispel Tribe of Indians' Class III gaming ordinance by the Chairman of the National Indian Gaming Commission.

DATES: This notice is applicable July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Dena Wynn, Office of General Counsel at the National Indian Gaming Commission, 202–632–7003, or by facsimile at 202–632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) 25 U.S.C. 2701 *et seq.,* established the National Indian Gaming Commission (Commission). Section 2710 of IGRA authorizes the Chairman of the Commission to approve Class II and Class III tribal gaming ordinances. Section 2710(d)(2)(B) of IGRA, as implemented by NIGC regulations, 25 CFR 522.8, requires the Chairman to publish, in the **Federal Register**, approved Class III tribal gaming ordinances and the approvals thereof.

IGRA requires all tribal gaming ordinances to contain the same requirements concerning tribes' sole proprietary interest and responsibility for the gaming activity, use of net revenues, annual audits, health and safety, background investigations and licensing of key employees and primary management officials. The Commission, therefore, believes that publication of each ordinance in the **Federal Register** would be redundant and result in unnecessary cost to the Commission.

Thus, the Commission believes that publishing a notice of approved Class III tribal gaming ordinances in the **Federal Register** is sufficient to meet the requirements of 25 U.S.C. 2710(d)(2)(B). Every ordinance and approval thereof is posted on the Commission's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances within five (5) business days of approval.

On June 2, 2022, the Chairman of the National Indian Gaming Commission approved Kalispel Tribe of Indians' Class III Gaming Ordinance. A copy of the approval letter is posted with this notice and can be found with the approved ordinance on the NIGC's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances. A copy of the approved Class III ordinance will also be made available upon request. Requests can be made in writing to the Office of General Counsel, National Indian Gaming Commission, Attn: Dena Wynn, 1849 C Street NW, MS #1621, Washington, DC 20240 or at *info@nigc.gov.*

National Indian Gaming Commission.
Dated: June 28, 2022.

Michael Hoenig,

General Counsel.

June 2, 2022
VIA EMAIL
Glen Nenema, Chairman
P.O. Box 39
Usk, WA 99180
Re: Gaming Ordinance Amendment
Dear Mr. Nenema:

This letter responds to your request for the National Indian Gaming Commission (NIGC) Chairman to review and approve the Kalispel Tribe of Indians' Gaming Ordinance amendment. The Kalispel Business Committee amended its Gaming Ordinance on March 22, 2022, by Kalispel Resolution No. 2022–50.

Thank you for bringing the gaming ordinance to the Agency's attention and for providing a copy. I approve the ordinance as it is consistent with the Indian Gaming Regulatory Act and NIGC regulations. As the Tribal Gaming Agency (TGA) will be changing its process for conducting a criminal history check, I want to remind the Tribe that as long as Criminal History Record Information that has been received from the NIGC still resides within the TGA's system(s), the Federal Bureau of Investigation Criminal Justice Information Services (CJIS) Security Policy requirements apply until such time as the information is securely disposed of, in accordance with the Security Policy.

If you have any questions, please contact Senior Attorney Esther Dittler at 202–853–7511.

Sincerely,
E. Sequoyah Simermeyer
Chairman

[FR Doc. 2022–14292 Filed 7–5–22; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 221S180110; S2D2S SS08011000 SX064A000 22XS501520; OMB Control Number 1029–0113]

Submission to the Office of Management and Budget for Review and Approval; General Reclamation Requirements

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before September 6, 2022.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0113 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at 202–208–2716. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) is the collection necessary to the proper functions of the agency; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the agency enhance the quality, utility, and clarity of the information to be collected; and (5) how might the agency minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Part 874 establishes land and water eligibility requirements, reclamation objectives and priorities and reclamation contractor responsibility. The regulations at 30 CFR 874.17 require consultation between the Abandoned Mine Land (AML) agency and the appropriate Title V regulatory authority on the likelihood of removing the coal under a Title V permit and concurrences between the AML agency and the appropriate Title V regulatory authority on the AML project boundary and the amount of coal that would be extracted under the AML reclamation project.

Title of Collection: General Reclamation Requirements.

OMB Control Number: 1029–0113.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal governments.

Total Estimated Number of Annual Respondents: 3.

Total Estimated Number of Annual Responses: 3.

Estimated Completion Time per Response: 83 hours.

Total Estimated Number of Annual Burden Hours: 249.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: $0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Division of Regulatory Support.

[FR Doc. 2022–14371 Filed 7–5–22; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 221S180110; S2D2S SS08011000 SX064A000 22XS501520; OMB Control Number 1029–0049]

Special Permanent Program Performance Standards—Operations in Alluvial Valley Floors

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before September 6, 2022.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov*. Please reference OMB Control Number 1029–0049 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at 202–208–2716. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *https://www.reginfo.gov/public/do/PRAMain*.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) is the collection necessary to the proper functions of the agency; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the agency enhance the quality, utility, and clarity of the information to be collected; and (5) how might the agency minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: This Part implements the requirements in Sections 510(b)(5) and 515(b)(10)(F) of the Surface Coal Mining and Reclamation Act of 1977 (the Act) to protect alluvial valley floors from the adverse effects of surface coal mining operations west of the 100th meridian. Part 822 requires the permittee to install, maintain, and operate a monitoring system to provide specific protection for alluvial valley floors. This information is necessary to determine whether the unique hydrologic conditions of alluvial valley floors are protected according to the Act.

Title of Collection: Special Permanent Program Performance Standards—Operations in Alluvial Valley Floors.

OMB Control Number: 1029–0049.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal governments and businesses.

Total Estimated Number of Annual Respondents: 3.

Total Estimated Number of Annual Responses: 60.

Estimated Completion Time per Response: Varies 15 hours to 160 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 5,250.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: $0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Division of Regulatory Support.

[FR Doc. 2022–14373 Filed 7–5–22; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1284]

Certain Electronic Devices Having Wireless Communication Capabilities and Components Thereof; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation as to Blu Products, Inc.; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 23) of the presiding administrative law judge (''ALJ''), terminating the investigation as to respondent BLU Products, Inc. of Doral, Florida (''BLU'') based on a settlement agreement. Because BLU is the last remaining respondent, this investigation is terminated in its entirety.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 *https://www.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 instituted this investigation on November 2, 2021, based on a complaint filed on behalf of Bell Northern Research, LLC of Chicago, Illinois (''BNR''). 86 FR 60467 (Nov. 2, 2021). The complaint alleged a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electronic devices having wireless communication capabilities and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 8,204,554; 7,319,889; RE 48,629; and 8,416,862. *Id.* at 60467–

68. The complaint further alleged that an industry in the United States exists as required by section 337. *Id.* The Commission's notice of investigation named the following as respondents: BLU; TCL Electronics Holdings Limited of Hong Kong; TCT Mobile (US) Inc. of Irvine, California; TTE Technology, Inc. of Corona, California; HMD Global Oy of Espoo, Finland; HMD America, Inc. of Miami, Florida; Lenovo Group Ltd. of Beijing, China; Lenovo (United States), Inc. of Morrisville, North Carolina; Motorola Mobility LLC of Chicago, Illinois; OnePlus Technology Co. Ltd. of Shenzhen, China; BBK Electronics Corp. of Dongguan, China; and Sonim Technologies, Inc. of Austin, Texas. *Id.* The Office of Unfair Import Investigations (''OUII'') was named as a party in this investigation. *Id.*

On May 31, 2022, pursuant to Commission Rule 210.21(b) (19 CFR 210.21(b)), complainant BNR and respondent BLU filed a joint motion to terminate this investigation as to BLU based on a settlement agreement. On June 10, 2022, OUII filed a response supporting the motion.

On June 16, 2022, the ALJ issued Order No. 23, the subject ID, which granted the motion. The ID found that the motion complied with the Commission's Rules and that terminating the investigation as to BLU would not be contrary to the public interest. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID.

The investigation is hereby terminated as to BLU Products, Inc. of Doral, Florida. Because BLU is the last remaining respondent, this investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on June 29, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: June 30, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–14369 Filed 7–5–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1263]

Certain Televisions, Remote Controls, and Components Thereof Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on June 28, 2022, the presiding administrative law judge (''ALJ'') issued an Initial Determination on Violation of Section 337. The ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 *https://www.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: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

> unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: a limited exclusion order directed to certain televisions, remote controls, and components thereof imported, sold for importation, and/or sold after importation by respondents Universal Electronics, Inc., Gemstar Technology (Qinzhou) Co. Ltd., Gemstar Technology (Yangzhou) Co. Ltd., C.G. Development Ltd., Universal Electronics BV, and CG México Remote Controls, S. de R.L. de C.V. (collectively, ''UEI''); Charter Communications, Inc., Charter Communications Operating, LLC, and Spectrum Management Holding Company, LLC (collectively, ''Charter''); Altice USA, Inc., Cablevision Systems Corp., and Cequel Communications, LLC d/b/a Suddenlink Communications (collectively, ''Altice''); and WideOpenWest, Inc. (''WOW''); and cease and desist orders directed to UEI, Charter, Altice, and WOW. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on June 28, 2022. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, 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 recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended 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 recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on July 29, 2022.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1263'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: June 30, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–14368 Filed 7–5–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0075]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Transactions Among Licensees/Permittees, Limited

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice

ACTION: 30-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ) will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until August 5, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension with Change, of a Currently Approved Collection.

(2) *The Title of the Form/Collection:* Strategic Transactions Among Licensees/Permittees, Limited.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: None. Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. Abstract: This information collection outlines specific requirements regarding limited explosive permits, and also allows the Bureau of Alcohol, Tobacco, Firearms and Explosives to implement provisions of the Safe Explosives Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 100 respondents will respond to this collection once annually, and it will take each respondent approximately 30 minutes to complete their responses.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 50 hours, which is equal to 100 (total respondents) * 1 (# of response per respondent) * .5 (30 minutes or the time taken to prepare each response).

(7) *An Explanation of the Change in Estimates:* Due to fewer limited explosive permitees, both the total responses and burden hours have reduced from 125 and 63 hours respectively during the last renewal in 2019, to 100 and 50 hours currently.

If additional information is required contact: Robert Houser, Assistant Director, Policy and Planning Staff, Office of the Chief Information Officer, United States Department of Justice, Justice Management Division, Two Constitution Square, 145 N Street NE, Mail Stop 3.E–206, Washington, DC 20530.

Dated: June 29, 2022.

Robert Houser,

Assistant Director, Policy and Planning Staff, U.S. Department of Justice.

[FR Doc. 2022–14305 Filed 7–5–22; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Modifications of Consent Decree Under the Clean Water Act

On June 29, 2022, the Department of Justice lodged proposed modifications to a Consent Decree with the United States District Court for the Eastern District of Pennsylvania in *United States and the Commonwealth of Pennsylvania* v. *Bristol Township,* Civil Case No. 2:10–cv–5049 (E.D. Pa.).

The original Consent Decree was entered in January, 2011, and resolved civil claims under the Clean Water Act including: the discharge of pollutants, including raw sewage, from Bristol Township's (''Bristol'') sanitary sewer system to navigable waters; violations of the operation and maintenance requirements of Bristol's National Pollutant Discharge Elimination System (''NPDES'') permit; and violations of the Pennsylvania Clean Streams Law. The Consent Decree included measures to ensure compliance with Bristol's NPDES permit limitations and requirements, proper operation and maintenance of the waste water treatment plant and the collection system, and effective implementation of Bristol's Pretreatment Program.

The parties to the Consent Decree have agreed to certain modifications set forth in the Second Amendment to the Decree. The Second Amendment builds upon the previous amendment to the Consent Decree, which was entered by the Court in May 2012. The Second Amendment is meant to address the continuing hydraulic overload of Bristol's sewer system. The Second Amendment provides for Bristol to conduct additional inflow and infiltration (''I&I'') work through the implementation of its I&I Abatement Plan, and construct a new clarifier at its waste water treatment plant. The Second Amendment also modifies certain notice requirements for the parties and resolves certain stipulated penalties.

The publication of this notice opens a period for public comment on the proposed modifications to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the Commonwealth of Pennsylvania* v. *Bristol Township,* Civil Case No. 2:10–cv–5049 (E.D. Pa.), D.J. Ref. No. 90–5–1–1–09460/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed amendments to the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed amendments upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $4.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Jeffrey Sands,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022–14337 Filed 7–5–22; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[A.G. Order No. 5453–2022]

Office of the Attorney General; Clarifying Lawful Overseas Use of Data Act; Attorney General Certification and Determination

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: In accordance with the Clarifying Lawful Overseas Use of Data Act (''CLOUD Act'') relating to an executive agreement governing access by a foreign government to electronic data, notice is given that on December 15, 2021, the Attorney General certified his determination that the laws of the Government of Australia and the Agreement between the Government of the United States of America (''U.S.'' or the ''United States'') and the Government of Australia on Access to Electronic Data for the Purpose of Countering Serious Crime (the ''U.S.-Australia CLOUD Agreement'' or ''Agreement'') satisfy the requirements of the CLOUD Act. On December 22, 2021, the Attorney General submitted a written certification of his determination to Congress.

DATES: The U.S.-Australia CLOUD Agreement will enter into force not earlier than June 20, 2022, unless Congress enacts a joint resolution of disapproval, in accordance with the CLOUD Act, and after the United States and Australia have exchanged diplomatic notes indicating that each country has taken the steps necessary to bring the agreement into force.

FOR FURTHER INFORMATION CONTACT: Richard Downing, Deputy Assistant Attorney General, Criminal Division, 950 Pennsylvania Avenue NW, Washington, DC 20530–0001, email: *Criminal.Division@usdoj.gov,* phone: 202–514–2000.

SUPPLEMENTARY INFORMATION: The CLOUD Act, Public Law 115–141, Div. V, 132 Stat. 1213–25 (2018), lifts certain restrictions under U.S. law on companies disclosing electronic data, in response to qualifying, lawful orders in investigations of serious crime, directly to a qualifying foreign government with which the United States has entered into an executive agreement governing access by the foreign government to covered data. 132 Stat. at 1213–17.

Before such an agreement can go into effect, the Attorney General, with the concurrence of the Secretary of State, must determine that the considerations outlined in 18 U.S.C. 2523(b) have been met. The Attorney General must then submit a written certification of his determination to Congress, including an explanation of each consideration required by 18 U.S.C. 2523(b), not later than 7 days after the date on which the Attorney General certifies the executive agreement. 18 U.S.C. 2523(d)(1). The executive agreement will enter into force not earlier than 180 days after the date the Attorney General notifies Congress, unless Congress enacts a joint resolution of disapproval, in accordance with the CLOUD Act, 18 U.S.C. 2523(d)(2), and after the United States and Australia have exchanged diplomatic notes indicating that each country has taken the steps necessary to bring the agreement into force.

Under 18 U.S.C. 2523(g), the Attorney General's determination or certification under 18 U.S.C. 2523(b) must be published in the **Federal Register** as soon as is reasonably practicable.

Determination and Certification Pursuant to Section 2523(b)

On December 15, 2021, the Minister for Home Affairs of Australia and the Attorney General of the United States signed the U.S.-Australia CLOUD Agreement. A copy of the U.S.-Australia CLOUD Agreement is available at: *https://www.justice.gov/dag/cloudact.* On December 15, 2021, the Attorney General certified his determination that the laws of the Government of Australia and the U.S.-Australia CLOUD Agreement satisfy the requirements of 18 U.S.C. 2523(b). The Attorney General's determination was based on the considerations in paragraphs (1), (2), (3), and (4) of 18 U.S.C. 2523(b), as explained in the ''Explanation of each consideration in determining that the Agreement satisfies the requirements of 18 U.S.C. 2523(b),'' available at: *https://www.justice.gov/dag/cloudact.* Secretary of State Blinken concurred with the Attorney General's determination.

Notification to Congress Pursuant to Section 2523(d)

The Department of Justice transmitted the U.S.-Australia CLOUD Agreement certification to Congress December 22, 2021. The Attorney General provided the certification to the Senate Committee on the Judiciary, the Senate Committee on Foreign Relations, the House Committee on the Judiciary, and the House Committee on Foreign Affairs. The U.S.-Australia CLOUD Agreement will enter into force not earlier than June 20, 2022, unless Congress enacts a joint resolution of disapproval, in accordance with 18 U.S.C. 2523(d), and after the United States and Australia have exchanged diplomatic notes indicating that each country has taken the steps necessary to bring the agreement into force.

Non-Reviewable Determination and Certification

In accordance with 18 U.S.C. 2523(c), the determination and certification by the Attorney General described in this notice are not subject to judicial or administrative review.

Dated: June 24, 2022.

Merrick B. Garland,

Attorney General.

[FR Doc. 2022–14320 Filed 7–5–22; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

[OMB Number: 1121–0341 and 1121–0342]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension With Change of a Previously Approved Collection; Office for Victims of Crime Training and Technical Assistance Center (OVC TTAC) Feedback Form Package

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until September 6, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Tom Talbot, Senior Policy Advisor, Office of Justice Programs, Bureau of Justice Assistance, 810 Seventh Street NW, Washington, DC 20531,*Thomas.Talbot@usdoj.gov,* 202–514–9482. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Assistance, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension with change of a currently approved collection.

2. *The Title of the Form/Collection:* OVC TTAC Feedback Form Package.

3. *The agency form number:* Office for Victims of Crime, Office of Justice Programs, Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: State, Local, or Tribal agencies/organizations. Other: Federal Government; Individuals or households; Not-for-profit institutions; Businesses or other for-profit. Abstract: The Office for Victims of Crime Training and Technical Assistance Center (OVC TTAC) Feedback Form Package is designed to collect the data necessary to continuously assess the satisfaction and outcomes of assistance provided through OVC TTAC for both monitoring and accountability purposes to continuously meet the needs of the victim services field. OVC TTAC will give these forms to recipients of training and technical assistance, scholarship applicants, users of the website and call center, consultants/instructors providing training, agencies requesting services, and other professionals receiving assistance from OVC TTAC. The purpose of this data collection will be to capture important feedback on the respondents' satisfaction and outcomes of the resources provided. The data will then be used to advise OVC on ways to improve the support that it provides to the victim services field at-large.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are approximately 26,825 respondents who will require an average of 20 minutes (ranging from 5 to 20 minutes across all forms) to respond to a single form each year.

6. *An estimate of the total public burden (in hours) associated with the collection:* The total annual public burden hours for this information collection are estimated to be 6,409 hours.

If additional information is required contact: Robert Houser, Assistant

Director, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: June 30, 2022.

Robert Houser,

Assistant Director, Policy and Planning Staff, U.S. Department of Justice.

[FR Doc. 2022–14339 Filed 7–5–22; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Agency Information Collection Activities; Comment Request; Notice of Termination, Suspension, Reduction, or Increase in Benefit Payment

AGENCY: Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by September 6, 2022.

ADDRESSES: A copy of this information collection request (ICR) with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.* Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Office of Workers' Compensation Programs, Room S3323, and 200 Constitution Avenue NW, Washington, DC 20210; by email: *suggs.anjanette@dol.gov.*

FOR FURTHER INFORMATION CONTACT: 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.

This ICR seeks approval under the PRA for an extension of an existing collection Notice of Termination, Suspension, Reduction or Increase in Benefit Payments (CM–908). The Office of Workers' Compensation Programs (OWCP) administers the Black Lung Benefits Act (BLBA), 30 U.S.C. 901 *et seq.* Coal mine operators, their representatives, or their insurers who have been identified as responsible for paying Black Lung benefits to an eligible miner or an eligible surviving dependent of the miner are called Responsible Operators (RO's). RO's that pay benefits are required to report any change in the benefit amount to the Department of Labor (DOL). The CM–908, when completed and sent to DOL, notifies DOL of the change in the beneficiary's benefit amount and the reason for the change. The BLBA and 20 CFR 725.621 necessitate this information collection. This information collection is currently approved for use through February 28, 2025.

The Department of Labor is particularly interested in comments which:

* 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 submissions of responses.

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 Department of Labor 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 submissions of responses.

The Department of Labor seeks approval for the extension of this currently approved information collection to insure that the correct benefits are paid by RO's. If this information were not gathered, there would be no way to insure that black lung beneficiaries who receive benefit payments from RO's are receiving the correct amount of benefits.

Agency: DOL–OWCP–DCMWC.

Type of Review: Revision.

Title of Collection: Notice of Termination, Suspension, Reduction or Increase In Benefit Payment.

Form: Notice of Termination, Suspension, Reduction or Increase In Benefit Payment, CM–908.

OMB Control Number: 1240–0030.

Affected Public: Business or other for profit.

Total Respondents: 6,081.

Total Annual Responses: 6,081.

Average Time per Response: 12 minutes.

Estimated Total Burden Hours: 1,216 hours.

Frequency: On occasion and annually.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $22,155.00.

Authority: 30 U.S.C. and 20 CFR 725.621.

Anjanette Suggs,

Agency Clearance Officer.

[FR Doc. 2022–14284 Filed 7–5–22; 8:45 am]

BILLING CODE 4510–CK–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting

DATES: The Legal Services Corporation's (LSC) Board of Directors and its several committees will meet July 13–14, 2022. On Wednesday, July 13, the first meeting will begin at 10:30 a.m. Central Daylight Time (CDT), with the next meeting commencing promptly upon adjournment of the immediately preceding meeting. On Thursday, July 14, the first meeting will again begin at 8:30 a.m., CDT, with the next meeting commencing promptly upon adjournment of the immediately preceding meeting.

ADDRESSES: *Public Notice of Virtual Meeting.*

LSC will conduct the July 13–14, 2022 meetings in-person and via Zoom.

Public Observation: Unless otherwise noted herein, the Board and all committee meetings will be open to public observation via Zoom. Members of the public who wish to participate remotely in the public proceedings may do so by following the directions provided below.

Directions for Open Sessions

Wednesday, July 13, 2022

- To join the Zoom meeting by computer, please use this link.
- *https://lsc-gov.zoom.us/j/88115224073?pwd=Yy83UmQ0TmlndjlNU0x6V0JSWTdsUT09*
  - *Meeting ID:* 881 1522 4073
  - *Passcode:* 71322
- To join the Zoom meeting with one tap from your mobile phone, please click dial:
  - +16468769923,,88115224073# US (New York)
  - +13017158592,,88115224073# US (Washington DC)
- To join the Zoom meeting by telephone, please dial one of the following numbers:
  - +1 301 715 8592 US (Washington DC)
  - +1 646 876 9923 US (New York)
  - +1 312 626 6799 US (Chicago)
  - +1 669 900 6833 US (San Jose)
  - +1 253 215 8782 US (Tacoma)
  - +1 346 248 7799 US (Houston)
  - +1 408 638 0968 US (San Jose)
  - *Meeting ID:* 881 1522 4073
  - *Passcode:* 71322
  - If calling from outside the U.S., find your local number here: *https://lsc-gov.zoom.us/u/acCVpRj1FD.*

Thursday, July 14, 2022

- To join the Zoom meeting by computer, please use this link.
- *https://lsc-gov.zoom.us/j/89560898298?pwd=b2NWUkF5TVlrajNHK25GSmNoTGo1Zz09*
  - *Meeting ID:* 895 6089 8298
  - *Passcode:* 71422
- To join the Zoom meeting with one tap from your mobile phone, please click dial:
  - +13017158592,,89560898298# US (Washington DC)
  - +13126266799,,89560898298# US (Chicago)
- To join the Zoom meeting by telephone, please dial one of the following numbers:
  - +1 301 715 8592 US (Washington DC)
  - +1 312 626 6799 US (Chicago)
  - +1 646 876 9923 US (New York)
  - +1 408 638 0968 US (San Jose)
  - +1 669 900 6833 US (San Jose)
  - +1 253 215 8782 US (Tacoma)
  - +1 346 248 7799 US (Houston)
  - *Meeting ID:* 895 6089 8298
  - *Passcode:* 71422
  - If calling from outside the U.S., find your local number here: *https://lsc-gov.zoom.us/u/acCVpRj1FD.*

Once connected to Zoom, please immediately mute your computer or telephone. Members of the public are asked to keep their computers or telephones muted to eliminate background noise. To avoid disrupting the meetings, please refrain from placing the call on hold if doing so will trigger recorded music or other sound.

From time to time, the Board or Committee Chair may solicit comments from the public. To participate in the meeting during public comment, use the 'raise your hand' or 'chat' functions in Zoom and wait to be recognized by the Chair before stating your questions and/or comments.

STATUS: Open, except as noted below.

Audit Committee—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to receive a briefing on internal controls that are designed to minimize the risk of fraud, theft, corruption, or misuse of funds.

Institutional Advancement Committee—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to receive a briefing on development activities, receive a briefing on 50th Anniversary fundraising activities and to discuss prospective new members of the Leaders Council and Emerging Leaders Council.

Board of Directors—Open, except that, upon a vote of the Board of Directors, a portion of the meeting may be closed to the public for briefings by management and LSC's Inspector General, and to consider and act on the General Counsel's report on potential and pending litigation involving LSC, and as well as a list of prospective Leaders Council and Emerging Leaders Council members.

Any portion of the closed session consisting solely of briefings does not fall within the Sunshine Act's definition of the term ''meeting'' and, therefore, the requirements of the Sunshine Act do not apply to such portion of the closed session.[1]

A verbatim written transcript will be made of the closed session of the Audit, Board, and Institutional Advancement Committee meetings. The transcript of any portions of the closed sessions falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6), (7), (9) and (10), will not be available for public inspection. A copy of the General Counsel's Certification that, in his opinion, the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

MEETING SCHEDULE

	Start time (all CDT)
Wednesday, July 13, 2022:	
1. Institutional Advancement Committee (IAC) Meeting	10:30 a.m. CDT.
2. Audit Committee Meeting.	
3. Delivery of Legal Services Commmittee Meeting.	
Thursday, July 14, 2022:	
1. Communications Subcommittee of the IAC Meeting	8:30 a.m. CDT.
2. Finance Commtitee Meeting.	

[1] 5 U.S.C. 552b(a)(2) and (b). See also 45 CFR 1622.2 & 1622.3.

MEETING SCHEDULE—Continued

	Start time (all CDT)
3. Open Board Meeting. 4. Closed Board Meeting.	

Wednesday, July 13, 2022

Institutional Advancement Committee (IAC) Meeting

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Institutional Advancement Committee's Open Session Meeting on April 5, 2022
3. Update on Leaders Council and Emerging Leaders Council
   - *John G. Levi, Chairman of the Board, Legal Services Corporation*
4. Development Report
   - *Nadia Elguindy, Director of Institutional Advancement, Legal Services Corporation*
5. Update on the Eviction Study and Midwest Capstone Disaster Conference
   - *Lynn Jennings, Vice President for Grants Management, Legal Services Corporation*
6. Update on Rural Justice Task Force
   - *Jessica Wechter, Special Assistant to the President, Legal Services Corporation*
7. Public Comment
8. Consider and Act on Other Business
9. Consider and Act on Motion to Adjourn the Open Session Meeting and Proceed to a Closed Session

Closed Session

1. Approval of Minutes of the Institutional Advancement Committee's Closed Session Meeting on April 5, 2022
2. Development Activities Report
   - *Nadia Elguindy, Director of Institutional Advancement, Legal Services Corporation*
3. Update on LSC's 50th Anniversary Fundraising Campaign
   - *Nadia Elguindy, Director of Institutional Advancement, Legal Services Corporation*
   - *Leo Latz, Latz & Company*
4. Consider and Act on Motion to Approve Leaders Council and Emerging Leaders Council Invitees
5. Consider and Act on Other Business
6. Consider and Act on Motion to Adjourn the Meeting

Audit Committee Meeting

Open Session

1. Approval of Agenda
2. Approval of Minutes of Committee's Open Session Meeting on April 4, 2022
3. Approval of the Minutes of the Combined Audit and Finance Committee's Open Session Meeting on April 4, 2022
4. Briefing by the Office of Inspector General
   - *Roxanne Caruso, Acting Inspector General, Office of Inspector General, Legal Services Corporation*
5. Management Update Regarding Risk Management
   - *Will Gunn, Vice President for Legal Affairs & General Counsel, Legal Services Corporation*
6. Briefing on Real Estate Purchases and Improvements Made by LSC Grantees
   - *Mark Freedman, Senior Associate General Counsel, Office of Legal Affairs, Legal Services Corporation*
   - *Megan Lacchini, Deputy Director for General Compliance, Office of Compliance and Enforcement, Legal Services Corporation*
   - *Lora Rath, Director, Office of Compliance and Enforcement, Legal Services Corporation*
7. Briefing on Management/Office of Inspector General Relations
   - *Ron Flagg, President, Legal Services Corporation*
   - *Roxanne Caruso, Acting Inspector General, Office of the Inspector General, Legal Services Corporation*
8. Briefing About Follow-Up by the Office of Compliance and Enforcement on Referrals by the Office of Inspector General Regarding Audit Reports and Annual Financial Statement Audits of Grantees
   - *Lora Rath, Director, Office of Compliance and Enforcement, Legal Services Corporation*
   - *Roxanne Caruso, Acting Inspector General, Office of the Inspector General, Legal Services Corporation*
9. Briefing on the 403(b) Audit Report
   - *Debbie Moore, Chief Financial Officer & Treasurer, Legal Services Corporation*
10. Public Comment
11. Consider and Act on Other Business
12. Consider and Act on Motion to Adjourn the Open Session Meeting and Proceed to a Closed Session

Closed Session

1. Approval of Minutes of Committee's Closed Session Meeting on April 4, 2022
2. Approval of Minutes of the Combined Audit and Finance Committee's Closed Session Meeting on April 4, 2022
3. Briefing Pursuant to Section VIII(C)(1) of the Committee Charter, Regarding LSC's Systems of Internal Controls that Are Designed to Minimize the Risk of Fraud, Theft, Corruption, or Misuse of Funds
   - *Debbie Moore, Chief Financial Officer & Treasurer, Legal Services Corporation*
4. Consider and Act on Motion to Adjourn the Meeting

Delivery of Legal Services Commmittee Meeting

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Committee's Open Session Meeting on April 4, 2022
3. LSC Performance Criteria Revisions Update
   - *Lynn Jennings, Vice President for Grants Management, Legal Services Corporation*
   - *Joyce McGee, Director, Office of Program Performance, Legal Services Corporation*
4. Panel Discussion: The Impact of the Pandemic on Consumer Law Cases
   - *Hadassa Santini Colberg, Executive Director, Puerto Rico Legal Services, Inc.*
   - *Michael Forton, Director of Advocacy, Legal Services Alabama*
   - *Ashley E. Lowe, CEO, Lakeshore Legal Aid (MI)*
   - *Johnnie Larrie, Managing Attorney, Consumer Practice Group and Economic Justice Initiative, Legal Aid of North Carolina, Inc.*
   - *Moderator: James Scruggs, Deputy Director, Office of Program Performance, Legal Services Corporation*
5. Public Comment
6. Consider and Act on Other Business
7. Consider and Act on a Motion to Adjourn the Meeting

Meeting of the Communications Subcommittee of the IAC

Open Session

1. Approval of Agenda
2. Approval of Minutes of the Subcommittee's Open Session Meeting on April 5, 2022
3. Communications and Social Media Update
   - *Carl Rauscher, Director of Communications and Media Relations, Legal Services Corporation*
4. Public Comment
5. Consider and Act on Other Business
6. Consider and Act on Motion to Adjourn the Meeting

Finance Committee Meeting

Open Session

1. Approval of Agenda
2. Approval of the Minutes of the Combined Audit and Finance Committee's Open Session Meeting on April 4, 2022
3. Approval of the Minutes of the Combined Audit and Finance Committee's Closed Session Meeting on April 4, 2022
4. Presentation of LSC's Financial Report for the First Eight Months of Fiscal Year 2022 (Period Ending May 31, 2022)
   - *Debbie Moore, Chief Financial Officer & Treasurer, Legal Services Corporation*
5. Report on the Fiscal Year 2023 Appropriations Process and Supplemental Appropriations
   - *Carol Bergman, Vice President, Government Relations & Public Affairs, Legal Services Corporation*
6. Consider and Act on Resolution #2022–XXX, Fiscal Year 2023 Temporary Operating Authority
7. Consider and Act on Resolution #2022–XXX, Adopting LSC's Fiscal Appropriation Request for Fiscal Year 2024
8. Public Comment
9. Consider and Act on Other Business
10. Consider and Act on Motion to Adjourn the Meeting

Board of Directors

Open Session

1. Pledge of Allegiance
2. Approval of Agenda
3. Approval of Minutes of the Board's Open Session Meeting on May 23, 2022
4. Chairman's Report
5. Members' Reports
6. President's Report
   - Update from LSC's Office of Data Governance and Analysis
7. Inspector General's Report
   - Fraud Awareness Presentation
8. Consider and Act on the Report of the Operations and Regulations Committee, following its June 30, 2022, Videoconference Meeting
9. Consider and Act on the Report of the Governance and Performance Review Committee, following its July 1, 2022, Videoconference Meeting
10. Consider and Act on the Report of the Institutional Advancement Committee
11. Consider and Act on the Report of the Audit Committee
12. Consider and Act on the Report of the Delivery of Legal Services Committee
13. Consider and Act on the Report of the Finance Committee
14. Public Comment
15. Consider and Act on Other Business
16. Consider and Act on Whether to Authorize a Closed Session of the Board to Address Items Listed Below

Closed Session

1. Approval of Minutes of the Board's Closed Session Meeting on April 5, 2022
2. Management Briefing
3. Inspector General Briefing
4. Consider and Act on General Counsel's Report on Potential and Pending Litigation Involving Legal Services Corporation
5. Consider and Act on List of Prospective Leaders Council and Emerging Council Invitees
6. Consider and Act on Motion to Adjourn the Meeting

CONTACT PERSON FOR MORE INFORMATION: Kaitlin Brown, Executive and Board Project Coordinator, at (202) 295–1555. Questions may also be sent by electronic mail to *brownk@lsc.gov.*

Non-Confidential Meeting Materials: Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at *https://www.lsc.gov/about-lsc/board-meeting-materials.*

Dated: June 30, 2022.

Kaitlin D. Brown,

Executive and Board Project Coordinator, Legal Services Corporation.

[FR Doc. 2022–14406 Filed 7–1–22; 11:15 am]

BILLING CODE 7050–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (22–049)]

Earth Science Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Aeronautics and Space Administration (NASA) announces a meeting of the Earth Science Advisory Committee (ESAC). This Committee functions in an advisory capacity to the Director, Earth Science Division, in the NASA Science Mission Directorate. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Tuesday, August 2, 2022, 8:30 a.m.–5:00 p.m., and Wednesday, August 3, 2022, 8:30 a.m.–3:00 p.m., Eastern Time.

ADDRESSES: NASA Headquarters, Room 3H42A, 300 E Street SW, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. KarShelia Kinard, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355, fax (202) 358–2779, or *karshelia.kinard@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the meeting room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may call the USA toll free number 1–415–527–5035 or toll number 1–312–500–3163, Access code: 276 363 15585, for August 2, 2022, to participate in this meeting by telephone. The WebEx link is *https://nasaevents.webex.com/nasaevents/j.php?MTID=m0234136c4bedf0b0fb3c880ce1030282* the meeting number is 2763 631 5585, password is imUpRbJj547 (case sensitive). For the second day, August 3, 2022 the USA toll free number +1–415–527–5035 or toll number +1–312–500–3163, Access code: 276 307 46285. The WebEx link is *https://nasaevents.webex.com/nasaevents/j.php?MTID=mc2af8861a271c5f6a2fee56aa119a5ed* the meeting number is 2763 074 6285, password is yExmRdzy368 (case sensitive). The agenda for the meeting includes the following topics:

—Earth Science Division Update

—Earth Science Decadal Survey Implementation (Earth System Observatory, Explorer missions)
— Earth Venture Program status
—Incubation Studies
—Open Science, Commercial Data Buy
—Diversity, Equity and Inclusion

The agenda will be posted on the ESAC web page: *https://science.nasa.gov/researchers/nac/science-advisory-committees/esac.*

Attendees will be requested to sign a register and to comply with NASA Headquarters security requirements, including the presentation of a valid picture ID to Security before access to NASA Headquarters. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 days prior to the meeting: full name; gender; date/place of birth; citizenship; passport information (number, country, telephone); visa information (number, type, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizens and Permanent Residents (green card holders) may provide full name and citizenship status no less than 3 working days in advance by contacting Ms. KarShelia Kinard via email at *karshelia.kinard@nasa.gov* or by fax at 202–358–2779. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Carol J. Hamilton,

Acting Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2022–14340 Filed 7–5–22; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0091]

Regulatory Analysis Guidelines

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG appendices; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment two draft appendices to NUREG/BR–0058, Revision 5, ''Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission.'' Guidance in these draft appendices provides information that the staff will use when performing cost-benefit analyses in support of regulatory decisions. Section II of this document describes each draft appendix.

DATES: Submit comments by September 6, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC can only ensure the consideration of comments received before this date.

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

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2017–0091. 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 directions on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Pamela Noto, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 –0001; telephone: 301–415–6795; email: *Pamela.Noto@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2017–0091 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–2017–0091.
- *NRC 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.
- *NRC PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to 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–2017–0091 in your comment submission.

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

II. Discussion

Appendix K, ''Monetary Valuation of Nonfatal Cancer Risk for Use in Cost-Benefit Analysis,'' to NUREG/BR–0058 provides guidance for valuing morbidity risks from radiation exposure for use in cost-benefit analyses at the NRC. This appendix includes (1) evidence-based estimates for the value of nonfatal cancers, (2) an overview of the technical approach, assumptions, and data sources used to develop these estimates, (3) a discussion of the uncertainties, and (4) guidance on how to apply these estimates in cost-benefit analyses to capture averted health risks from changes in radiation exposure. This valuation method is analogous to the

dollar per person-rem conversion factor for fatality risks detailed in NUREG–1530, Revision 1, ''Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy,'' issued February 2022. The evaluation of morbidity impacts of nonfatal cancers will provide a more complete and realistic treatment of potential health effects due to radiation exposure in NRC cost-benefit analyses.

Appendix L, ''Replacement Energy Costs,'' provides guidance on how to apply information in NUREG–2242, ''Replacement Energy Cost Estimates for Nuclear Power Plants: 2020–2030,'' issued June 2021, to estimate replacement energy costs associated with regulatory actions that may result in the temporary or permanent loss of electrical power generation from a nuclear reactor. The term ''replacement energy cost'' refers to the change in wholesale power prices that could result when a reactor unit is taken offline. This appendix presents methods and examples showing how to use the information in NUREG–2242 to (1) quantify replacement energy costs in cost-benefit analyses, including the calculation of shutdown costs related to installing or implementing mandated safety changes, and (2) estimate present value of averted onsite costs due to changes in reactor accident frequencies.

The NRC staff plans to hold a public information meeting with a question and answer session to discuss these draft appendices to NUREG/BR–0058, Revision 5. The public meeting will be noticed on the NRC's public meeting website at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting website at *https://www.nrc.gov/pmns/mtg* for additional information.

III. Availability of Documents

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

Document	ADAMS accession No.
Draft NUREG/BR-0058, Revision 5, Appendix K, ''Monetary Valuation of Nonfatal Cancer Risk for Use in Cost-Benefit Analysis''.	ML22175A202.
Draft NUREG/BR-0058, Revision 5, Appendix L, ''Replacement Energy Costs''	ML22175A203.
SECY-20-0008, ''NUREG/BR-0058, Revision 5, 'Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission' ''.	ML19261A277 (Package).
SECY-22-0028, ''Appendices to NUREG/BR-0058, Revision 5, 'Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission' ''.	ML21228A118 (Package).
NUREG-2242, ''Replacement Energy Cost Estimates for Nuclear Power Plants: 2020–2030''	ML21174A176.
NUREG-1530, Revision 1, ''Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy''	ML22053A025.

Dated: June 29, 2022.

For the Nuclear Regulatory Commission.

John R. Tappert,

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

[FR Doc. 2022–14287 Filed 7–5–22; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. MC2022–60; Order No. 6212]

Modification of Special Services Product List

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is extending the comment deadline in this docket.

DATES: *Comments are due:* July 7, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION: The Postal Regulatory Commission (Commission) initiated the instant docket to examine the potential need to make a modification to the Mail Classification Schedule (MCS) in order to fulfill the Commission's responsibilities under the Postal Accountability and Enhancement Act (PAEA), Public Law 109–435, 120 Stat. 3198 (2006), and the Postal Service Reform Act of 2022, Public Law 117–89, 136 Stat. 1127 (2022), and pursuant to 39 CFR 3040 subpart D.[1] The Commission invited ''comments on whether the Postal Service's Pilot Program comports with 39 CFR 3035, 39 CFR 3040, 39 CFR 3045, 39 U.S.C. 404, 39 U.S.C. 3632, 39 U.S.C. 3633, and 39 U.S.C. 3641.'' Order No. 6174 at 6. The Commission established a deadline of June 30, 2022 for such comments. *See id.* at 7.

On June 27, 2022, the American Postal Workers Union, AFL–CIO (APWU) filed a motion for an extension of time until July 7, 2022 to file its comments.[2] APWU requests this extension ''to be able to collect information that may be relevant to the Commission and to offer insight on the legality of this docket'' in light of the recent unavailability of key personnel and the upcoming July Fourth holiday. Motion at 2. Furthermore, APWU asserts that the requested extension ''would not significantly delay the ultimate resolution of this proceeding, nor adversely affect any possible participants.'' *Id.*

The requested extension will not significantly delay this proceeding. *See* 39 CFR 3010.162(c). Further, the requested extension, if provided to all participants, will not have a potential adverse impact on other participants. *See id.* Consequently, the Commission will extend the deadline for filing comments until July 7, 2022 for all commenters.

It is ordered:

1. The American Postal Workers Union, AFL–CIO Motion for Extension of Time to File Public Comment, filed on June 27, 2022, which requests an extension of time until July 7, 2022, is granted.

2. Comments are due no later than July 7, 2022.

3. The Secretary of the Commission shall arrange for prompt publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2022–14300 Filed 7–5–22; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice and Order Concerning Potential Modification of Special Services on the Competitive Product List, May 16, 2022, at 1 (Order No. 6174).

[2] American Postal Workers Union, AFL–CIO Motion for Extension of Time to File Public Comment, June 27, 2022, at 1–2 (Motion).

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information; Cislunar Science and Technology Subcommittee

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of request for information.

SUMMARY: The White House Office of Science and Technology Policy (OSTP)—on behalf of the Cislunar Science and Technology Subcommittee of the National Science and Technology Council (NSTC)—requests input to help inform development of a national science and technology strategy on U.S. activities in cislunar space. For the purposes of this RFI, cislunar space is defined as the entire region beyond Earth's geostationary orbit still subject to the Earth's and/or Moon's gravity, including orbits around the Moon and the lunar surface. The strategy will include key U.S. government research and development (R&D) priorities and proposed technical standards to enable a robust, cooperative, and sustainable ecosystem in cislunar space.

DATES: Responses must be received by July 20, 2022 to be considered.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: cislunar@ostp.eop.gov,* include *Cislunar RFI* in the subject line of the message.
- *Mail:* Attn: NSTC Cislunar Science & Technology Subcommittee, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Ave. NW, Washington, DC 20504.

Instructions: Response to this RFI is voluntary. Respondents need not reply to all questions listed. Each individual or institution is requested to submit only one response. Electronic responses must be provided as attachments to an email. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.* zipped) to ensure message delivery. Please identify your answers by responding to a specific question or topic if possible. Respondents may answer as many or as few questions as they wish. Comments of seven pages or fewer (3,500 words) are requested; longer responses will not be considered.

Any information obtained from this RFI is intended to be used by the Government on a non-attribution basis for planning and strategy development. OSTP will not respond to individual submissions. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed. This RFI is not accepting applications for financial assistance or financial incentives. Responses to this RFI may be posted without change online. OSTP therefore requests that no proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI. Please note that the United States Government will not pay for response preparation, or for the use of any information contained in a response.

FOR FURTHER INFORMATION CONTACT: *cislunar@ostp.eop.gov* or Matt Daniels at 202–456–4444.

SUPPLEMENTARY INFORMATION: Pursuant to 42 U.S.C. 6617, OSTP is soliciting public input through an RFI to obtain feedback from a wide variety of stakeholders, including individuals, industry, academia, research laboratories, nonprofits, and think tanks. OSTP is specifically interested in public input to inform a national science and technology strategy for U.S. activities in cislunar space, referring to the entire region beyond Earth's geostationary orbit still subject to the Earth's and/or Moon's gravity, including orbits around the Moon and the lunar surface. OSTP seeks response to either or both of the following questions:

1. What research and development should the U.S. government prioritize to help advance a robust, cooperative, and sustainable ecosystem in cislunar space in the next 10 years? And over the next 50 years?

2. What key technical standards are most useful to develop in support of activities in cislunar space, and how could these standards enable and support a vibrant and sustainable cislunar ecosystem?

Dated: June 29, 2022.

Stacy Murphy,

Operations Manager.

[FR Doc. 2022–14316 Filed 7–5–22; 8:45 am]

BILLING CODE 3270–F2–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95179; File No. SR–NYSEArca–2021–89]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Disapproving a Proposed Rule Change To List and Trade Shares of the Bitwise Bitcoin ETP Trust Under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares)

June 29, 2022.

I. Introduction

On October 14, 2021, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the Bitwise Bitcoin ETP Trust (''Trust'') under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on November 3, 2021.[3]

On December 15, 2021, pursuant to Section 19(b)(2) of the Exchange 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 February 1, 2022, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act [6] to determine whether to approve or disapprove the proposed rule change.[7] On April 22, 2022, the Commission designated a longer period for Commission action on the proposed rule change.[8]

This order disapproves the proposed rule change. The Commission concludes that NYSE Arca has not met its burden under the Exchange Act and the Commission's Rules of Practice to demonstrate that its proposal is consistent with the requirements of Exchange Act Section 6(b)(5), which

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93445 (Oct. 28, 2021), 86 FR 60695 (''Notice''). Comments on the proposed rule change are available at: *https://www.sec.gov/comments/sr-nysearca-2021-89/srnysearca202189.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 93790, 86 FR 72300 (Dec. 21, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 94126, 87 FR 6903 (Feb. 7, 2022).

[8] *See* Securities Exchange Act Release No. 94781, 87 FR 25327 (Apr. 28, 2022).

requires, in relevant part, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices'' and ''to protect investors and the public interest.'' [9]

When considering whether NYSE Arca's proposal to list and trade the Shares is designed to prevent fraudulent and manipulative acts and practices, the Commission applies the same analytical framework used in its orders considering previous proposals to list bitcoin [10]-based commodity trusts and bitcoin-based trust issued receipts to assess whether a listing exchange of an exchange-traded product (''ETP'') can meet its obligations under Exchange Act Section 6(b)(5).[11] As the Commission has explained, an exchange that lists bitcoin-based ETPs can meet its obligations under Exchange Act Section 6(b)(5) by demonstrating that the exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying or reference bitcoin assets.[12]

In this context, the terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which (a) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[13] A surveillance-sharing agreement must be entered into with a ''significant market'' to assist in detecting and deterring manipulation of the ETP, because a person attempting to manipulate the ETP is reasonably likely to also engage in trading activity on that ''significant market.'' [14]

Although surveillance-sharing agreements are not the exclusive means by which a listing exchange of a commodity-trust ETP can meet its obligations under Exchange Act Section 6(b)(5), such agreements have previously provided the basis for the exchanges that list commodity-trust ETPs to meet those obligations, and the Commission has historically recognized their importance. And where, as here, a listing exchange does not establish that other means to prevent fraudulent and manipulative acts and practices will be sufficient,[15] the listing exchange must enter into a surveillance-sharing agreement with a regulated market of significant size because such agreements detect and deter fraudulent and manipulative activity.[16]

In previous orders,[17] the Commission has identified possible sources of fraud and manipulation in the spot bitcoin market, including (1) ''wash'' trading,[18] (2) persons with a dominant position in bitcoin manipulating bitcoin pricing, (3) hacking of the bitcoin network and

[9] 15 U.S.C. 78f(b)(5).

[10] Bitcoins are digital assets that are issued and transferred via a decentralized, open-source protocol used by a peer-to-peer computer network through which transactions are recorded on a public transaction ledger known as the ''bitcoin blockchain.'' The bitcoin protocol governs the creation of new bitcoins and the cryptographic system that secures and verifies bitcoin transactions. *See, e.g.,* Notice, 86 FR at 60696.

[11] *See* Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Trust, Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (Aug. 1, 2018) (SR–BatsBZX–2016–30) (''Winklevoss Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, To Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and To List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 88284 (Feb. 26, 2020), 85 FR 12595 (Mar. 3, 2020) (SR–NYSEArca–2019–39) (''USBT Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the WisdomTree Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 93700 (Dec. 1, 2021), 86 FR 69322 (Dec. 7, 2021) (SR–CboeBZX–2021–024) (''WisdomTree Order''); Order Disapproving 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), Securities Exchange Act Release No. 93859 (Dec. 22, 2021), 86 FR 74156 (Dec. 29, 2021) (SR–NYSEArca–2021–31) (''Valkyrie Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the Kryptoin Bitcoin ETF Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 93860 (Dec. 22, 2021), 86 FR 74166 (Dec. 29, 2021) (SR–CboeBZX–2021–029) (''Kryptoin Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the First Trust SkyBridge Bitcoin ETF Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 94006 (Jan. 20, 2022), 87 FR 3869 (Jan. 25, 2022) (SR–NYSEArca–2021–37) (''SkyBridge Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the Wise Origin Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 94080 (Jan. 27, 2022), 87 FR 5527 (Feb. 1, 2022) (SR–CboeBZX–2021–039) (''Wise Origin Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the NYDIG Bitcoin ETF Under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares), Securities Exchange Act Release No. 94395 (Mar. 10, 2022), 87 FR 14932 (Mar. 16, 2022) (SR–NYSEArca–2021–57) (''NYDIG Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the Global X Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 94396 (Mar. 10, 2022), 87 FR 14912 (Mar. 16, 2022) (SR–CboeBZX–2021–052) (''Global X Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the ARK 21Shares Bitcoin ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 94571 (Mar. 31, 2022), 87 FR 20014 (Apr. 6, 2022) (SR–CboeBZX–2021–051) (''ARK 21Shares Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the One River Carbon Neutral Bitcoin Trust Under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares), Securities Exchange Act Release No. 94999 (May 27, 2022), 87 FR 33548 (June 2, 2022) (SR–NYSEArca–2021–67) (''One River Order''). In addition, orders were issued by delegated authority on the following matters: Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Listing and Trading of Shares of the SolidX Bitcoin Trust Under NYSE Arca Equities Rule 8.201, Securities Exchange Act Release No. 80319 (Mar. 28, 2017), 82 FR 16247 (Apr. 3, 2017) (SR–NYSEArca–2016–101) (''SolidX Order''); Order Disapproving a Proposed Rule Change To List and Trade the Shares of the ProShares Bitcoin ETF and the ProShares Short Bitcoin ETF, Securities Exchange Act Release No. 83904 (Aug. 22, 2018), 83 FR 43934 (Aug. 28, 2018) (SR–NYSEArca–2017–139) (''ProShares Order''); Order Disapproving a Proposed Rule Change To List and Trade the Shares of the GraniteShares Bitcoin ETF and the GraniteShares Short Bitcoin ETF, Securities Exchange Act Release No. 83913 (Aug. 22, 2018), 83 FR 43923 (Aug. 28, 2018) (SR–CboeBZX–2018–001) (''GraniteShares Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the VanEck Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 93559 (Nov. 12, 2021), 86 FR 64539 (Nov. 18, 2021) (SR–CboeBZX–2021–019) (''VanEck Order''); Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To List and Trade Shares of the Teucrium Bitcoin Futures Fund Under NYSE Arca Rule 8.200–E, Commentary .02 (Trust Issued Receipts), Securities Exchange Act Release No. 94620 (Apr. 6, 2022), 87 FR 21676 (Apr. 12, 2022) (SR–NYSEArca–2021–53) (''Teucrium Order''); Order Granting Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To List and Trade Shares of the Valkyrie XBTO Bitcoin Futures Fund Under Nasdaq Rule 5711(g), Securities Exchange Act Release No. 94853 (May 5, 2022), 87 FR 28848 (May 11, 2022) (SR–NASDAQ–2021–066) (''Valkyrie XBTO Order'').

[12] *See* USBT Order, 85 FR at 12596. *See also* Winklevoss Order, 83 FR at 37592 n.202 and accompanying text (discussing previous Commission approvals of commodity-trust ETPs); GraniteShares Order, 83 FR at 43925–27 nn.35–39 and accompanying text (discussing previous Commission approvals of commodity-futures ETPs).

[13] *See* Winklevoss Order, 83 FR at 37594. *See also* USBT Order, 85 FR at 12596–97; WisdomTree Order, 86 FR at 69322.

[14] *See* USBT Order, 85 FR at 12597.

[15] Listing exchanges have also attempted to demonstrate that other means besides surveillance-sharing agreements will be sufficient to prevent fraudulent and manipulative acts and practices, including that the bitcoin market as a whole or the relevant underlying bitcoin market is ''uniquely'' and ''inherently'' resistant to fraud and manipulation. *See* USBT Order, 85 FR at 12597. The Exchange, however, does not make any such arguments with respect to this proposal.

[16] *See* Amendment to Rule Filing Requirements for Self-Regulatory Organizations Regarding New Derivative Securities Products, Securities Exchange Act Release No. 40761 (Dec. 8, 1998), 63 FR 70952, 70954, 70959 (Dec. 22, 1998) (File No. S7–13–98) (''NDSP Adopting Release''). *See also* Winklevoss Order, 83 FR at 37593–94; ProShares Order, 83 FR at 43936; GraniteShares Order, 83 FR at 43924; USBT Order, 85 FR at 12596.

[17] *See, e.g.,* One River Order, 87 FR at 33554.

[18] *See also CFTC* v. *Gemini Trust Co., LLC,* No. 22–cv–4563 (S.D.N.Y. filed June 2, 2022) (alleging, among other things, failure by Gemini personnel to disclose to the CFTC that Gemini customers could and did engage in collusive or wash trading).

trading platforms, (4) malicious control of the bitcoin network, (5) trading based on material, non-public information, including the dissemination of false and misleading information, (6) manipulative activity involving purported ''stablecoins,'' including Tether (USDT), and (7) fraud and manipulation at bitcoin trading platforms. The Exchange does not refute the presence of these possible sources of fraud and manipulation.[19]

The Commission has long recognized that surveillance-sharing agreements ''provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur'' and thus ''enable the Commission to continue to effectively protect investors and promote the public interest.'' [20] As the Commission has emphasized, it is essential for an exchange listing a derivative securities product to have the ability that surveillance-sharing agreements provide to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities laws and rules.[21] The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.[22]

The Commission has explained that the ability of a national securities exchange to enter into surveillance-sharing agreements ''furthers the protection of investors and the public interest because it will enable the [e]xchange to conduct prompt investigations into possible trading violations and other regulatory improprieties.'' [23] The Commission has also long taken the position that surveillance-sharing agreements are important in the context of exchange listing of derivative security products, such as equity options, because a surveillance-sharing agreement ''permits the sharing of information'' that is ''necessary to detect'' manipulation and ''provide[s] an important deterrent to manipulation because [it] facilitate[s] the availability of information needed to fully investigate a potential manipulation if it were to occur.'' [24] With respect to ETPs, when approving the listing and trading of one of the first commodity-linked ETPs—a commodity-linked exchange-traded note—on a national securities exchange, the Commission continued to emphasize the importance of surveillance-sharing agreements, stating that the listing exchange had entered into surveillance-sharing agreements with each of the futures markets on which pricing of the ETP would be based and stating that ''[t]hese agreements should help to ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses, thereby making [the commodity-linked notes] less readily susceptible to manipulation.'' [25]

Consistent with these statements, for the commodity-trust ETPs approved to date for listing and trading, there has been in *every* case at least one significant, regulated market for trading futures on the underlying commodity and the ETP listing exchange has entered into surveillance-sharing agreements with, or held Intermarket Surveillance Group (''ISG'') membership in common with, that market.[26] Moreover, the surveillance-sharing agreements have been consistently present whenever the Commission has approved the listing and trading of derivative securities, even where the underlying securities were also listed on national securities exchanges—such as options based on an index of stocks traded on a national securities exchange—and were thus subject to the

[19] The Trust's Registration Statement also acknowledges that ''[o]ver the past several years, a number of digital asset trading platforms have been closed or faced issues due to fraud, failure, security breaches or governmental regulations''; that ''[t]he platforms on which users trade bitcoin are relatively new and, in some cases, largely unregulated, and, therefore, may be more exposed to fraud and security breaches than established, regulated exchanges for other financial assets or instruments''; that ''[t]he nature of the assets held at digital asset trading platforms makes them appealing targets for hackers and a number of digital asset trading platforms have been victims of cybercrimes''; that bitcoin networks are susceptible to a ''51% attack,'' in which ''[i]f a malicious actor or botnet obtains control of more than 50% of the processing power on the [b]itcoin network, or otherwise obtains control over the [b]itcoin network through its influence over core developers or otherwise, such actor or botnet could manipulate how data is recorded [on] the [bitcoin blockchain]''; that ''it is believed that certain mining pools may have exceeded the 50% threshold on the [b]itcoin network on a temporary basis''; that the inputs to the CME US Reference Rate ''may be subject to technological error, manipulative activity, or fraudulent reporting from their initial source''; and that ''in the past, flaws in the source code for digital assets have been exposed and exploited.'' *See* Registration Statement on Form S–1, filed by the Trust on October 14, 2021, at 11–12, 17–18. *See also Are Blockchains Decentralized? Unintended Centralities in Distributed Ledgers,* prepared by Trail of Bits based upon work supported by the Defense Advanced Research Projects Agency, June 2022, available at: *https://assets-global.website-files.com/5fd11235b3950c2c1a3b6df4/62af6c641a672b3329b9a480_Unintended_Centralities_in_Distributed_Ledgers.pdf.*

[20] *See* NDSP Adopting Release, 63 FR at 70954, 70959. *See also id.* at 70959 (''It is essential that the SRO [self-regulatory organization] have the ability to obtain the information necessary to detect and deter market manipulation, illegal trading and other abuses involving the new derivative securities product. Specifically, there should be a comprehensive ISA [information-sharing agreement] that covers trading in the new derivative securities product and its underlying securities in place between the SRO listing or trading a derivative product and the markets trading the securities underlying the new derivative securities product.'').

[21] *See* NDSP Adopting Release, 63 FR at 70959.

[22] *See* Winklevoss Order, 83 FR at 37592–93 (discussing Letter from Brandon Becker, Director, Division of Market Regulation, Commission, to Gerard D. O'Connell, Chairman, Intermarket Surveillance Group (June 3, 1994), available at *https://www.sec.gov/divisions/marketreg/mr-noaction/isg060394.htm*).

[23] Securities Exchange Act Release No. 27877 (Apr. 4, 1990), 55 FR 13344 (Apr. 10, 1990) (SR–NYSE–90–14).

[24] Securities Exchange Act Release No. 33555 (Jan. 31, 1994), 59 FR 5619, 5621 (Feb. 7, 1994) (SR–Amex–93–28) (order approving listing of options on American Depositary Receipts (''ADR'')) (''ADR Option Order''). The Commission further stated that it ''generally believes that having a comprehensive surveillance sharing agreement in place, between the exchange where the ADR option trades and the exchange where the foreign security underlying the ADR primarily trades, will ensure the integrity of the marketplace. The Commission further believes that the ability to obtain relevant surveillance information, including, among other things, the identity of the ultimate purchasers and sellers of securities, is an essential and necessary component of a comprehensive surveillance sharing agreement.'' *Id.*

[25] Securities Exchange Act Release No. 35518 (Mar. 21, 1995), 60 FR 15804, 15807 (Mar. 27, 1995) (SR–Amex–94–30). *See also* Winklevoss Order, 83 FR at 37593 n.206.

[26] *See* Winklevoss Order, 83 FR at 37594. Furthermore, the Commission notes that those cases dealt with a futures market that had been trading for a long period of time before an exchange proposed a commodity-trust ETP based on the asset underlying those futures. For example, silver futures and gold futures began trading in 1933 and 1974, respectively, *see https://www.cmegroup.com/media-room/historical-first-trade-dates.html,* and the first ETPs based on spot silver and gold were approved for listing and trading in 2006 and 2004. *See* Securities Exchange Act Release No. 53521 (Mar. 20, 2006), 71 FR 14967 (Mar. 24, 2006) (SR–Amex–2005–072) (order approving iShares Silver Trust); Securities Exchange Act Release No. 50603 (Oct. 28, 2004), 69 FR 64614 (Nov. 5, 2004) (SR–NYSE–2004–22) (order approving streetTRACKS Gold Shares). Platinum futures and palladium futures began trading in 1956 and 1968, respectively, *see https://www.cmegroup.com/media-room/historical-first-trade-dates.html,* and the first ETPs based on spot platinum and palladium were approved for listing and trading in 2009. *See* Securities Exchange Act Release No. 61220 (Dec. 22, 2009), 74 FR 68895 (Dec. 29, 2009) (SR–NYSEArca–2009–94) (order approving ETFS Palladium Trust); Securities Exchange Act Release No. 61219 (Dec. 22, 2009), 74 FR 68886 (Dec. 29, 2009) (SR–NYSEArca–2009–95) (order approving ETFS Platinum Trust).

Commission's direct regulatory authority.[27]

Here, NYSE Arca contends that approval of the proposal is consistent with Section 6(b)(5) of the Exchange Act, and, in particular, Section 6(b)(5)'s requirement that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest.[28] As discussed in more detail below, NYSE Arca asserts that the proposal is consistent with Section 6(b)(5) of the Exchange Act because the Exchange has a comprehensive surveillance-sharing agreement with the Chicago Mercantile Exchange (''CME''), which the Exchange argues is a regulated market of significant size in the context of the proposed spot bitcoin ETP.[29]

Based on its analysis, as discussed below in Section III.B, the Commission concludes that NYSE Arca has not established that it has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin, the underlying bitcoin assets that would be held by the Trust. In addition, the Commission examines in Section III.C other arguments raised by NYSE Arca and commenters, and concludes that NYSE Arca has not demonstrated that the proposed rule change is consistent with the statutory requirements of Exchange Act Section 6(b)(5).

The Commission emphasizes that its disapproval of this proposed rule change does not rest on an evaluation of the relative investment quality of a product holding spot bitcoin versus a product holding CME bitcoin futures, or an assessment of whether bitcoin, or blockchain technology more generally, has utility or value as an innovation or an investment. Rather, the Commission is disapproving this proposed rule change because, as discussed below, NYSE Arca has not met its burden to demonstrate that its proposal is consistent with the requirements of Exchange Act Section 6(b)(5).

II. Description of the Proposed Rule Change

As described in more detail in the Notice,[30] the Exchange proposes to list and trade the Shares of the Trust under NYSE Arca Rule 8.201–E, which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

The investment objective of the Trust is to seek to provide exposure to the value of bitcoin held by the Trust, less the expenses of the Trust's operations.[31] The Shares would represent units of undivided beneficial ownership of the Trust.[32] Under normal circumstances, the Trust's only asset would be bitcoin, and, under limited circumstances, cash.[33] The Trust would not use derivatives that may subject the Trust to counterparty and credit risks.[34]

The Trust's net asset value (''NAV'') and NAV per Share would be determined by the Administrator once each Exchange trading day as of 4:00 p.m. E.T., or as soon thereafter as practicable, by reference to the CF Bitcoin-Dollar US Settlement Price (''CME US Reference Rate'').[35] The Administrator would calculate the NAV by multiplying the number of bitcoins held by the Trust by the CME US Reference Rate for such day, and subtracting the accrued but unpaid expenses and liabilities of the Trust.[36] The CME US Reference Rate is a daily reference rate of the U.S. dollar price of one bitcoin, calculated at 4:00 p.m. E.T.[37]

The CME US Reference Rate aggregates during a calculation window the trade flow of several spot bitcoin trading platforms into the U.S. dollar price of one bitcoin as of its calculation time. The current constituent bitcoin platforms of the CME US Reference Rate are Bitstamp, Coinbase, Gemini, itBit, and Kraken (''Constituent Platforms'').[38] In calculating the CME US Reference Rate, the methodology creates a joint list of certain trade prices and sizes from the Constituent Platforms. The methodology then divides this list into a number of equally sized time intervals, and it calculates the volume-weighted median trade price for each of those intervals. The CME US Reference Rate is the equally weighted average of the volume-weighted medians of all intervals.[39]

The Trust would provide website disclosure of its holdings daily.[40] In addition, each trading day, the Exchange would calculate and disseminate an intraday trust value (''ITV'') every 15 seconds during the NYSE Arca Core Trading Session.[41] The ITV would be calculated throughout the

[27] *See* USBT Order, 85 FR at 12597; ADR Option Order, 59 FR at 5621. The Commission has also recognized that surveillance-sharing agreements provide a necessary deterrent to fraud and manipulation in the context of index options even when (i) all of the underlying index component stocks were either registered with the Commission or exempt from registration under the Exchange Act; (ii) all of the underlying index component stocks were traded in the U.S. either directly or as ADRs on a national securities exchange; and (iii) effective international ADR arbitrage alleviated concerns over the relatively smaller ADR trading volume, helped to ensure that ADR prices reflected the pricing on the home market, and helped to ensure more reliable price determinations for settlement purposes, due to the unique composition of the index and reliance on ADR prices. *See* Securities Exchange Act Release No. 26653 (Mar. 21, 1989), 54 FR 12705, 12708 (Mar. 28, 1989) (SR–Amex–87–25) (stating that ''surveillance-sharing agreements between the exchange on which the index option trades and the markets that trade the underlying securities are necessary'' and that ''[t]he exchange of surveillance data by the exchange trading a stock index option and the markets for the securities comprising the index is important to the detection and deterrence of intermarket manipulation''). And the Commission has explained that surveillance-sharing agreements ''ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses'' even when approving options based on an index of stocks traded on a national securities exchange. *See* Securities Exchange Act Release No. 30830 (June 18, 1992), 57 FR 28221, 28224 (June 24, 1992) (SR–Amex–91–22).

[28] *See* Notice, 86 FR at 60700–15.

[29] *See id.*

[30] *See* Notice, *supra* note 3.

[31] *See id.* at 60696. Bitwise Investment Advisers, LLC (''Sponsor'') is the sponsor of the Trust, and Delaware Trust Company is the trustee. The Trust would engage a third party custodian to maintain custody of the Trust's bitcoin assets. The Trust also would engage a third party service provider to serve as the administrator (''Administrator'') and transfer agent of the Trust. *See id.*

[32] *See id.*

[33] *See id.* The Trust may sell bitcoin and temporarily hold cash as part of a liquidation of the Trust or to pay certain extraordinary expenses not assumed by the Sponsor. According to the Exchange, the Trust also may, from time to time, passively receive, by virtue of holding bitcoin, certain additional digital assets or rights to receive such digital assets through a fork of the bitcoin blockchain or an airdrop of assets. *See id.* at 60696 n.12.

[34] *See id.* at 60696.

[35] *See id.* at 60696, 60699.

[36] *See id.* at 60699.

[37] The Exchange states that the CME US Reference Rate utilizes the same methodology as the CME CF Bitcoin Reference Rate, which is calculated at 4:00 p.m., London time, and is used to settle bitcoin futures on the CME. *See id.* at 60696 n.11, 60698–99.

[38] *See id.* at 60699. None of these platforms are ''regulated'' as a national securities exchange. National securities exchanges are required to have rules that are ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.'' 15 U.S.C. 78f(b)(5). Moreover, national securities exchanges must file proposed rules with the Commission regarding certain material aspects of their operations (17 CFR 240.19b–4(a)(6)(i)), and the Commission has the authority to disapprove any such rule that is not consistent with the requirements of the Exchange Act (15 U.S.C. 78s(b)). Thus, national securities exchanges are subject to Commission oversight of, among other things, their governance, membership qualifications, trading rules, disciplinary procedures, recordkeeping, and fees. *See* Winklevoss Order, 83 FR at 37597. The Constituent Platforms have none of these requirements (none are registered as a national securities exchange).

[39] *See* Notice, 86 FR at 60699.

[40] *See id.* at 60715.

[41] *See id.* at 60699. The ITV would also be widely disseminated by one or more major market data vendors during the NYSE Arca Core Trading Session. *See id.*

trading day by using the prior day's holdings at close of business and the most recently reported price level of the CME Bitcoin Real Time Price [42] as reported by Bloomberg, L.P., or another reporting service, or another price of bitcoin derived from updated bids and offers indicative of the spot price of bitcoin.[43]

The Trust would create and redeem Shares from time to time, but only in one or more Creation Units. A Creation Unit would initially consist of at least 25,000 Shares, but may be subject to change.[44] The Trust would process all creations and redemptions in-kind, and accrue all ordinary fees in bitcoin (rather than cash), as a way of seeking to ensure that the Trust holds the desired amount of bitcoin-per-share. The Trust would not purchase or sell bitcoins, other than if the Trust liquidates or must pay expenses not contractually assumed by the Sponsor. Instead, financial institutions authorized to create and redeem Shares (''Authorized Participants'') would deliver, or cause to be delivered, bitcoins to the Trust in exchange for Shares of the Trust, and the Trust would deliver bitcoins to Authorized Participants when those Authorized Participants redeem Shares of the Trust.[45]

III. Discussion

A. The Applicable Standard for Review

The Commission must consider whether NYSE Arca's proposal is consistent with the Exchange Act. Section 6(b)(5) of the Exchange Act requires, in relevant part, that the rules of a national securities exchange be designed ''to prevent fraudulent and manipulative acts and practices'' and ''to protect investors and the public interest.'' [46] Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the rule change.'' [47]

The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[48] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations.[49] Moreover, ''unquestioning reliance'' on an SRO's representations in a proposed rule change is not sufficient to justify Commission approval of a proposed rule change.[50]

B. Whether NYSE Arca Has Met Its Burden To Demonstrate That the Proposal Is Designed To Prevent Fraudulent and Manipulative Acts and Practices

As stated above, an exchange can meet its obligations under Exchange Act Section 6(b)(5) by demonstrating that the exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying bitcoin assets. In this context, the term ''market of significant size'' includes a market (or group of markets) as to which (i) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (ii) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[51]

As the Commission has explained, it considers two markets that are members of the ISG to have a comprehensive surveillance-sharing agreement with one another, even if they do not have a separate bilateral surveillance-sharing agreement.[52] Accordingly, based on the common membership of NYSE Arca and the CME in the ISG,[53] NYSE Arca has the equivalent of a comprehensive surveillance-sharing agreement with the CME. However, while the Commission recognizes that the CFTC regulates the CME futures market,[54] including the CME bitcoin futures market, and thus such market is ''regulated,'' in the context of the proposed ETP, the record does not, as explained further below, establish that the CME bitcoin futures market is a ''market of significant size'' related to spot bitcoin, the underlying bitcoin assets that would be held by the Trust.

(1) Whether There is a Reasonable Likelihood That a Person Attempting to Manipulate the ETP Would Also Have to Trade on the CME Bitcoin Futures Market to Successfully Manipulate the ETP

The first prong in establishing whether the CME bitcoin futures market constitutes a ''market of significant size'' related to spot bitcoin is the determination that there is a reasonable likelihood that a person attempting to manipulate the ETP would have to trade on the CME bitcoin futures market to successfully manipulate the ETP.

In previous Commission orders, the Commission explained that the lead-lag relationship between the bitcoin futures market and the spot market is ''central to understanding'' the first prong.[55] In

[42] The CME Bitcoin Real Time Price is a continuous real-time bitcoin price index published by the CME Group and Crypto Facilities Ltd. using data from the Constituent Platforms. *See id.*

[43] *See id.*

[44] *See id.*

[45] *See id.* at 60696.

[46] 15 U.S.C. 78f(b)(5). Pursuant to Section 19(b)(2) of the Exchange Act, 15 U.S.C. 78s(b)(2), the Commission must disapprove a proposed rule change filed by a national securities exchange if it does not find that the proposed rule change is consistent with the applicable requirements of the Exchange Act. Exchange Act Section 6(b)(5) states that an exchange shall not be registered as a national securities exchange unless the Commission determines that ''[t]he rules of the exchange are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, or to regulate by virtue of any authority conferred by this title matters not related to the purposes of this title or the administration of the exchange.'' 15 U.S.C. 78f(b)(5).

[47] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[48] *See id.*

[49] *See id.*

[50] *Susquehanna Int'l Group, LLP* v. *Securities and Exchange Commission,* 866 F.3d 442, 447 (D.C. Cir. 2017).

[51] *See* Winklevoss Order, 83 FR at 37594. *See also supra* note 13.

[52] *See* Winklevoss Order, 83 FR at 37580 n.19.

[53] *See* Notice, 86 FR at 60703.

[54] While the Commission recognizes that the CFTC regulates the CME, the CFTC is not responsible for direct, comprehensive regulation of the underlying spot bitcoin market. *See* Winklevoss Order, 83 FR at 37587, 37599. *See also* WisdomTree Order, 86 FR at 69330 n.118; Kryptoin Order, 86 FR at 74174 n.119; SkyBridge Order, 87 FR at 3874 n.80; Wise Origin Order, 87 FR at 5534 n.93.

[55] *See, e.g.,* USBT Order, 85 FR at 12612 (''[E]stablishing a lead-lag relationship between the bitcoin futures market and the spot market is central to understanding whether it is reasonably likely that a would-be manipulator of the ETP would need to trade on the bitcoin futures market to successfully manipulate prices on those spot platforms that feed into the proposed ETP's pricing mechanism. In particular, if the spot market leads the futures market, this would indicate that it would not be necessary to trade on the futures market to manipulate the proposed ETP, even if arbitrage worked efficiently, because the futures price would move to meet the spot price.''). When considering past proposals for spot bitcoin ETPs, the Commission has discussed whether there is a lead-lag relationship between the regulated market (*e.g.,* the CME) and the market on which the assets held by the ETP would have traded (*i.e.,* spot bitcoin platforms), as part of an analysis of whether a would-be manipulator of the spot bitcoin ETP would need to trade on the regulated market to

response, the Exchange's Notice and Exhibit 3A thereto [56] describe the methodology and results of statistical analysis undertaken by Bitwise Asset Management, Inc. (''Bitwise''), the parent of the Sponsor, which, according to the Exchange, shows that prices on the CME bitcoin futures market ''consistently lead prices on the bitcoin spot market and the unregulated bitcoin futures market.'' [57] As explained in more detail in the Notice and Exhibit 3A, Bitwise used data from Coin Metrics, CoinAPI, CoinGecko, and the CME for its analysis of the relationship between CME bitcoin futures prices and prices on 10 unregulated spot bitcoin platforms [58] and seven unregulated bitcoin futures platforms.[59] For each of these 17 unregulated platforms, Bitwise performed three types of analysis: (1) information share (''IS'') price discovery analysis, which Bitwise describes as measuring ''who moves first'' to incorporate new information into a common ''efficient'' price for an asset being traded on multiple platforms; [60] (2) component share (''CS'') price discovery analysis, which Bitwise describes as measuring the ''component weight'' or contribution to the common ''efficient'' price; [61] and (3) time-shift lead-lag (''TSLL'') analysis, which Bitwise describes as off-setting (or ''shifting'') two time series against each other to find the direction and length of the lead-lag relationship between the two series that maximizes the predictive strength of one series against the other.[62]

As described in more detail in the Notice and Exhibit 3A, Bitwise removed trades that occurred during non-CME trading hours and made certain other adjustments to the data. Bitwise then performed each type of analysis (IS, CS, and TSLL) on each of the 17 unregulated platforms for each day in its sample period. For each type of analysis (IS, CS, and TSLL) and each platform, Bitwise then averaged the daily results both by month (to evaluate the potential for time variation in price discovery leadership) and across the full sample period. Bitwise ran statistical significance tests with a 95% confidence interval on the resulting monthly and full-sample averages.[63]

According to Bitwise, with respect to its IS/CS analysis, the full-sample average results demonstrate that the CME bitcoin futures market leads all evaluated bitcoin spot and futures trading platforms and that the results are statistically significant for all platforms from an IS perspective, and for 16 of the 17 platforms from a CS perspective.[64] According to Bitwise, on a month-by-month basis, each trading platform generates a slightly different profile and has slightly different results; but on average, the CME led the 10 spot trading platforms from an IS perspective in 89% of evaluated months, and from a CS perspective in 80% of evaluated months.[65]

According to Bitwise, with respect to its TSLL analysis, the full-sample average results indicate that CME leads, and all such results are statistically significant.[66] According to Bitwise, on a month-by-month basis, each trading platform generates a slightly different profile and has slightly different results; but the CME led consistently throughout the study period in a statistically significant manner.[67] Bitwise also states that, with respect to the 10 unregulated spot platforms, the monthly TSLL results display a ''general trend'' where the CME's ''lead'' starts out long, with wide confidence bands, and then ''tightens'' over time ''and becomes more consistent.'' [68]

In addition, Bitwise performed a review of academic and industry literature pertaining to the relationship between the CME bitcoin futures market and unregulated bitcoin markets.[69] Bitwise states that a majority (7 of 10) of the papers that it reviewed that use IS and/or CS support the view that the CME bitcoin futures market leads price discovery as compared with the spot bitcoin market; [70] and that one paper that uses a similar TSLL approach as Bitwise arrives at nearly identical conclusions: that the CME bitcoin futures market leads all other markets

effect such manipulation. *See, e.g.,* USBT Order, 85 FR at 12612. *See also* VanEck Order, 86 FR at 64547; WisdomTree Order, 86 FR at 69330–31; Kryptoin Order, 86 FR at 74176 n.144; SkyBridge Order, 87 FR at 3876 n.101; Wise Origin Order, 87 FR at 5535 n.107; ARK 21Shares Order, 87 FR at 20024 n.138.

[56] Exhibit 3A is available at: *https://www.sec.gov/rules/sro/nysearca/2021/34-93445-ex3a.pdf.*

[57] *See* Notice, 86 FR at 60703–04.

[58] The 10 unregulated spot bitcoin platforms are Bitstamp, Coinbase, Gemini, itBit, and Kraken, which the Exchange states are the trading platforms represented in the CME US Reference Rate (*see id.* at 60707); as well as Binance, Bitfinex, Huobi, LBank, and OKEx. The Exchange states that these trading platforms include both the largest USD–BTC pair trading platform by reported volume (Coinbase) and the largest tether-BTC pair trading platform by reported volume (Binance). *See id.*

[59] The seven unregulated bitcoin futures platforms are Binance, BitMEX, Bybit, Deribit, FTX, Huobi, and OKEx. *See id.* at 60709.

[60] *See* Exhibit 3A, *supra* note 56, at 143–44.

[61] *See id.*

[62] *See id.* at 143, 157.

[63] *See id.* at 152, 159.

[64] *See id.* at 152, 168.

[65] *See id.* at 154–156. Exhibit 3A does not provide corresponding averages with respect to the seven unregulated futures platforms. The month-by-month results for each unregulated futures platform indicate that the CME has led IS/CS price discovery in a majority of months for each such platform. *See id.* at 170.

[66] *See id.* at 160, 170–171.

[67] *See id.* at 161, 173.

[68] *See id.* at 161.

[69] Bitwise considered the following papers in Exhibit 3A (*see id.* at 145–151): S. Corbet, B. Lucey, M. Peat & S. Vigne, *Bitcoin Futures—What use are they?,* 172 Econ. Letters 23 (2018); D. Baur & T. Dimpfl, *Price discovery in bitcoin spot or futures?,* 39 J. Futures Mkts. 803 (2019); B. Kapar & J. Olmo, *An analysis of price discovery between Bitcoin futures and spot markets,* 174 Econ. Letters 62 (2019) (''Kapar & Olmo); C. Alexander & D. Heck, *Price Discovery, High-Frequency Trading and Jumps in Bitcoin Markets* (2019), working paper available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3383147* (''Alexander & Heck 2019''); Y. Hu, Y. Hou & L. Oxley, *What role do futures markets play in Bitcoin pricing? Causality, cointegration and price discovery from a time-varying perspective,* 72 Int'l Rev. of Fin. Analysis 101569 (2020) (''Hu, Hou & Oxley''); E. Akyildirim, S. Corbet, P. Katsiampa, N. Kellard & A. Sensoy, *The development of Bitcoin futures: Exploring the interactions between cryptocurrency derivatives,* 34 Fin. Res. Letters 101234 (2020); A. Fassas, S. Papadamou, & A. Koulis, *Price discovery in bitcoin futures,* 52 Res. Int'l Bus. Fin. 101116 (2020); O. Entrop, B. Frijns & M. Seruset, *The determinants of price discovery on bitcoin markets,* 40 J. Futures Mkts. 816 (2020); S. Aleti & B. Mizrach, *Bitcoin spot and futures market microstructure,* 41 J. Futures Mkts. 194 (2021); A. Chang, W. Herrmann & W. Cai, *Efficient Price Discovery in the Bitcoin Markets,* Wilshire Phoenix, Oct. 14, 2020, working paper available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3733924.* Bitwise also submitted a comment letter that discusses K. Robertson & J. Zhang, *Suitable Price Discovery Measurement of Bitcoin Spot and Futures Markets,* Fidelity Investments Inc., Jan. 12, 2022, working paper available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4012165* (''Fidelity Paper''). *See* letter from Katherine Dowling, Matt Hougan, and Paul Fusaro, Bitwise, dated Feb. 25, 2022 (''Bitwise Letter 1'').

[70] *See* Exhibit 3A, *supra* note 56, at 151. Bitwise states that an eighth paper has aggregate results in favor of the CME leading; and that of the two remaining papers that conclude that the spot market leads, one was an early paper that potentially studied a very limited time period, and the other has an important methodological flaw. *See id.* Bitwise also references C. Alexander & D. Heck, *Price discovery in Bitcoin: The impact of unregulated markets,* 50 J. Financial Stability 100776 (2020) (''Alexander & Heck 2020''). *See id.* at 148. This published paper is a later version of the working paper Alexander & Heck 2019, and finds, employing a multidimensional approach to price discovery, including the main price leaders within futures, perpetuals, and spot markets, that CME bitcoin futures have a very minor effect on price discovery; and that faster speed of adjustment and information absorption occurs on the unregulated spot and derivatives platforms than on the CME bitcoin futures market. *See also infra* notes 91–94 and accompanying text. With respect to the Commission's citation of the ''mixed'' literature in its prior disapproval orders for spot bitcoin ETPs, the Exchange asserts that ''[o]f course, the existence of variable results in IS/CS analysis, either within one study or a group of studies, is not in isolation sufficient to determine that a commodity futures market does not satisfy the concerns of the [Exchange] Act,'' and that there have been multiple commodity markets where the Commission has approved ETPs where ''select IS/CS studies find that the related derivatives market is not the main source of price discovery.'' *See* Notice, 86 FR at 60706 n.52.

considered in the paper's pairwise TSLL analysis, and that the CME's lead has tightened over time.[71]

The Exchange concludes from Bitwise's consideration of the literature and Bitwise's own IS, CS, and TSLL analysis that ''the Sponsor has demonstrated that the CME [bitcoin futures market] leads the bitcoin spot market and the unregulated bitcoin futures market, such that it is reasonably likely that a person attempting to manipulate the ETP would also have to trade on the CME [bitcoin futures market].'' [72]

The Commission disagrees. The evidence in the record for the proposal is inadequate to conclude that an interrelationship exists between the CME bitcoin futures market and the spot bitcoin market such that it is reasonably likely that a person attempting to manipulate the proposed spot bitcoin ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP.[73]

The Commission raises particular disagreements with the Sponsor's assertions regarding its analysis below, but even accepting at face value the results of Bitwise's statistical analysis of the relationship between the CME bitcoin futures market and the spot market, such results are only part of the ''mixed'' record on the topic of bitcoin price discovery.[74] Bitwise's literature review considered 10 papers that undertook IS/CS analysis, each using different methodologies, time periods, data, and data aggregation techniques.[75] Bitwise states that 7 of these 10 studies find that the CME bitcoin futures market leads price discovery.[76] Bitwise does not, however, address issues that the Commission has raised with respect to two of these papers purportedly supporting the CME bitcoin futures market's lead in past disapproval orders.[77] Nor does Bitwise discuss these 10 IS/CS studies in light of Bitwise's acknowledgment that ''classic'' price discovery metrics like IS/CS could be misspecified, with potentially biased results, when price data have a high level of sparsity.[78] Further, beyond the 10 studies considered by Bitwise, subsequent bitcoin price discovery literature likewise includes some studies finding that the spot bitcoin market dominates price discovery [79] and other studies finding that the CME bitcoin futures market dominates.[80] As in previous disapprovals, because the evidence regarding whether the CME bitcoin futures market leads the spot market remains inconclusive,[81] the Commission is unable to find that an interrelationship exists between the CME bitcoin futures market and the spot bitcoin market such that it is reasonably likely that a person attempting to manipulate the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP. Accordingly, the Commission concludes that the Sponsor has not demonstrated that the CME bitcoin futures market constitutes a market of significant size related to spot bitcoin.

Beyond the Commission's overarching concern about the divergent conclusions of the econometric evidence about the lead-lag relationship between the CME bitcoin futures market and spot market, the Commission also has particular disagreements with the Sponsor's assertions regarding its analysis. Those disagreements support the Commission's determination that NYSE Arca has not provided a sufficient basis to conclude that it is reasonably likely that a would-be manipulator of the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP.

First, Bitwise's first comment letter casts doubt on its own IS/CS results. Bitwise's first comment letter acknowledges that ''classic'' price discovery metrics like IS and CS ''face difficulties based on the model assumptions of VECM [the Vector Error Correction Model] when the prices under consideration are asynchronous and/or infrequent,'' [82] citing an academic study by Buccheri et al.[83] that investigates the difficulties to identifying price discovery with VECM models due to the high sparsity of data in markets that record trades at the sub-millisecond level. Bitwise also acknowledges that, ''when prices have a high level of sparsity, the VECM is clearly misspecified and the estimates are potentially biased.'' [84] However, while Bitwise claims that ''[t]he limitations of classic IS and CS analysis informed Bitwise's specific methodological approach to IS and CS analysis,'' [85] Bitwise neither explains how its IS/CS approach was ''informed'' by such limitations, nor provides any information on whether the price data that Bitwise used in its IS/CS analysis have a high level of sparsity. Moreover, Bitwise's acknowledgement of the Fidelity Paper's finding that ''there is a high level of sparsity in bitcoin data'' [86] suggests that, by its own admission, Bitwise's IS/CS approach is misspecified and its estimates potentially biased.

Second, Bitwise performed its IS, CS, and TSLL analysis for each of the 17 unregulated platforms *per day* and then averaged the daily results both by month and across the full sample period.[87] However, neither the Exchange nor Bitwise explains why Bitwise chose a *daily* basis to compute its IS, CS, and TSLL estimates; provides any information about how variable the daily estimates are, before the monthly and/or full-sample averaging was applied; or provides any information on the robustness of the estimates—that is, whether these daily estimates or the statistical significance of the monthly

[71] *See* Bitwise Letter 1 at 4.

[72] *See* Notice, 86 FR at 60711.

[73] *See* USBT Order, 85 FR at 12611.

[74] *See* Bitwise Letter 1 at 3.

[75] *See supra* note 69.

[76] *See* Exhibit 3A, *supra* note 56, at 151.

[77] *See, e.g.,* USBT Order, 85 FR at 12613 n.244 (discussing that the use of daily price data, as opposed to intraday prices, by Kapar & Olmo and Hu, Hou & Oxley (in an unpublished version of the paper) may not be able to distinguish which market incorporates new information faster; and discussing that the (unpublished version of the) Hu, Hou & Oxley paper found inconclusive evidence that futures prices lead spot bitcoin prices—in particular, that the months at the end of the paper's sample period showed, using Granger causality methodology, that the spot market was the leading market—and that the record did not include evidence to explain why this would not indicate a shift towards prices in the spot market leading the futures market that would be expected to persist into the future).

[78] *See* Bitwise Letter 1 at 3.

[79] *See, e.g.,* J. Hung, H. Liu & J. Yang, *Trading activity and price discovery in Bitcoin futures markets,* 62 J. Empirical Finance 107 (2021).

[80] *See, e.g.,* J. Wu, K. Xu, X. Zheng & J. Chen, *Fractional cointegration in bitcoin spot and futures markets,* 41 J. Futures Mkts. 1478 (2021). In addition, the Exchange claims that, based on its review of past commodity-trust ETP approvals and ''select'' IS/CS studies, a mixed result ''is not in isolation sufficient to determine that a commodity futures market does *not* satisfy the concerns of the [Exchange] Act.'' Notice, 86 FR at 60706 n.52 (emphasis added). However, the applicable standard of review is whether a listing exchange has provided sufficient evidence to demonstrate that its proposal *is* consistent with the Exchange Act. *See supra* notes 46–50 and accompanying text. For each proposal, the Commission considers the totality of the evidence provided by the listing exchange and on its own merits.

[81] As the academic literature and listing exchanges' analyses pertaining to the pricing relationship between the CME bitcoin futures market and spot bitcoin market have developed, the Commission has critically reviewed those materials. *See* ARK 21Shares Order, 87 FR at 20024; Global X Order, 87 FR at 14920; Wise Origin Order, 87 FR at 5535–36, 5539–40; Kryptoin Order, 86 FR at 74176; WisdomTree Order, 86 FR at 69330–32; VanEck Order, 86 FR at 64547–48; USBT Order, 85 FR at 12613.

[82] Bitwise Letter 1 at 3, quoting Fidelity Paper at 12–13.

[83] G. Buccheri, G. Bormetti, F. Corsi & F. Lillo, *Comment on: Price discovery in high resolution,* 19 J. Financial Econometrics 439 (2021).

[84] Bitwise Letter 1 at 3, quoting Fidelity Paper at 13.

[85] Bitwise Letter 1 at 3.

[86] *Id.*

[87] *See* Exhibit 3A, *supra* note 56, at 152, 159.

and/or full-sample averages of such daily estimates are sensitive to different choices that Bitwise could have made for the analysis (*e.g.,* to compute intraday estimates).

Third, the pairwise IS/CS full-sample average results for CME compared to each of the 10 spot platforms ranged between 52.97% (the CS result versus itBit) to 68.03% (the CS result versus Bitstamp).[88] Even accepting these results and their statistical significance at face value, these results suggest that spot bitcoin markets still account for approximately 32%–47% of price discovery. Yet neither Bitwise nor the Exchange has explained why, notwithstanding this amount of price discovery occurring on spot platforms, it is reasonably likely that a would-be manipulator would nonetheless have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP.

Fourth, taking Bitwise's TSLL results at face value, as Bitwise acknowledges, the extent to which the CME bitcoin futures market ''leads'' the 10 unregulated spot platforms has decreased since 2019 to the end of Bitwise's sample period in September 2020.[89] This general trend is also observed in the Fidelity Paper's TSLL analysis, which uses a longer sample period (to Q1 2021) and finds that the CME's average ''lead'' time has ''steadily decreased'' among all evaluated markets to about one second in Q4 2020 and Q1 2021.[90] The record, however, does not explain the implication of the CME's decreasing lead over the identified spot platforms, nor why the CME's ''lead'' time against spot platforms would not be expected to continue to decrease throughout 2021 and 2022 until it ''lags'' spot platforms. Moreover, neither Bitwise nor the Exchange has explained why, notwithstanding such decreasing ''lead'' times against spot platforms, it is nonetheless reasonably likely that a would-be manipulator would have to trade on the CME to successfully manipulate the proposed ETP.

Fifth, all of Bitwise's statistical results—IS, CS, and TSLL—are based on pairwise, two-dimensional analysis (*e.g.,* CME compared to Coinbase; CME compared to Gemini; etc.). At least one multidimensional approach to price discovery (Alexander & Heck 2020) finds that CME bitcoin futures ''have a very minor effect on price discovery,'' and that ''a faster speed of adjustment and information absorption [occurs] on the unregulated spot and derivatives [platforms] than on CME bitcoin futures.'' [91] Specifically, Alexander & Heck's multidimensional analysis—which simultaneously includes unregulated futures, regulated futures, perpetual futures, and spot markets—finds that CME bitcoin futures have never accounted for more than 9% of price discovery (and unregulated markets collectively account for more than 91% of price discovery), and have always contributed the least to price discovery among all venues considered, except during July 2019.[92] While Bitwise acknowledges the Alexander & Heck 2020 paper, Bitwise merely states that the paper ''involves a complex, multidimensional approach to price discovery analysis conducted across eight different markets and four different exposure types (unregulated futures, regulated futures, perpetual futures, and spot markets), each with different levels of microstructure friction and data integrity,'' and that ''these complications make it difficult to draw a direct comparison'' to the 10 IS/CS papers that Bitwise considered.[93] Bitwise neither critiques the multidimensional Alexander & Heck 2020 approach; nor attempts to apply the approach to Bitwise's own data; nor discusses the robustness of Bitwise's two-dimensional methodology in response to the critique in Alexander & Heck 2020 that: ''omitting substantial information flows from other markets can produce misleading results. . . . [I]n a two-dimensional model one or other of the instruments must necessarily be identified as price leader.'' [94] In other words, a two-dimensional model might erroneously attribute information share or component share of omitted platforms to one of the two platforms included in the pairwise estimate, because the two shares must necessarily sum up to 100%. As such, the Exchange has not adequately addressed whether Bitwise's conclusion that the CME bitcoin futures market ''leads'' price discovery continues to hold up when the entirety of the bitcoin-related market (spot and futures) is simultaneously considered.

The Commission thus concludes that the information that NYSE Arca provides is not a sufficient basis to support a determination that it is reasonably likely that a would-be manipulator of the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP.[95] Therefore, the information in the record also does not establish that the CME bitcoin futures market is a ''market of significant size'' related to spot bitcoin.

(2) Whether It is Unlikely that Trading in the Proposed ETP Would Be the Predominant Influence on Prices in the CME Bitcoin Futures Market

[88] *See id.* at 153.

[89] *See id.* at 161.

[90] *See* Fidelity Paper at 17.

[91] *See* Alexander & Heck 2020 at 1–2.

[92] *See id.* at 13. Alexander & Heck attribute these findings to: (i) the trading volume of each individual unregulated derivatives in their data set being much larger than that of CME bitcoin futures; (ii) many smaller players in bitcoin markets (such as miners or crypto-specialized hedge funds), who have easy access to unregulated platforms and ultra-high-frequency trading platforms, may be considered as more informed bitcoin investors than the CME's clients; and (iii) investors who want to manipulate the price of bitcoin ''may do so much more easily on an unregulated [platform] rather than on the CME, which is heavily regulated by the CFTC.'' *See id.*

[93] *See* Exhibit 3A, *supra* note 56, at 148.

[94] Alexander & Heck 2020 at 2.

[95] In the Teucrium Order and Valkyrie XBTO Order, the Commission determined that it is unnecessary for the listing exchanges to establish a reasonable likelihood that a would-be manipulator would have to trade on the CME itself to manipulate a proposed ETP whose only non-cash holdings would be CME bitcoin futures contracts. As the Commission explains in those Orders, in each such case, the proposed ''significant'' regulated market (*i.e.,* the CME) with which the listing exchange has a surveillance-sharing agreement would be the *same* market on which the underlying bitcoin assets (*i.e.,* CME bitcoin futures contracts) trade. Consequently, in the circumstances under consideration in the Teucrium Order and Valkyrie XBTO Order, the CME's surveillance can reasonably be relied upon to capture the effects on the CME bitcoin futures market caused by a person attempting to manipulate a CME bitcoin futures-based ETP by manipulating the price of CME bitcoin futures contracts, whether that attempt is made by directly trading on the CME bitcoin futures market or indirectly by trading outside of the CME bitcoin futures market. *See* Teucrium Order, 87 FR at 21679; Valkyrie XBTO Order, 87 FR at 28851. However, as the Commission also states in those Orders, this reasoning does not extend to spot bitcoin ETPs. Spot bitcoin markets are not currently ''regulated.'' *See* Teucrium Order, 87 FR at 21679 n.46 (citing USBT Order, 85 FR at 12604; NYDIG Order, 87 FR at 14936 nn.65–67). *See also* Valkyrie XBTO Order, 87 FR at 28851 n.42. Thus if an exchange seeking to list a spot bitcoin ETP relies on the CME as the regulated market with which it has a comprehensive surveillance-sharing agreement, the assets held by the spot bitcoin ETP would not be traded on the CME; and because of this important difference, with respect to a spot bitcoin ETP, there would be reason to question whether a surveillance-sharing agreement with the CME would, in fact, assist in detecting and deterring fraudulent and manipulative misconduct affecting the price of the spot bitcoin held by that ETP. If, however, an exchange proposing to list and trade a spot bitcoin ETP identifies the CME as the regulated market with which it has a comprehensive surveillance-sharing agreement, the exchange could overcome the Commission's concern by demonstrating that there is a reasonable likelihood that a person attempting to manipulate the spot bitcoin ETP would have to trade *on the CME* in order to manipulate the ETP, because such demonstration would help establish that the exchange's surveillance-sharing agreement with the CME would have the intended effect of aiding in the detection and deterrence of fraudulent and manipulative misconduct related to the spot bitcoin held by the ETP. *See* Teucrium Order, 87 FR at 21679 n.46; Valkyrie XBTO Order, 87 FR at 28851 n.42.

The second prong in establishing whether the CME bitcoin futures market constitutes a ''market of significant size'' related to spot bitcoin is whether it is unlikely that trading in the proposed ETP would be the predominant influence on prices in the CME bitcoin futures market.[96]

As described in more detail in the Notice and Exhibit 3B thereto,[97] the Exchange asserts that trading in the Trust is unlikely to become the predominant influence on prices in the CME bitcoin futures market based on Bitwise's estimates for the maximum likely first-year flows into, and average daily trading volume of, the Trust, and Bitwise's analysis of whether such flows and trading volume would be likely to impact CME bitcoin futures prices.[98]

To estimate the likely first-year flows into the proposed ETP, Bitwise first examined first-year flows into all ETPs currently listed on the market. Bitwise concluded that it is unlikely that a bitcoin ETP will attract more first-year flow than the ETP with the highest first-year flows in history (Invesco QQQ Trust, $5.35 billion), particularly given the relative size of the bitcoin market compared to the markets captured by the most successful ETPs in the past, which target parts or all of the equity, bond, real estate, and gold markets.[99] Bitwise also examined first-year flows into first-to-market single-commodity ETPs, which Bitwise considers to provide additional context on the likely ''upper bound'' of potential flows into a bitcoin ETP.[100] Finally, Bitwise examined the Grayscale Bitcoin Trust (''GBTC''), which Bitwise describes as a publicly traded grantor trust that holds bitcoin directly with a third-party custodian and that has been accessible to U.S. investors since 2015.[101] Bitwise states that, according to Grayscale Investments, GBTC attracted a record $4.7 billion in inflows in 2020.[102]

Extrapolating from this historical information, Bitwise uses $4.7 billion as its estimate for first-year flows into a new bitcoin ETP. Bitwise asserts that its $4.7 billion estimate is ''aggressive'' because it assumes that a bitcoin ETP would ''[b]e the third-fastest-growing ETP in history,'' would ''[s]ignificantly surpass (by more than 50%) the first-year flows into GLD,'' and would ''[m]atch the highest annual flow in GBTC's history, achieved during a strong bull market, all while the new ETP is forced to compete for market share with GBTC itself.'' [103]

As described in more detail in Exhibit 3B, to evaluate the potential impact of ETP inflows on prices in the CME bitcoin futures market, Bitwise conducted a correlation analysis examining the relationship of daily and weekly flows into GBTC in 2020 and changes in a *spot* bitcoin-based reference price.[104] According to Bitwise, the data show there is no meaningful relationship between daily and weekly flows into GBTC and changes in that spot bitcoin price, despite the aggregate yearly flows being $4.7 billion.[105] According to Bitwise, its analysis of outlier days and weeks with large flows also supports this conclusion.[106] Bitwise thus concludes that it is unlikely that $4.7 billion in flows into a bitcoin ETP in a single year will cause it to become the predominant influence on prices in the CME bitcoin futures market.[107]

Bitwise also considered whether secondary market trading in the Shares would be likely to become the predominant influence on prices in the CME bitcoin futures market. To do so, as described in more detail in Exhibit 3B, Bitwise applied the 2020 ratio of average daily volume (''ADV'') to assets under management (''AUM'') (''ADV/AUM'') for both GBTC and GLD to the $4.7 billion estimate of first-year flows into a new bitcoin ETP.[108] In so doing, for the Shares, Bitwise calculated an estimated $72 million ADV and $143 million ADV, corresponding to the ADV/AUM ratio of GBTC and GLD, respectively.[109] And for the purposes of its analysis, Bitwise uses the higher figure—$143 million—as its estimate for a new bitcoin ETP's average daily trading volume after a year on the market. Bitwise asserts that this estimate is ''aggressive'' because it assumes that a bitcoin ETP would ''[b]e the third-fastest-growing ETP in history'' and would ''[h]ave an ADV/AUM ratio two times higher than that of GBTC, which competes in the same market.'' [110]

Bitwise ''believe[s] it is unlikely that trading in the ETP will become the predominant influence on prices in the CME [bitcoin futures market] if such trading activity is substantially smaller than the trading activity on the CME bitcoin futures market,'' which Bitwise states it has demonstrated to be the leading source of price discovery in the bitcoin market.[111] As described in Exhibit 3B, Bitwise estimated CME bitcoin futures' average daily trading volume in 2020 to be $392 million, which Bitwise states is 174% higher than its $143 million estimate of a new bitcoin ETP's likely average daily trading volume. Bitwise thus concludes that it is unlikely that trading in a new bitcoin ETP will cause it to become the predominant influence on prices in the CME bitcoin futures market.[112]

Bitwise makes three additional arguments in support of its conclusion. First, Bitwise argues that a new bitcoin ETP is unlikely to experience a GLD-like rapid start.[113] Bitwise states that, ''[w]hile there is interest in a bitcoin ETP,'' it is unlikely to match the level of demand experienced by GLD after its 2004 launch because (1) bitcoin is a substantially smaller market (approximately 74% smaller) than gold was at its launch; (2) unlike GLD, U.S. retail investors already have ''multiple easy ways'' to directly purchase bitcoin; and (3) unlike GLD, a bitcoin ETP will ''face stiff competition from GBTC, a $20 billion product with high levels of liquidity that can be easily accessed through a brokerage setting.'' [114]

Second, Bitwise considered internationally listed spot bitcoin ETPs, specifically the German ETC Group Physical Bitcoin ETP (''BTCE'') and the Canadian Purpose Bitcoin ETF (''BTCC''). Using the same correlation assessment as it used for GBTC inflows, Bitwise finds that there is no meaningful relationship between daily or weekly flows into BTCE (over the period June 2020 to March 2021) or BTCC (over a six-week period in February–March 2021) and daily or

[96] *See* Winklevoss Order, 83 FR at 37594; USBT Order, 85 FR at 12596–97.

[97] Exhibit 3B is available at: *https://www.sec.gov/rules/sro/nysearca/2021/34-93445-ex3b.pdf.*

[98] *See* Notice, 86 FR at 60711–15.

[99] *See* Exhibit 3B, *supra* note 97, at 249–50.

[100] *See id.* at 250–51. Bitwise states that first-year flows range from $3.01 billion for the SPDR Gold Shares (''GLD'') to negative $1 million for the iPath Bloomberg Lead Subindex Total Return ETN. *See id.* at 250.

[101] *See id.* at 251–252.

[102] *See id.* at 252.

[103] *See id.*

[104] Daily or weekly percentage price changes of bitcoin were calculated using the 4 p.m. E.T. bitcoin reference rate from Coin Metrics. *See id.* at 253.

[105] *See id.* at 254.

[106] *See id.* at 254–55.

[107] *See id.* at 255.

[108] Bitwise asserts that, although the absolute size of the ADV for GBTC ranges widely across 2020, the monthly ADV/AUM ratio stays fairly consistent, ranging from 1.10% to 2.21%. *See id.* at 256. Bitwise does not, however, indicate whether a consistent ADV/AUM ratio is common among commodity-based products, or why a consistent ratio would otherwise be expected to persist into future months/years. In addition, ultimately, Bitwise uses GLD's average 2020 ADV/AUM ratio for its estimate, not the GBTC ratio. The 2020 monthly ADV/AUM for GLD varies more widely, ranging from 1.65% to 5.93%. *See id.* at 257.

[109] *See id.* at 256–58.

[110] *See id.* at 258.

[111] *See id.* at 259.

[112] *See id.* at 259–60.

[113] According to Bitwise, GLD gained approximately $1.26 billion in flows in its first week. *See id.* at 262.

[114] *See id.* at 262–64.

weekly changes in the *spot* bitcoin price.[115]

Third, Bitwise argues that evidence from the 2021 launch of CME bitcoin futures-based exchange traded funds (''ETFs'')—ProShares Bitcoin Strategy ETF (''BITO''), Valkyrie Bitcoin Strategy ETF (''BTF''), and VanEck Bitcoin Strategy ETF (''XBTF'')—strengthens its arguments. Bitwise states that the fact that these ETFs took in $1.55 billion in their first month on the market, and have taken in just $216 million since, strengthens its belief that the estimate of $4.7 billion in first-year flows into a spot bitcoin ETP is an aggressive estimate. Bitwise also asserts that the bitcoin market is ''incredibly and increasingly crowded'' with options for investors, and a spot bitcoin ETP would ''face steep competition.'' [116]

Based on Bitwise's analysis, the Exchange concludes that trading in the Trust is unlikely to become the predominant influence on prices in the CME bitcoin futures market.[117]

The Commission disagrees. The evidence in the record for the proposal does not support the conclusion that it is unlikely that trading in the proposed ETP would be the predominant influence on prices in the CME bitcoin futures market.

First, Bitwise's conflicting claims with respect to the demand for a spot bitcoin ETP undermine Bitwise's expectations for the likely size of such an ETP and the rapidity of inflows into it. On the one hand, Bitwise downplays potential investor demand, stating that ''[w]hile there is interest in a bitcoin ETP,'' [118] the bitcoin market is ''incredibly and increasingly crowded'' with options for investors, noting that investors today can buy bitcoin on crypto trading apps, finance apps, through over-the-counter trusts, via bitcoin futures ETFs, and ''in many other ways.'' [119] Bitwise states that a spot bitcoin ETP ''would now be the fourth bitcoin-linked ETP to come to market,'' and ''would face steep competition from the already liquid and highly correlated bitcoin futures-based competitors.'' [120] Bitwise describes GBTC in particular as competition for a new bitcoin ETP, asserting that GBTC has ''high levels of liquidity'' and can be ''easily accessed through a brokerage setting,'' and thus that ''a good portion of the brokerage-access demand that would otherwise be waiting for an ETP is already being met by GBTC.'' [121] On the other hand, when asserting public interest and investor protection arguments in favor of its proposal (*see also* Section III.C, below), Bitwise highlights that ''a great many (and an ever-increasing number of) investors already'' directly invest in bitcoin.[122] Bitwise also highlights that, unlike GBTC, the proposed ETP would allow for daily creations and redemptions; can be expected to ''closely track the value of [b]itcoin, and not periodically trade at substantial premiums to and discounts from the value of [b]itcoin''; and would be ''professionally managed, SEC-regulated, highly-liquid, fully transparent, and listed on the NYSE Arca''; and that ''at least some segment'' of retail and other investors would benefit from such characteristics and would be ''affirmatively disadvantaged'' by not having access to it.[123] Bitwise also states that the proposed ETP ''would add material protections for the millions of U.S. investors who currently use other less protected and transparent avenues to access the bitcoin market, as well as for any future investors who may choose to do so.'' [124] If, as Bitwise claims, U.S. investors have been and are ever-increasingly investing in bitcoin, and the proposed ETP ''would add material protections'' that are not currently available through GBTC or otherwise for some segment of investors, and would, unlike GBTC, be available to trade immediately on a national securities exchange with daily creations and redemptions,[125] it is not clear that Bitwise's use of the GBTC historical record of $4.7 billion in inflows is a likely, let alone ''aggressive,'' estimate for first-year inflows into a new spot bitcoin ETP.

Likewise, on the one hand, Bitwise claims that it is unlikely that a new bitcoin ETP would experience rapid one-week inflows similar to GLD, which had first-week inflows of approximately $1.26 billion.[126] On the other hand, Bitwise highlights that BTCC—the first bitcoin ETP launched in Canada—''experienced three days of very high inflows shortly after its launch''; [127] and that the three CME bitcoin futures-based ETFs took in $1.55 billion in their first month on the market, with just $216 million since.[128] BITO—the first such ETF to launch—took in $1.21 billion AUM within three days of its launch.[129]

Second, it is not clear from Bitwise's correlation analysis what would be the likely impact of inflows into a new bitcoin ETP on CME bitcoin futures prices. Bitwise assessed correlations of inflows (into GBTC in 2020; into BTCE in 2020–21; and into BTCC in 2021) using a *spot* bitcoin-based reference price.[130] Bitwise does not explain why it chose to use bitcoin *spot* prices instead of *CME bitcoin futures* prices themselves, despite the CME bitcoin futures market having been operating since 2017 and its price data being readily available to Bitwise. Bitwise's decision to run its correlations against spot prices is particularly puzzling, given its claims (discussed above) that CME bitcoin futures prices lead price discovery. Put in another way, given that Bitwise identifies the CME bitcoin futures market as the relevant regulated market of significant size, the use of a spot bitcoin price for its correlation analysis could render the analysis immaterial.

Moreover, Bitwise's correlation analysis does not control for any other factors that may have been affecting spot bitcoin prices during the daily or weekly aggregation periods. Thus, the results do not isolate the statistical relationship between spot bitcoin prices and the factor of interest (*i.e.,* flows into GBTC, BTCE, or BTCC).

Third, Bitwise's analysis regarding the potential effects of trading in the Shares on CME bitcoin futures prices is vague and conclusory. Bitwise states that it ''believes'' that it is unlikely that trading in a new bitcoin ETP will become the predominant influence on prices in the CME bitcoin futures market ''if such trading activity is substantially smaller than the trading activity on the CME bitcoin futures market.'' [131] Bitwise, however, does not provide any explanation or basis for its ''belief.'' With this ''belief'' in hand, Bitwise then calculates that CME bitcoin futures' average daily trading volume in 2020 ($392 million) is 174% higher than its estimate of a new bitcoin ETP's likely average daily trading volume ($143

[115] *See id.* at 265–69.

[116] *See* Bitwise Letter 1 at 5–6.

[117] *See* Notice, 86 FR at 60715.

[118] Exhibit 3B, *supra* note 97, at 264.

[119] Bitwise Letter 1 at 6.

[120] *Id.*

[121] Exhibit 3B, *supra* note 97, at 263–64.

[122] *See* letter from Robert H. Rosenblum, Wilson Sonsini Goodrich & Rosati, P.C., and Kathleen H. Moriarty, Chapman and Cutler LLP, on behalf of Bitwise, dated Mar. 7, 2022 (''Bitwise Letter 2''), at 4.

[123] *See id.* at 3–4.

[124] Bitwise Letter 1 at 6.

[125] *See* Exhibit 3B, *supra* note 97, at 251 (''GBTC is different from an ETP is certain ways, including that the structure does not allow for redemptions . . .'') and 253 (''While GBTC allows for daily creations, unlike an ETF, those shares are not immediately available to be sold in the secondary market. After purchasing shares, an investor must hold the shares for 6-months before they are permitted to be traded on the secondary market.'').

[126] *See* Exhibit 3B, *supra* note 97, at 262–64.

[127] *See id.* at 269.

[128] *See* Bitwise Letter 1 at 5.

[129] *See* Teucrium Order, 87 FR at 21681.

[130] *See* Exhibit 3B, *supra* note 97, at 253–55, 266–69.

[131] *Id.* at 259.

million), which then is the sole premise for Bitwise to conclude that trading in the Shares would not likely be the predominant influence on CME bitcoin futures prices.[132]

However, an alternative calculation using Bitwise's statistics is that a *single* bitcoin ETP's average daily trading volume could be approximately 36.5% ($143 million divided by $392 million)—more than one-third—of the size of CME bitcoin futures' average daily trading volume. On top of that, assuming, as Bitwise does, potentially $4.7 billion in first-year inflows, such a spot bitcoin ETP could have AUM that exceeds the value of all open interest in CME bitcoin futures contracts.[133] Bitwise has not directly addressed why, given this relative size of estimated daily trading in the Shares compared with daily trading in CME bitcoin futures contracts, and the relative size of the Trust's estimated AUM itself compared with all open interest in CME bitcoin futures contracts, it is nonetheless unlikely that trading in the proposed ETP would be the predominant influence on prices in the CME bitcoin futures market.

Pursuant to Section 19(b)(2) of the Exchange Act, the Commission must disapprove a proposed rule change filed by a national securities exchange if it does not find that the proposed rule change is consistent with the applicable requirements of the Exchange Act—including the requirement under Section 6(b)(5) that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices.[134] For all of the reasons discussed above, NYSE Arca has not provided sufficient information to establish both prongs of the ''market of significant size'' determination, and thus the Commission cannot conclude that the CME bitcoin futures market is a ''market of significant size'' related to spot bitcoin such that NYSE Arca would be able to rely on a surveillance-sharing agreement with the CME to provide sufficient protection against fraudulent and manipulative acts and practices. Therefore, NYSE Arca has not met its burden of demonstrating that the proposal is consistent with Exchange Act Section 6(b)(5),[135] and, accordingly, the Commission must disapprove the proposal.[136]

C. Other Arguments and Comments

In a second comment letter,[137] Bitwise argues that the Commission, ''when analyzing the applicable legal standards for approving the [proposed ETP], should consider—and should interpret those standards in recognition of—the wide-spread use and adoption of [b]itcoin among retail investors, merchants, public and private companies, payment processors, and others in the U.S. business and investment community.'' [138] Bitwise argues that the fundamental question before the Commission should be ''whether, in light of the wide-spread retail holdings, investment in, and use of [b]itcoin, at least some segment of retail (and other) investors would benefit from having access to an investment product that provides exposure to [b]itcoin'' and that is traded on a regulated national securities exchange, that is reasonably expected to closely track the value of bitcoin without substantial premiums or discounts, and that would relieve investors from custodial and other transactional burdens of bitcoin.[139]

Bitwise asserts that ''the public interest is best served by giving retail (and other) investors access to a publicly-traded [b]itcoin ETP like the Trust, that at least some segment of the investing public would be affirmatively disadvantaged by not having access to the Trust, and that no part of the investing public would be harmed by having access to the Trust.'' [140] Bitwise concludes that, for these reasons, the proposal ''overwhelmingly'' meets Exchange Act Section 6(b)(5)'s requirement that a proposed rule change ''protect investors and the public interest.'' [141] Bitwise also asserts that Exchange Act Section 6(b)(5)'s requirement that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices should be considered ''in light of the large and increasing number of U.S. investors who directly invest in and trade [b]itcoin'' and who ''may in fact be subject to increased risks of fraud and manipulation.'' [142]

In essence, Bitwise asserts that the risky nature of direct investment in bitcoin and the potential benefits of a spot bitcoin ETP compel approval of the proposed rule change. The Commission disagrees. Here, even if it were true that, compared to trading in unregulated spot bitcoin markets, trading a bitcoin-based ETP on a national securities exchange provides some additional protection to investors, the Commission must consider this potential benefit in the broader context of whether the proposal meets each of the applicable requirements of the Exchange Act.[143] Pursuant to Section 19(b)(2) of the Exchange Act, the Commission must approve a proposed rule change filed by a national securities exchange if it finds that the proposed rule change is consistent with the applicable requirements of the Exchange Act—including the requirement under Section 6(b)(5) that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices—and it must disapprove the filing if it does not make such a finding.[144] Thus, even if a proposed rule change purports to protect investors from a particular type of investment risk—such as the susceptibility of an asset to loss or theft, or premiums or discounts to underlying asset value—the proposed rule change may still fail to meet the requirements under the Exchange Act.[145] For the reasons discussed above, NYSE Arca has not met its burden of demonstrating

[132] *See id.*

[133] As of May 31, 2022, the value of open interest in the front two month CME BTC contracts was approximately $1.7 billion (source: CME Group).

[134] *See* 15 U.S.C. 78s(b)(2)(C).

[135] 15 U.S.C. 78f(b)(5).

[136] In disapproving the proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[137] *See* Bitwise Letter 2.

[138] *See id.* at 2.

[139] *See id.* at 3–4. Similarly, one commenter also states that approval of a spot bitcoin ETP would protect investors by, among other things, imposing less transaction costs than CME bitcoin futures ETFs, reducing risks associated with custodying spot bitcoin, and ''[c]hanneling investor interest into a regulated space.'' *See* Letter from James J. Angel, Associate Professor of Finance, Georgetown University, dated April 17, 2022 (''Angel Letter''), at 7–9.

[140] *See* Bitwise Letter 2 at 4.

[141] 15 U.S.C. 78f(b)(5).

[142] *See* Bitwise Letter 2 at 4. Bitwise also argues that the Commission ''must be able to work with the digital asset community to find a way to approve more digital asset products for investors'' (*see id.* at 5) and states that it ''was willing to change the structure or operation of the Trust as needed to resolve good faith legal and regulatory concerns'' (*see id.* at 6). The Commission assesses each proposed rule change—as proposed—on its particular facts and on whether it is consistent with the requirements of the Exchange Act. Pursuant to the Commission's Rules of Practice, the SRO must provide all information elicited by Form 19b–4, and the description of the proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding. *See* Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[143] *See* Winklevoss Order, 83 FR at 37602. *See also* GraniteShares Order, 83 FR at 43931; ProShares Order, 83 FR at 43941; USBT Order, 85 FR at 12615.

[144] *See* Exchange Act Section 19(b)(2)(C), 15 U.S.C. 78s(b)(2)(C). *See also Affiliated Ute Citizens of Utah* v. *United States,* 406 U.S. 128, 151 (1972) (Congress enacted the Exchange Act largely ''for the purpose of avoiding frauds''); *Gabelli* v. *SEC,* 568 U.S. 442, 451 (2013) (The ''SEC's very purpose'' is to detect and mitigate fraud.).

[145] *See* SolidX Order, 82 FR at 16259; WisdomTree Order, 86 FR at 69334.

an adequate basis in the record for the Commission to find that the proposal is consistent with Exchange Act Section 6(b)(5),[146] and, accordingly, the Commission must disapprove the proposal.

In another commenter letter, a commenter questions why the Commission would disallow a spot bitcoin ETP when it has allowed a spot gold ETP.[147] The commenter states that ''[t]he argument that a spot [b]itcoin [ETP] should not be allowed because the SEC doesn't have the ability to regulate outside exchanges trading it doesn't hold water.'' The commenter states that ''[g]old trades around the world and around the clock in many areas unregulated by the SEC.''

As the Commission has clearly and consistently stated, an exchange that lists bitcoin-based ETPs can meet its obligation under Exchange Act Section 6(b)(5) that its rules be designed to prevent fraudulent and manipulative acts and practices by demonstrating that the exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying or reference bitcoin assets.[148] As discussed in detail in Section III.B, the Commission has considered the Exchange's arguments with respect to the CME bitcoin futures market, and the Commission concludes that the Exchange has failed to demonstrate that the CME bitcoin futures market is such a ''market of significant size'' related to spot bitcoin. As the Commission has also previously stated, comparisons to the markets for *other* asset classes (such as gold) are not persuasive, and do not help the Exchange to meet its burden with respect to a bitcoin-based ETP.[149]

Another commenter asserts that bitcoin futures-based ETFs ''derive their price from the spot [bitcoin] market,'' and questions why then a ''generally more efficient investment vehicle'' such as a spot bitcoin ETP ''that tracks the same spot [bitcoin] market'' would be disapproved.[150] The commenter, however, provides no information on how prices of bitcoin futures-based ETFs relate to spot bitcoin prices; how such an assertion would be compatible with the claims of the Exchange in this filing that CME bitcoin futures prices ''lead'' spot bitcoin prices; or why, even if such an assertion is true, it would necessitate the approval of this proposal.

An additional commenter argues that it is inconsistent for the Commission to approve the listing and trading of CME bitcoin futures-based ETFs but not spot-based ETPs.[151] Among other things, this commenter asserts that ''[t]he spot and futures markets are so interconnected that actions on one instantly affect the other'' and that ''[a]ny manipulations in the spot market instantly affect the futures prices and vice versa.'' [152] This commenter states that CME bitcoin futures contracts' ''ultimate cash settlement'' is based on the ''BRR Bitcoin Reference Rate Index'' (''BRR''),[153] which is calculated by aggregating the trade flow of major bitcoin spot platforms, and that a spot bitcoin ETP would be less vulnerable to manipulation than a CME bitcoin futures-based ETF because CME bitcoin futures contracts can be manipulated on both the CME and through the spot bitcoin platforms that are included in the BRR.[154]

The Commission disagrees with this commenter's assertions. The proposed rule change does not relate to the same underlying holdings as either exchange-traded funds regulated under the Investment Company Act of 1940 (''1940 Act'') that provide exposure to bitcoin through CME bitcoin futures or CME bitcoin futures-based ETPs registered under the Securities Act of 1933 but not regulated under the 1940 Act. The Commission considers the proposed rule change on its own merits and under the standards applicable to it. Namely, with respect to this proposed rule change, the Commission must apply the standards as provided by Section 6(b)(5) of the Exchange Act, which it has applied in connection with its orders considering previous proposals to list bitcoin-based commodity trusts and bitcoin-based trust issued receipts.[155]

For this proposed rule change, the relevant analysis, as discussed above in Section III.B, is whether the Exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin. As discussed above, the record in the current proposal does not support a determination that the CME bitcoin futures market is a regulated market of significant size related to spot bitcoin.[156]

Moreover, the commenter argues that, because CME bitcoin futures contracts' ''ultimate cash settlement'' is based on the BRR, CME bitcoin futures face risks from both manipulation of the CME market itself, and manipulation of the spot bitcoin markets whose prices feed into the BRR. What is relevant for the ''significant market'' analysis, however, is not the number of potential sources of manipulation, but rather, as discussed in the Teucrium Order and the Valkyrie XBTO Order, whether the CME's surveillance can be reasonably relied upon to capture the effects of a person attempting to manipulate the assets underlying the proposed ETP.[157]

As explained in the Teucrium Order and the Valkyrie XBTO Order, if an exchange seeking to list a spot bitcoin ETP relies on the CME as the regulated market with which it has a comprehensive surveillance-sharing agreement, the assets held by the spot bitcoin ETP would not be traded on the CME; and thus there would be reason to question whether a surveillance-sharing agreement with the CME would, in fact, assist in detecting and deterring fraudulent and manipulative misconduct affecting the price of the spot bitcoin held by that ETP.[158] While the commenter asserts that ''[t]he spot and futures markets are so interconnected that actions on one instantly affect the other,'' and that ''manipulations in the spot market instantly affect the futures prices and vice versa,'' [159] the commenter provides no evidence in support of these assertions. Moreover, the commenter's observation that CME bitcoin futures contracts' ''ultimate cash settlement'' is based on the BRR is also insufficient to support these assertions. The BRR is used for a CME bitcoin futures contract's *final* cash settlement; it is not generally used for *daily* cash settlements (which, under normal procedures, are generally based on the volume-weighted average price of trading activity on CME Globex between 2:59 p.m. and 3:00 p.m., Central Time),[160] nor is the BRR

[146] 15 U.S.C. 78f(b)(5).

[147] *See* letter from Anonymous, dated Feb. 18, 2022.

[148] *See supra* note 12 and accompanying text. *See also* Wise Origin Order, 87 FR at 5539; ARK 21Shares Order, 87 FR at 20027.

[149] *See* USBT Order, 85 FR at 12613; Wise Origin Order, 87 FR at 5540; Teucrium Order, 87 FR at 21679–80.

[150] *See* letter from Brandon Gunderson, dated Feb. 4, 2022.

[151] *See* Angel Letter at 5.

[152] *See id.*

[153] The Commission understands the commenter's use of ''BRR Bitcoin Reference Rate'' to mean the CME CF Bitcoin Reference Rate.

[154] *See* Angel Letter at 6.

[155] *See supra* note 11.

[156] *See supra* Section III.B.1 and III.B.2.

[157] *See* Teucrium Order, 87 FR at 21679; Valkyrie XBTO Order, 87 FR at 28851.

[158] *See* Teucrium Order, 87 FR at 21679 n.46; Valkyrie XBTO Order, 87 FR at 28851 n.42. There is reason to question whether the CME's surveillance would capture manipulation of spot bitcoin that occurs off of the CME if, for example, off-CME manipulation of spot bitcoin does not also similarly impact CME bitcoin futures contracts.

[159] *See* Angel Letter at 5.

[160] A description of CME bitcoin futures daily settlement procedures is available at: *https://*

Continued

claimed to be used for any intra-day trading of the contract. And even if the BRR is a potential link between prices on certain spot bitcoin platforms and CME bitcoin futures prices, it does not—absent supporting data—necessarily follow that manipulation that impacts spot bitcoin also similarly impacts CME bitcoin futures contracts.[161]

Moreover, the Commission's determination in the Teucrium Order and the Valkyrie XBTO Order to approve the listing and trading of the relevant CME bitcoin futures ETPs was not based on the ETPs' use—or lack of use—of the BRR (or any other similar pricing mechanism) for the calculation of NAV, or on the fact that the BRR is used for the final cash settlement of CME bitcoin futures contracts. Rather, the Commission approved the listing and trading of such CME bitcoin futures ETPs, not because of the BRR, but because the Commission found that the listing exchanges satisfy the requirement pertaining to a surveillance-sharing agreement with a regulated market of significant size related to the underlying bitcoin assets—which for such ETPs, are CME bitcoin futures contracts, not spot bitcoin.

This commenter also addresses, among other things, the general nature and uses of bitcoin [162] and suggestions for improving regulation of bitcoin and other digital assets markets and related market participants.[163] Ultimately, however, additional discussion of these topics is unnecessary, as they do not bear on the basis for the Commission's decision to disapprove the proposal.

IV. Conclusion

For the reasons set forth above, the Commission does not find, pursuant to Section 19(b)(2) of the Exchange Act, that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, with Section 6(b)(5) of the Exchange Act.

It is Therefore Ordered, pursuant to Section 19(b)(2) of the Exchange Act, that proposed rule change SR–NYSEArca-2021–89 be, and hereby is, disapproved.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–14309 Filed 7–5–22; 8:45 am]

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www.cmegroup.com/confluence/display/EPICSANDBOX/Bitcoin.

[161] The commenter also has not explained how the assertions that ''[t]he spot and futures markets are so interconnected that actions on one instantly affect the other,'' and that ''manipulations in the spot market instantly affect the futures prices and vice versa,'' would be compatible with the claims of the Exchange in this filing that CME bitcoin futures prices lead spot bitcoin prices.

[162] *See* Angel Letter at 2–4.

[163] *See, e.g.,* Angel Letter at 9–40.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95175; File No. SR–CboeBZX–2021–086]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 2, To Amend the Opening Auction Process Provided Under Rule 11.23(b)(2)(B)

June 29, 2022.

On December 21, 2021, Cboe BZX Exchange, Inc. (''BZX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to to amend the Opening Auction process under BZX Rule 11.23(b)(2)(B). The proposed rule change was published for comment in the **Federal Register** on January 5, 2022.[3] On February 14, 2022, 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 April 1, 2022, the Exchange filed Amendment No. 2 to the proposed rule change, which amended and superseded the proposed rule change as originally filed.[6] On April 4, 2022, the Commission noticed the filing of Amendment No. 2 and instituted proceedings under Section 19(b)(2)(B) of the Act [7] to determine whether to approve or disapprove the proposed rule change.[8]

Section 19(b)(2) of the Act [9] 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 the 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 the **Federal Register** on January 5, 2022.[10] The 180th day after publication of the proposed rule change is July 4, 2022. The Commission is extending the time period for approving or disapproving the proposal 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, as modified by Amendment No. 2. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[11] designates September 2, 2022, as the date by which the Commission should either approve or disapprove the proposed rule change (File No. SR–CboeBZX–2021–086), as modified by Amendment No. 2.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–14288 Filed 7–5–22; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93888 (December 30, 2021), 87 FR 532.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 94238, 87 FR 9399 (February 18, 2022). The Commission designated April 5, 2022, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] On March 31, 2022, the Exchange submitted Amendment No. 1 to the proposed rule change, and on April 1, 2022, the Exchange withdrew Amendment No. 1 to the proposed rule change. Amendment No. 2 is available on the Commission's website at: *https://www.sec.gov/comments/sr-cboebzx-2021-086/srcboebzx2021086-20122189-278229.pdf.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 94601, 87 FR 20895 (April 8, 2022).

[9] 15 U.S.C. 78s(b)(2).

[10] *See supra* note 3 and accompanying text.

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95170; File No. SR–Phlx–2022–27]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Pricing for Options on a Nasdaq-100® Volatility Index

June 29, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on June 16, 2022, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule at Options 7, Section 5, Index and Singly Listed Options (Includes options overlying FX Options, equities, ETFs, ETNs, and indexes not listed on another exchange), to adopt pricing for options on a Nasdaq-100® Volatility Index (''VOLQ'').[4]

Additionally, the proposal amends Options 7, Section 2, Customer Rebate Program; Options 7, Section 4, Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY); and Options 7, Section 6, Other Transaction Fees.

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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange received approval to list index options on VOLQ.[5] The Exchange will commence listing VOLQ options on June 14, 2022. At this time, the Exchange proposes to amend its Pricing Schedule at Options 7, Section 5.A., Broad-Based Index Options, to adopt pricing for VOLQ Options for transactions executed electronically and on the floor.[6]

Additionally, the proposal amends Options 7, Section 2, Customer Rebate Program; Options 7, Section 4, Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY); and Options 7, Section 6, Other Transaction Fees. Each change is described below.

The Exchange proposes to assess Professionals,[7] Lead Market Makers,[8] Market Makers,[9] Broker-Dealers [10] and Firms [11] a $0.40 per contract fee to transact simple and complex VOLQ options electronically and on the floor. Customers [12] will not be assessed a transaction fee to transact VOLQ options electronically or on the floor.

Additionally, the Exchange will assess a surcharge [13] of $0.10 per contract to Non-Customers [14] who transact VOLQ options, in addition to the transaction fees.

The Exchange proposes to pay a rebate of $0.40 per contract to Lead Market Makers and Market Makers who add liquidity in VOLQ. The Exchange proposes to note within the rule text that, with respect to Section 5 of this Options 7 Pricing Schedule, the order that is received by the trading system first in time shall be considered an order adding liquidity and an order that trades against that order shall be considered an order removing liquidity.

The Exchange also proposes to amend various sections of the Pricing Schedule to make clear that pricing for broad-based index options symbols listed within Options 7, Section 5.A. is

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] VOLQ a new index that measures changes in 30-day implied volatility of the Nasdaq-100® Index. *See* Securities Exchange Act Release No. 91781 (May 5, 2021), 86 FR 25918 (May 11, 2021) (SR–Phlx–2020–41) (Notice of Filing of Amendment Nos. 1 and 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To List and Trade Options on a Nasdaq-100 Volatility Index). *See also* Securities Exchange Act Release No. 93628 (November 19, 2021), 86 FR 67555 (November 26, 2021) (SR–Phlx–2021–56) (Order Approving a Proposed Rule Change To Amend Options 4A, Section 12 Regarding the Calculation of the Closing Volume Weighted Average Price for Options on the Nasdaq-100 Volatility Index in Certain Circumstances).

[5] *See* note 3 above.

[6] The term ''floor transaction'' is a transaction that is effected in open outcry on the Exchange's Trading Floor. *See* Options 7, Section 1(c).

[7] The term ''Professional'' applies to transactions for the accounts of Professionals, as defined in Options 1, Section 1(b)(45) means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Options 7, Section 1(c).

[8] The term ''Lead Market Maker'' applies to transactions for the account of a Lead Market Maker (as defined in Options 2, Section 12(a)). A Lead Market Maker is an Exchange member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a). An options Lead Market Maker includes a Remote Lead Market Maker which is defined as an options Lead Market Maker in one or more classes that does not have a physical presence on an Exchange floor and is approved by the Exchange pursuant to Options 2, Section 11. *See* Options 7, Section 1(c). The term ''Floor Lead Market Maker'' is a member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a) and has a physical presence on the Exchange's trading floor. *See* Options 8, Section 2(a)(3).

[9] The term ''Market Maker'' is defined in Options 1, Section 1(b)(28) as a member of the Exchange who is registered as an options Market Maker pursuant to Options 2, Section 12(a). A Market Maker includes SQTs and RSQTs as well as Floor Market Makers. *See* Options 7, Section 1(c). The term ''Floor Market Maker'' is a Market Maker who is neither an SQT or an RSQT. A Floor Market Maker may provide a quote in open outcry. *See* Options 8, Section 2(a)(4).

[10] The term ''Broker-Dealer'' applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category. *See* Options 7, Section 1(c).

[11] The term ''Firm'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at The Options Clearing Corporation. *See* Options 7, Section 1(c).

[12] The term ''Customer'' applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of a broker or dealer or for the account of a ''Professional'' (as that term is defined in Options 1, Section 1(b)(45)). *See* Options 7, Section 1(c).

[13] The surcharge is assessed because VOLQ is a proprietary product and there is a license associated with this product.

[14] The term ''Non-Customer'' applies to transactions for the accounts of Lead Market Makers, Market Makers, Firms, Professionals, Broker-Dealers and JBOs. The term ''Joint Back Office'' or ''JBO'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC and is identified with an origin code as a JBO. A JBO will be priced the same as a Broker-Dealer. A JBO participant is a member, member organization or non-member organization that maintains a JBO arrangement with a clearing broker-dealer (''JBO Broker'') subject to the requirements of Regulation T Section 220.7 of the Federal Reserve System as further discussed at Options 6D, Section 1. *See* Options 7, Section 1(c).

governed by the pricing within Options 7, Section 5.A. Today, the Pricing Schedule makes note where options symbols currently listed within Options 7, Section 5.A. (NDX, NDXP and XND) are excluded from pricing. For example, Options 7, Section 2 Customer Rebates are not paid on NDX, NDXP, or XND contracts. The Exchange proposes to also exclude VOLQ options from Customer Rebates, similar to NDX, NDXP, and XND. The pricing for certain broad-based proprietary index options, NDX, NDXP, and XND, and now VOLQ, is specified within Options 7, Section 5.A. and other pricing within Options 7 does not apply to these products. The Exchange specifically makes clear within Options 7, Sections 2, 4, and 6 that the pricing within Options 7, Section 5.A. will govern for NDX, NDXP, XND and now VOLQ.

Also, today, a member's transacted options volume for broad-based options symbols currently listed within Options 7, Section 5.A. (NDX, NDXP, and XND) may count toward certain volume requirements despite these symbols not being eligible for corresponding rebates. For example, NDX, NDXP, and XND contracts count toward the volume requirement to qualify for a Customer Rebate Tier within Options 7, Section 2, and continue to not be eligible for Customer rebates. VOLQ will also count toward the volume requirement to qualify for a Customer Rebate Tier within Options 7, Section 2, and not be eligible for Customer rebates.

The Exchange is replacing rule text within Options 7 concerning NDX, NDXP, and XND with rule text that instead refers to ''broad-based index options symbols within Options 7, Section 5.A.'' which exclusively includes NDX, NDXP, XND and now VOLQ. Within Options 7, Section 4, the Exchange proposes to amend the title of the rule to state that broad-based index options symbols listed within Options 7, Section 5.A are excluded in place of noting the exclusion by symbol within the table in that section. Additionally, the Exchange proposes to note that broad-based index options symbols listed within Options 7, Section 5.A are excluded from the $0.12 per contract surcharge assessed to Non-Customer electronic Complex Orders that remove liquidity from the Complex Order Book and auctions within Options 7, Section 4. The surcharges for NDX, NDXP, XND, and VOLQ are noted within Options 7, Section 5.A. Likewise, broad-based index options symbols listed within Options 7, Section 5.A are excluded from the Monthly Market Maker Cap, Monthly Firm Fee Cap, Firm Floor Options Transaction Charge and Broker-Dealer Floor Options Transaction Charge waivers, Monthly Strategy Cap, and Marketing Fees within Options 7, Section 4 and the PIXL Pricing, FLEX Transaction Fees and MARS pricing within Options 7, Section 6. Making clear which section of the Options 7 Pricing Schedule governs for particular products will provide members and member organizations easy references to how Phlx's pricing will be applied.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[16] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed changes to the pricing schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for order flow, which constrains its pricing determinations. The fact that the market for order flow is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [17]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention to determine prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [18]

Congress directed the Commission to ''rely on 'competition, whenever possible, in meeting its regulatory responsibilities for overseeing the SROs and the national market system.' '' [19] As a result, the Commission has historically relied on competitive forces to determine whether a fee proposal is equitable, fair, reasonable, and not unreasonably or unfairly discriminatory. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [20] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [21]

Proposed Pricing Is Reasonable

The Exchange believes that it is reasonable to assess Professionals, Lead Market Makers, Market Makers, Broker-Dealers and Firms a $0.40 per contract fee to transact simple and complex VOLQ options electronically and on the floor while assessing Customers no such fee. Additionally, the Exchange believes that it is reasonable to assess a surcharge of $0.10 per contract to Non-Customers who transact VOLQ options, in addition to transaction fees. Finally, the Exchange believes that it is reasonable to offer a rebate of $0.40 per contract to Lead Market Makers and Market Makers who add liquidity in VOLQ. The proposed pricing is reasonably designed because it is intended to incentivize market participants to transact VOLQ index options on the Exchange, which enables the Exchange to improve its overall competitiveness and strengthen its market quality for all market participants.

VOLQ is subject to significant substitution-based competitive forces; market participants can substitute options on VOLQ for products offered by other exchanges, for example, the options on the Cboe Volatility Index®

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(4) and (5).

[17] *See NetCoalition,* 615 F.3d at 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[18] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[19] *See NetCoalition,* 615 F.3d at 534–35; *see also* H.R. Rep. No. 94–229 at 92 (1975) (''[I]t is the intent of the conferees that the national market system evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed.'').

[20] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR–NYSEArca–2006–21).

[21] *Id.*

(''VIX'') [22] and options on the SPIKES Volatility Index (''SPIKES®'').[23] The proposed fees and rebates are in line with those of other options markets for similar products. The Exchange notes that if the fees are not within the range of fees offered by competitors, the proposed pricing may cause market participants to select other substitutes to Phlx's VOLQ product, so the most efficient price-setting strategy is to set prices at the same level as competing products.

Today, Cboe Exchange, Inc. (''Cboe'') assesses Customers VIX simple order fees based on tiered premium price which ranges from $0.10 to $0.45 per contract and complex order fees based on tiered premium price which ranges from $0.05 to $0.45 per contract.[24] A Clearing Trading Permit Holder Proprietary is assessed a VIX fee based on a VIX sliding scale which ranges from $0.25 to $0.01 per contract.[25] A Cboe Options Market-Maker/DPM/LMM are assessed fees based on tiered premium price which ranges from $0.05 to $0.23 per contract.[26] Joint Back Office, Non-Trading Permit Holder Market Makers, and Professionals are assessed a VIX $0.40 per contract fee.[27] VIX transactions are assessed a Surcharge Fee/Index License of $0.10 ($0.00 for capacity codes F and L for VIX transactions where the VIX Premium is ≤$0.10 and the related series has an expiration of seven (7) calendar days or less).[28]

Miami International Securities Exchange, LLC (''MIAX'') assesses SPIKE fees as follows: Priority Customers are assessed no fees; Market Makers are assessed a $0.20 per contract simple/complex taker fee and a $0.15 per contract simple opening fee; Non-MIAX Market Makers are assessed a $0.10 per contract simple/complex maker fee, a $0.25 per contract simple/complex taker fee and a $0.15 per contract simple opening fee; Broker-Dealers are assessed a $0.10 per contract simple/complex maker fee, a $0.25 per contract simple/complex taker fee and a $0.15 per contract simple opening fee; Firm Proprietary are assessed a $0.00 per contract simple/complex maker fee, a $0.20 per contract simple/complex taker fee [29] and a $0.15 per contract simple opening fee; and Public Customer that is not a Priority Customer are assessed a $0.10 per contract simple/complex maker fee, a $0.25 per contract simple/complex taker fee and a $0.15 per contract simple opening fee.[30] MIAX also offers a SPIKES Market Maker Incentive Program wherein Market Makers that satisfy the quote width requirement, 70% time in market requirement, and average quote size of 25 contracts are entitled to receive Incentive 1 for that particular month ($10,000 per Market Maker).[31]

Unlike Cboe's Customer fees for VIX, VOLQ will assess no fees to Customers. Today, Customers are not assessed fees for NDX, NDXP or XND. The $0.40 per contract fee proposed for Professionals, Lead Market Makers, Market Makers, Broker-Dealers and Firms to transact VOLQ simple and complex options electronically and on the floor is within the range of fees assessed by Cboe for VIX. Also, Phlx currently assesses a $0.75 per contract fee to Non-Customers for options transacted in NDX, a broad-based index. VOLQ is similarly a broad-based index. Because VOLQ is a new index, the Exchange proposes a lower fee as compared to NDX, a more mature product ($0.40 per contract for VOLQ vs. $0.75 per contract for NDX).

The $0.10 per contract surcharge proposed for Non-Customers who transact VOLQ options is within the range of the VIX surcharge. Customers would not pay a VOLQ surcharge as is the case today for all index option surcharges assessed by Phlx. Today, the Exchange assesses a $0.25 per contract surcharge for options transactions in NDX. The proposed VOLQ options surcharge is less than half the surcharge for NDX. The Exchange believes this surcharge is appropriate for options transactions on this new broad based index.

Finally, today MIAX offers a SPIKES Market Maker Incentive Program. The Exchange proposes offering Lead Market Makers and Market Makers a $0.40 per contract rebate when adding liquidity in VOLQ to offset the proposed transaction fee.[32] The Exchange believes that this rebate would incentivize Lead Market Makers and Market Makers to add liquidity to the Exchange in VOLQ.

The Exchange believes that there are many factors that may cause a market participant to decide to become a member of a particular exchange. Among various factors, the Exchange believes market participants consider when deciding to become a member are product offerings. Introducing new and innovative products to the marketplace designed to meet customer demands may attract market participants to become a member of a particular options venue. New products in the options industry may allow market participants greater trading and hedging opportunities, as well as new avenues to manage risks. The listing of new options products enhances competition among market participants by providing investors with additional investment vehicles, as well as competitive alternatives, to existing investment products. An exchange's proprietary product offering may attract order flow to a particular exchange to trade a particular options product and generally make that exchange a more desirable venue to transaction options, thereby attracting membership to that exchange.

Specifically, VOLQ introduces a cash-settled options contract focused on equity exposure using options on the NDX, which are actively traded equity option products, into the marketplace. The Exchange believes that VOLQ's novel structure will enhance competition among market participants, to the benefit of investors and the marketplace. The introduction of VOLQ is intended to attract market

[22] The VIX Index is a financial benchmark designed to be an up-to-the-minute market estimate of expected volatility of the S&P 500 Index, and is calculated by using the midpoint of real-time S&P 500® Index (SPX) option bid/ask quotes.

[23] The SPIKES Volatility Index is a measure of the expected 30-day volatility in the SPDR S&P 500 ETF.

[24] *See* Cboe's Fee Schedule. Transactions fees will be waived for Customer orders executed in VIX options during GTH through December 31, 2022.

[25] *See* Cboe's Fee Schedule.

[26] *See* Cboe's Fee Schedule.

[27] *See* Cboe's Fee Schedule.

[28] *See* Cboe's Fee Schedule. The Surcharge Fees apply to all non-public customer transactions (*i.e.,* Cboe Options and non-Trading Permit Holder market-maker, Clearing Trading Permit Holder, JBO participant, and broker-dealer), including professionals.

[29] Taker fees for options with a premium price of $0.10 or less will be charged $0.05 per contract. *See* MIAX's Options Exchange Fee Schedule.

[30] *See* MIAX's Options Exchange Fee Schedule.

[31] The compensation pool for Incentive 1 is capped at a total of $40,000 per month. If more than four (4) Market Makers satisfy the requirements for Incentive 1, each Market Maker will receive a pro-rata share of the compensation pool based on the total number of Market Makers that qualify in that particular month. Each Market Maker that meets or exceeds all the requirements of Incentive 1, (''qualifying Market Maker''), may earn an additional rebate each month. Each qualifying Market Maker's spread width for eligible ITM and OTM SPIKES options is calculated and ranked relative to each other qualifying Market Maker. Market Makers with the highest quality width spread (*i.e.,* the tightest spread) are eligible for compensation under Incentive 2. Each qualifying Market Maker receives a rebate, capped at $25,000 per Member per month, based on their relative ranking to each other qualifying Market Maker, with the top performer receiving the largest rebate amount and the bottom performer receiving the smallest rebate amount. The compensation pool size for Incentive 2 is generated by the market quality that is created by qualifying Market Makers, where $5,000 per basis point improvement over the market quality baseline, as established by MIAX, is contributed to fund Incentive Pool 2, which is capped at $100,000 per month.

[32] The order that is received by the trading system first in time shall be considered an order adding liquidity and an order that trades against that order shall be considered an order removing liquidity.

participants to Phlx in order to transact this solely listed product.

The Exchange's proposal to amend Options 7, Sections 2, 4, and 6 to make clear that the pricing within Options 7, Section 5.A. will govern for NDX, NDXP, XND and now VOLQ is reasonable, equitable and not unfairly discriminatory. Also, making clear within Options 7, Section 2, where VOLQ options volume would count toward the volume requirement to qualify for a Customer Rebate Tier within Options 7, Section 2, and not be eligible for Customer rebates, is reasonable, equitable and not unfairly discriminatory. The proposed rule text will make clear to members and member organizations how Phlx's pricing will be applied. Also, applying VOLQ options volume in the Customer Rebate Tiers is consistent with the manner in which other index options currently listed on Phlx are treated. The Exchange believes that excluding the broad-based index options symbols within Options 7, Section 5.A from other multiply-listed options pricing [33] on the Exchange is reasonable, equitable, and not unfairly discriminatory because multiply-listed options pricing assesses fees, pays rebates, waives pricing or discounts pricing for most multiply-listed option symbols generally, regardless of symbol.[34] In contrast, pricing for proprietary broad-based index options is specific to the product. It is not novel to assess different pricing for multiply-listed options as compared to proprietary singly-listed options.[35]

Finally, pricing by symbol is a common practice on many U.S. options exchanges as a means to incentivize order flow to be sent to an exchange for execution in particular products. Other options exchanges price by symbol.[36] Finally, it is reasonable, equitable and not unfairly discriminatory to assess the proposed fees and rebates for both simple and complex executions in VOLQ options, as is the case for other index options currently listed on Phlx.

Proposed Pricing Is Equitable and Not Unfairly Discriminatory

The Exchange believes that it is equitable and not unfairly discriminatory to assess Professionals, Lead Market Makers, Market Makers, Broker-Dealers and Firms a $0.40 per contract fee to transact simple and complex VOLQ options electronically and on the floor, and a $0.10 per contract surcharge, while assessing Customers no such transaction fee or surcharge. Customer order flow enhances liquidity on the Exchange for the benefit of all market participants. Customer liquidity provides more trading opportunities, which attracts Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The proposed pricing for Customer orders in VOLQ is intended to attract Customer trading volume to the Exchange. In addition, the proposed VOLQ pricing for Customers will apply equally to all Customer orders. Non-Customers (Professionals, Lead Market Makers, Market Makers, Broker-Dealers and Firms) would be uniformly assessed a $0.40 per contract fee to transact simple and complex VOLQ options electronically and on the floor and a $0.10 per contract surcharge in VOLQ. All Non-Customers may transact VOLQ options and would be assessed the same fees.

The Exchange believes that it is equitable and not unfairly discriminatory to pay Lead Market Makers and Market Makers a $0.40 per contract rebate when adding liquidity in VOLQ. Maker Makers take on a number of obligations,[37] including quoting obligations,[38] unlike other market participants. Further, the proposed pricing for Lead Market Makers and Market Makers in VOLQ is intended to incentivize them to quote and trade more on the Exchange, thereby providing more trading opportunities for all market participants. As noted above, the $0.40 per contract rebate when adding liquidity in VOLQ is intended to offset the $0.40 per contract VOLQ transaction fee. The Exchange believes the proposed pricing will incentivize Lead Market Makers and Market Makers to provide liquidity in the new product. Additionally, the proposed VOLQ rebate will be applied equally to all Lead Market Makers and Market Makers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

In terms of inter-market competition, the Exchange believes its proposal remains competitive with other options markets that offer similar substitute products, and will offer market participants with another choice of venue to transact options. While VOLQ options are singly-listed on Phlx, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. The Exchange notes that there are other volatility products available today on other options markets, such as VIX and SPIKES, which allow investors to gauge volatility. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result.

In terms of intra-market competition, the Exchange believes that the proposed pricing does not impose an undue burden on competition. Assessing no transaction fees or surcharge fees to Customer orders in VOLQ does not impose an undue burden on competition because Customer order flow enhances liquidity on the Exchange for the benefit of all market participants. Customer liquidity provides more trading opportunities, which attracts Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The proposed pricing for Customer orders in VOLQ is intended to attract Customer trading volume to the Exchange. In addition, the proposed VOLQ pricing for Customers will apply equally to all Customer orders. Further, uniformly assessing Non-Customers (Professionals, Lead Market Makers, Market Makers, Broker-Dealers and Firms) a $0.40 per contract fee to transact simple and complex VOLQ options electronically and on the floor and a $0.10 per contract surcharge in VOLQ does not impose an undue burden on competition. All Non-Customers may transact VOLQ options and would be assessed the same fees. Finally, paying Lead Market Makers and

[33] Broad-based index options symbols within Options 7, Section 5.A are excluded from Customer Rebates within Options 7, Section 2, the $0.12 per contract surcharge assessed to Non-Customer electronic Complex Orders that remove liquidity from the Complex Order Book and auctions, Monthly Market Maker Cap, Monthly Firm Fee Cap, Firm Floor Options Transaction Charge and Broker-Dealer Floor Options Transaction Charge waivers, Monthly Strategy Cap, and Marketing Fees within Options 7, Section 4 and the PIXL Pricing, FLEX Transaction Fees and MARS pricing within Options 7, Section 6.

[34] Today, Phlx prices options in SPY differently than other multiply-listed options symbols.

[35] Today, Cboe, MIAX and Phlx assess different pricing for singly-listed options and multiply-listed options.

[36] *See* pricing NQX on Nasdaq ISE, LLC.

[37] *See* Options 2, Section 4.

[38] *See* Options 2, Section 5 and Options 3, Section 8.

Market Makers a $0.40 per contract rebate when adding liquidity in VOLQ does not impose an undue burden on competition. Maker Makers take on a number of obligations,[39] including quoting obligations,[40] unlike other market participants. Further, the proposed pricing for Lead Market Makers and Market Makers in VOLQ is intended to incentivize them to quote and trade more on the Exchange, thereby providing more trading opportunities for all market participants. As noted above, the $0.40 per contract rebate when adding liquidity in VOLQ is intended to offset the $0.40 per contract VOLQ transaction fee. The Exchange believes the proposed pricing will incentivize Lead Market Makers and Market Makers to provide liquidity in the new product. Additionally, the proposed VOLQ rebate will be applied equally to all Lead Market Makers and Market Makers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[41]

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: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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–Phlx–2022–27 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–2022–27. 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–2022–27, and should be submitted on or before July 27, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

Jill M. Peterson,

Assistant Secretary.

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BILLING CODE 8011–01–P

[39] *See* Options 2, Section 4.

[40] *See* Options 2, Section 5 and Options 3, Section 8.

[41] 15 U.S.C. 78s(b)(3)(A)(ii).

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95180; File No. SR–NYSEArca–2021–90]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, to List and Trade Shares of Grayscale Bitcoin Trust Under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares)

June 29, 2022.

I. Introduction

On October 19, 2021, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of Grayscale Bitcoin Trust (''Trust'') under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on November 8, 2021.[3]

On December 15, 2021, pursuant to Section 19(b)(2) of the Exchange 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 February 4, 2022, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act[6] to determine whether to approve or disapprove the proposed rule change.[7] On April 21, 2022, the Exchange filed Amendment No. 1, which replaced and superseded the proposed rule change in its entirety, and on May 4, 2022, the Commission provided notice of Amendment No. 1 to the proposed rule change and designated a longer period for Commission action on the proposed rule change, as modified by Amendment No. 1.[8]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93504 (Nov. 2, 2021), 86 FR 61804. Comments received on the proposed rule change are available at: *https://www.sec.gov/comments/sr-nysearca-2021-90/srnysearca202190.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 93788, 86 FR 72291 (Dec. 21, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 94151, 87 FR 7889 (Feb. 10, 2022).

[8] *See* Securities Exchange Act Release No. 94844, 87 FR 28043 (May 10, 2022) (''Amendment No. 1''). Amendment No. 1 to the proposed rule change can

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This order disapproves the proposed rule change, as modified by Amendment No. 1. The Commission concludes that NYSE Arca has not met its burden under the Exchange Act and the Commission's Rules of Practice to demonstrate that its proposal is consistent with the requirements of Exchange Act Section 6(b)(5), which requires, in relevant part, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices'' and ''to protect investors and the public interest.'' [9]

When considering whether NYSE Arca's proposal to list and trade the Shares is designed to prevent fraudulent and manipulative acts and practices, the Commission applies the same analytical framework used in its orders considering previous proposals to list bitcoin [10]-based commodity trusts and bitcoin-based trust issued receipts to assess whether a listing exchange of an exchange-traded product (''ETP'') can meet its obligations under Exchange Act Section 6(b)(5).[11] As the Commission has explained, an exchange that lists bitcoin-based ETPs [12] can meet its obligations under Exchange Act Section 6(b)(5) by demonstrating that the exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying or reference bitcoin assets.[13]

In this context, the terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which (a) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[14] A surveillance-sharing agreement must be entered into with a ''significant market'' to assist in detecting and deterring manipulation of the ETP, because a person attempting to manipulate the ETP is reasonably likely to also engage in trading activity on that ''significant market.'' [15]

Although surveillance-sharing agreements are not the exclusive means by which a listing exchange of a commodity-trust ETP can meet its obligations under Exchange Act Section 6(b)(5), such agreements have previously provided the basis for the exchanges that list commodity-trust ETPs to meet those obligations, and the Commission has historically recognized their importance. And where, as here, a listing exchange fails to establish that other means to prevent fraudulent and manipulative acts and practices will be sufficient, the listing exchange must enter into a surveillance-sharing agreement with a regulated market of significant size because such agreements detect and deter fraudulent and manipulative activity.[16]

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be found at: *https://www.sec.gov/comments/sr-nysearca-2021-90/srnysearca202190-20125938-286383.pdf.*

[9] 15 U.S.C. 78f(b)(5).

[10] Bitcoins are digital assets that are issued and transferred via a decentralized, open-source protocol used by a peer-to-peer computer network through which transactions are recorded on a public transaction ledger known as the ''bitcoin blockchain.'' The bitcoin protocol governs the creation of new bitcoins and the cryptographic system that secures and verifies bitcoin transactions. *See, e.g.,* Amendment No. 1, 87 FR at 28045.

[11] *See* Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Trust, Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (Aug. 1, 2018) (SR–BatsBZX–2016–30) (''Winklevoss Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, To Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and To List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 88284 (Feb. 26, 2020), 85 FR 12595 (Mar. 3, 2020) (SR–NYSEArca–2019–39) (''USBT Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the WisdomTree Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 93700 (Dec. 1, 2021), 86 FR 69322 (Dec. 7, 2021) (SR–CboeBZX–2021–024) (''WisdomTree Order''); Order Disapproving 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), Securities Exchange Act Release No. 93859 (Dec. 22, 2021), 86 FR 74156 (Dec. 29, 2021) (SR–NYSEArca–2021–31) (''Valkyrie Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the Kryptoin Bitcoin ETF Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 93860 (Dec. 22, 2021), 86 FR 74166 (Dec. 29, 2021) (SR–CboeBZX–2021–029) (''Kryptoin Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the First Trust SkyBridge Bitcoin ETF Trust Under NYSE Arca Rule 8.201–E, Securities Exchange Act Release No. 94006 (Jan. 20, 2022), 87 FR 3869 (Jan. 25, 2022) (SR–NYSEArca–2021–37) (''SkyBridge Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the Wise Origin Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 94080 (Jan. 27, 2022), 87 FR 5527 (Feb. 1, 2022) (SR–CboeBZX–2021–039) (''Wise Origin Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the NYDIG Bitcoin ETF Under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares), Securities Exchange Act Release No. 94395 (Mar. 10, 2022), 87 FR 14932 (Mar. 16, 2022) (SR–NYSEArca–2021–57) (''NYDIG Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the Global X Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 94396 (Mar. 10, 2022), 87 FR 14912 (Mar. 16, 2022) (SR–CboeBZX–2021–052) (''Global X Order''); Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the ARK 21Shares Bitcoin ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 94571 (Mar. 31, 2022), 87 FR 20014 (Apr. 6, 2022) (SR–CboeBZX–2021–051) (''ARK 21Shares Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the One River Carbon Neutral Bitcoin Trust Under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares), Securities Exchange Act Release No. 94999 (May 27, 2022), 87 FR 33548 (June 2, 2022) (SR–NYSEArca–2021–67) (''One River Order''). In addition, orders were issued by delegated authority on the following matters: Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Listing and Trading of Shares of the SolidX Bitcoin Trust Under NYSE Arca Equities Rule 8.201, Securities Exchange Act Release No. 80319 (Mar. 28, 2017), 82 FR 16247 (Apr. 3, 2017) (SR–NYSEArca–2016–101) (''SolidX Order''); Order Disapproving a Proposed Rule Change To List and Trade the Shares of the ProShares Bitcoin ETF and the ProShares Short Bitcoin ETF, Securities Exchange Act Release No. 83904 (Aug. 22, 2018), 83 FR 43934 (Aug. 28, 2018) (SR–NYSEArca–2017–139) (''ProShares Order''); Order Disapproving a Proposed Rule Change To List and Trade the Shares of the GraniteShares Bitcoin ETF and the GraniteShares Short Bitcoin ETF, Securities Exchange Act Release No. 83913 (Aug. 22, 2018), 83 FR 43923 (Aug. 28, 2018) (SR–CboeBZX–2018–001) (''GraniteShares Order''); Order Disapproving a Proposed Rule Change To List and Trade Shares of the VanEck Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, Securities Exchange Act Release No. 93559 (Nov. 12, 2021), 86 FR 64539 (Nov. 18, 2021) (SR–CboeBZX–2021–019) (''VanEck Order''); Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To List and Trade Shares of the Teucrium Bitcoin Futures Fund Under NYSE Arca Rule 8.200–E, Commentary .02 (Trust Issued Receipts), Securities Exchange Act Release No. 94620 (Apr. 6, 2022), 87 FR 21676 (Apr. 12, 2022) (SR–NYSEArca–2021–53) (''Teucrium Order''); Order Granting Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To List and Trade Shares of the Valkyrie XBTO Bitcoin Futures Fund Under Nasdaq Rule 5711(g), Securities Exchange Act Release No. 94853 (May 5, 2022), 87 FR 28848 (May 11, 2022) (SR–NASDAQ–2021–066) (''Valkyrie XBTO Order'').

[12] As used in this order, the term ''ETFs'' refers to open-end funds that register the offer and sale of their shares under the Securities Act of 1933 (''Securities Act'') and are regulated as investment companies under the Investment Company Act of 1940 (''1940 Act''). The term ''ETPs'' refers to exchange-traded products that register the offer and sale of their shares under the Securities Act but are not regulated under the 1940 Act, such as commodity trusts and trust issued receipts. Commenters have sometimes used these terms interchangeably, and it is not always clear which type of product a commenter is referring to. Accordingly, unless clear from the context, the Commission interprets statements from the Exchange or a commenter to refer to an ETP.

[13] *See* USBT Order, 85 FR at 12596. *See also* Winklevoss Order, 83 FR at 37592 n.202 and accompanying text (discussing previous Commission approvals of commodity-trust ETPs); GraniteShares Order, 83 FR at 43925–27 nn.35–39 and accompanying text (discussing previous Commission approvals of commodity-futures ETPs).

[14] *See* Winklevoss Order, 83 FR at 37594. *See also* USBT Order, 85 FR at 12596–97; WisdomTree Order, 86 FR at 69322.

[15] *See* USBT Order, 85 FR at 12597.

[16] *See* Amendment to Rule Filing Requirements for Self-Regulatory Organizations Regarding New Derivative Securities Products, Securities Exchange

The Commission has long recognized that surveillance-sharing agreements ''provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur'' and thus ''enable the Commission to continue to effectively protect investors and promote the public interest.'' [17] As the Commission has emphasized, it is essential for an exchange listing a derivative securities product to have the ability that surveillance-sharing agreements provide to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities laws and rules.[18] The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.[19]

The Commission has explained that the ability of a national securities exchange to enter into surveillance-sharing agreements ''furthers the protection of investors and the public interest because it will enable the [e]xchange to conduct prompt investigations into possible trading violations and other regulatory improprieties.'' [20] The Commission has also long taken the position that surveillance-sharing agreements are important in the context of exchange listing of derivative security products, such as equity options, because a surveillance-sharing agreement ''permits the sharing of information'' that is ''necessary to detect'' manipulation and ''provide[s] an important deterrent to manipulation because [it] facilitate[s] the availability of information needed to fully investigate a potential manipulation if it were to occur.'' [21] With respect to ETPs, when approving the listing and trading of one of the first commodity-linked ETPs—a commodity-linked exchange-traded note—on a national securities exchange, the Commission continued to emphasize the importance of surveillance-sharing agreements, stating that the listing exchange had entered into surveillance-sharing agreements with each of the futures markets on which pricing of the ETP would be based and stating that ''[t]hese agreements should help to ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses, thereby making [the commodity-linked notes] less readily susceptible to manipulation.'' [22]

Consistent with these statements, for the commodity-trust ETPs approved to date for listing and trading, there has been in *every* case at least one significant, regulated market for trading futures on the underlying commodity and the ETP listing exchange has entered into surveillance-sharing agreements with, or held Intermarket Surveillance Group (''ISG'') membership in common with, that market.[23] Moreover, the surveillance-sharing agreements have been consistently present whenever the Commission has approved the listing and trading of derivative securities, even where the underlying securities were also listed on national securities exchanges—such as options based on an index of stocks traded on a national securities exchange—and were thus subject to the Commission's direct regulatory authority.[24]

Listing exchanges have also attempted to demonstrate that other means besides surveillance-sharing agreements will be sufficient to prevent fraudulent and manipulative acts and practices, including that the bitcoin market as a whole or the relevant underlying bitcoin

Act Release No. 40761 (Dec. 8, 1998), 63 FR 70952, 70954, 70959 (Dec. 22, 1998) (File No. S7–13–98) (''NDSP Adopting Release''). *See also* Winklevoss Order, 83 FR at 37593–94; ProShares Order, 83 FR at 43936; GraniteShares Order, 83 FR at 43924; USBT Order, 85 FR at 12596.

[17] *See* NDSP Adopting Release, 63 FR at 70954, 70959. *See also id.* at 70959 (''It is essential that the SRO [self-regulatory organization] have the ability to obtain the information necessary to detect and deter market manipulation, illegal trading and other abuses involving the new derivative securities product. Specifically, there should be a comprehensive ISA [information-sharing agreement] that covers trading in the new derivative securities product and its underlying securities in place between the SRO listing or trading a derivative product and the markets trading the securities underlying the new derivative securities product.'').

[18] *See* NDSP Adopting Release, 63 FR at 70959.

[19] *See* Winklevoss Order, 83 FR at 37592–93 (discussing Letter from Brandon Becker, Director, Division of Market Regulation, Commission, to Gerard D. O'Connell, Chairman, Intermarket Surveillance Group (June 3, 1994), *available at https://www.sec.gov/divisions/marketreg/mr-noaction/isg060394.htm*).

[20] Securities Exchange Act Release No. 27877 (Apr. 4, 1990), 55 FR 13344 (Apr. 10, 1990) (Notice of Filing and Order Granting Accelerated Approval to Proposed Rule Change Regarding Cooperative Agreements With Domestic and Foreign Self-Regulatory Organizations) (SR–NYSE–90–14).

[21] Securities Exchange Act Release No. 33555 (Jan. 31, 1994), 59 FR 5619, 5621 (Feb. 7, 1994) (SR–Amex–93–28) (order approving listing of options on American Depositary Receipts (''ADR'')) (''ADR Option Order''). The Commission further stated that it ''generally believes that having a comprehensive surveillance sharing agreement in place, between the exchange where the ADR option trades and the exchange where the foreign security underlying the ADR primarily trades, will ensure the integrity of the marketplace. The Commission further believes that the ability to obtain relevant surveillance information, including, among other things, the identity of the ultimate purchasers and sellers of securities, is an essential and necessary component of a comprehensive surveillance sharing agreement.'' *Id.*

[22] Securities Exchange Act Release No. 35518 (Mar. 21, 1995), 60 FR 15804, 15807 (Mar. 27, 1995) (SR–Amex–94–30). *See also* Winklevoss Order, 83 FR at 37593 n.206.

[23] *See* Winklevoss Order, 83 FR at 37594. Furthermore, the Commission notes that those cases dealt with a futures market that had been trading for a long period of time before an exchange proposed a commodity-trust ETP based on the asset underlying those futures. For example, silver futures and gold futures began trading in 1933 and 1974, respectively, *see https://www.cmegroup.com/media-room/historical-first-trade-dates.html,* and the first ETPs based on spot silver and gold were approved for listing and trading in 2006 and 2004. *See* Securities Exchange Act Release No. 53521 (Mar. 20, 2006), 71 FR 14967 (Mar. 24, 2006) (SR–Amex–2005–072) (order approving iShares Silver Trust); Securities Exchange Act Release No. 50603 (Oct. 28, 2004), 69 FR 64614 (Nov. 5, 2004) (SR–NYSE–2004–22) (order approving streetTRACKS Gold Shares). Platinum futures and palladium futures began trading in 1956 and 1968, respectively, *see https://www.cmegroup.com/media-room/historical-first-trade-dates.html,* and the first ETPs based on spot platinum and palladium were approved for listing and trading in 2009. *See* Securities Exchange Act Release No. 61220 (Dec. 22, 2009), 74 FR 68895 (Dec. 29, 2009) (SR–NYSEArca–2009–94) (order approving ETFS Palladium Trust); Securities Exchange Act Release No. 61219 (Dec. 22, 2009), 74 FR 68886 (Dec. 29, 2009) (SR–NYSEArca–2009–95) (order approving ETFS Platinum Trust).

[24] *See* USBT Order, 85 FR at 12597; ADR Option Order, 59 FR at 5621. The Commission has also recognized that surveillance-sharing agreements provide a necessary deterrent to fraud and manipulation in the context of index options even when (i) all of the underlying index component stocks were either registered with the Commission or exempt from registration under the Exchange Act; (ii) all of the underlying index component stocks were traded in the U.S. either directly or as ADRs on a national securities exchange; and (iii) effective international ADR arbitrage alleviated concerns over the relatively smaller ADR trading volume, helped to ensure that ADR prices reflected the pricing on the home market, and helped to ensure more reliable price determinations for settlement purposes, due to the unique composition of the index and reliance on ADR prices. *See* Securities Exchange Act Release No. 26653 (Mar. 21, 1989), 54 FR 12705, 12708 (Mar. 28, 1989) (SR–Amex–87–25) (stating that ''surveillance-sharing agreements between the exchange on which the index option trades and the markets that trade the underlying securities are necessary'' and that ''[t]he exchange of surveillance data by the exchange trading a stock index option and the markets for the securities comprising the index is important to the detection and deterrence of intermarket manipulation''). And the Commission has explained that surveillance-sharing agreements ''ensure the availability of information necessary to detect and deter potential manipulations and other trading abuses'' even when approving options based on an index of stocks traded on a national securities exchange. *See* Securities Exchange Act Release No. 30830 (June 18, 1992), 57 FR 28221, 28224 (June 24, 1992) (SR–Amex–91–22).

market is ''uniquely'' and ''inherently'' resistant to fraud and manipulation.[25] In response, the Commission has stated that, if a listing exchange could establish that the underlying market inherently possesses a unique resistance to manipulation beyond the protections that are utilized by traditional commodity or securities markets, the listing market would not necessarily need to enter into a surveillance-sharing agreement with a regulated significant market.[26] Such resistance to fraud and manipulation, however, must be novel and beyond those protections that exist in traditional commodity markets or securities markets for which surveillance-sharing agreements in the context of listing derivative securities products have been consistently present.[27]

Here, NYSE Arca contends that approval of the proposal is consistent with Section 6(b)(5) of the Exchange Act, and, in particular, Section 6(b)(5)'s requirement that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest.[28] As discussed in more detail below, NYSE Arca asserts that the proposal is consistent with Section 6(b)(5) of the Exchange Act because bitcoin offers novel protections beyond those that exist in traditional commodity markets or equity markets and the proposal's use of the Index (as described below) [29] represents an effective means to prevent fraudulent and manipulative acts and practices.[30] In addition, NYSE Arca asserts that the Chicago Mercantile Exchange (''CME'') bitcoin futures market is a significant, surveilled, and regulated market that is ''closely connected'' to the spot bitcoin market, and that the Exchange may obtain information from the CME bitcoin futures market and other entities that are members of the ISG to assist in detecting and deterring potential fraud and manipulation with respect to the Trust and the Shares.[31] In addition, NYSE Arca argues that the proposal would protect investors and the public interest because, among other things, the Exchange has in place surveillance procedures relating to trading in the Shares and the proposal would promote competition.[32]

In the analysis that follows, the Commission examines whether the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Exchange Act by addressing: in Section III.B.1 assertions that other means besides surveillance-sharing agreements will be sufficient to prevent fraudulent and manipulative acts and practices; in Section III.B.2 assertions that NYSE Arca has entered into a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin; in Section III.B.3 assertions that the Commission must approve the proposal because the Commission has approved the listing and trading of ETFs and ETPs that hold CME bitcoin futures; in Section III.C assertions that the proposal is consistent with the protection of investors and the public interest; and in Section III.D other arguments raised by commenters.

Based on its analysis, the Commission concludes that NYSE Arca has not established that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin. The Commission further concludes that NYSE Arca has not established that it has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin, the underlying bitcoin assets that would be held by the Trust. As a result, the Commission is unable to find that the proposed rule change is consistent with the statutory requirements of Exchange Act Section 6(b)(5).

The Commission emphasizes that its disapproval of this proposed rule change, as modified by Amendment No. 1, does not rest on an evaluation of the relative investment quality of a product holding spot bitcoin versus a product holding CME bitcoin futures, or an assessment of whether bitcoin, or blockchain technology more generally, has utility or value as an innovation or an investment. Rather, the Commission is disapproving this proposed rule change, as modified by Amendment No. 1, because, as discussed below, NYSE Arca has not met its burden to demonstrate that its proposal is consistent with the requirements of Exchange Act Section 6(b)(5).

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

As described in more detail in Amendment No. 1,[33] the Exchange proposes to list and trade the Shares of the Trust under NYSE Arca Rule 8.201–E, which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

The investment objective of the Trust is for the value of the Shares (based on bitcoin per Share) to reflect the value of the bitcoins held by the Trust, as determined by reference to the ''Index Price,'' less the Trust's expenses and other liabilities.[34] The ''Index Price'' is the U.S. dollar value of a bitcoin represented by the ''Index,'' calculated at 4:00 p.m., New York time, on each business day.[35] According to the Exchange, the Index Provider develops, calculates, and publishes the Index on a continuous basis using the price at certain spot bitcoin trading platforms selected by the Index Provider.[36] As of December 31, 2021, the spot bitcoin trading platforms included in the Index were: Coinbase Pro, Bitstamp, Kraken, and LMAX Digital (''Constituent Platforms'').[37] The Index applies an

[25] *See* USBT Order, 85 FR at 12597.

[26] *See* Winklevoss Order, 83 FR at 37580, 37582–91 (addressing assertions that ''bitcoin and [spot] bitcoin markets'' generally, as well as one bitcoin trading platform specifically, have unique resistance to fraud and manipulation). *See also* USBT Order, 85 FR at 12597.

[27] *See* USBT Order, 85 FR at 12597, 12599.

[28] *See* Amendment No. 1, 87 FR at 28051–54, 28059–60.

[29] *See infra* note 35 and accompanying text.

[30] *See* Amendment No. 1, 87 FR at 28051–53, 28059–60.

[31] *See id.* at 28054; 28060.

[32] *See id.* at 28060.

[33] *See supra* note 8. *See also* Amendment No. 1 to Registration Statement on Form 10, dated December 31, 2019, filed with the Commission on behalf of the Trust (''Registration Statement''); Annual Report on Form 10–K for the fiscal year ended December 31, 2021, filed with the Commission on the behalf of the Trust (''2021 10–K'').

[34] *See* Amendment No. 1, 87 FR at 28045. Grayscale Investments, LLC (''Sponsor'') is the sponsor of the Trust and is a wholly-owned subsidiary of Digital Currency Group, Inc. Delaware Trust Company (''Trustee'') is the trustee of the Trust. The custodian for the Trust is Coinbase Custody Trust Company, LLC (''Custodian''). *The administrator of the Trust is BNY Mellon Asset Servicing (''Administrator'').* The distribution and marketing agent for the Trust is Genesis. The Trust operates pursuant to a trust agreement (''Trust Agreement'') between the Sponsor and the Trustee. *See id.* at 28044.

[35] *See id.* at 28049. According to the Exchange, the index provider for the Trust is *CoinDesk Indices, Inc., formerly known as* TradeBlock, Inc. (''Index Provider''). *See id.* at 28044. While the Exchange, in the proposal, does not name the Index that the Trust would use to value the bitcoins held by the Trust, the Exchange does provide that the value of the Index, as well as additional information regarding the Index, may be found at: *https://tradeblock.com/markets/index/xbx. See id.* at 28058. Further, in its letter to the Commission, the Sponsor states that the Trust values its bitcoin holdings based on the CoinDesk Bitcoin Price Index (XBX) (formerly known as the Tradeblock XBX Index). *See* Letter from Davis Polk & Wardwell LLP, on behalf of the Sponsor, dated Nov. 29, 2021 (''Grayscale Letter I''), at 5.

[36] *See* Amendment No. 1, 87 FR at 28049.

[37] *See id.* at 28047, 28049, 28052 n.35. In its proposal, NYSE Arca uses the term ''U.S.-

algorithm to the price of bitcoin on the Constituent Platforms calculated on a per second basis over a 24-hour period.[38]

The Trust's assets will consist solely of bitcoins; Incidental Rights; [39] IR Virtual Currency; [40] proceeds from the sale of bitcoins, Incidental Rights, and IR Virtual Currency pending use of such cash for payment of Additional Trust Expenses [41] or distribution to the shareholders; and any rights of the Trust pursuant to any agreements, other than the Trust Agreement, to which the Trust is a party. Each Share represents a proportional interest, based on the total number of Shares outstanding, in each of the Trust's assets as determined in the case of bitcoin by reference to the Index Price, less the Trust's expenses and other liabilities (which include accrued but unpaid fees and expenses).[42]

On each business day at 4:00 p.m., New York time, or as soon thereafter as practicable, the Sponsor will evaluate the bitcoin held by the Trust and calculate and publish the ''Digital Asset Holdings'' of the Trust using the Index Price.[43] The Trust's website, as well as one or more major market data vendors, will provide an intra-day indicative value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third party financial data provider during the Exchange's Core Trading Session (9:30 a.m. to 4:00 p.m., E.T.). The IIV will be calculated using the same methodology as the Digital Asset Holdings of the Trust, specifically by using the prior day's closing Digital Asset Holdings per Share as a base and updating that value during the Exchange's Core Trading Session to reflect changes in the value of the Trust's Digital Asset Holdings during the trading day.[44] In addition, according to the Exchange, ''each investor will have access to the current Digital Asset Holdings of the Trust through the Trust's website, as well as from one or more major market data vendors.'' [45]

The Trust will issue Shares to authorized participants from time to time, but only in one or more Baskets (each ''Basket'' being a block of 100 Shares). The creation of Baskets will be made only in exchange for the delivery to the Trust of the number of whole and fractional bitcoins represented by each Basket being created.[46] The Trust may redeem Shares from time to time, but only in Baskets. The redemption of Baskets requires the distribution by the Trust of the number of bitcoins represented by the Baskets being redeemed. The redemption of a Basket will be made only in exchange for the distribution by the Trust of the number of whole and fractional bitcoins represented by each Basket being redeemed.[47] Creation and redemption orders may be placed either ''in-kind'' or ''in-cash.'' [48] Although the Trust will create Baskets only upon the receipt of bitcoins, and will redeem Baskets only by distributing bitcoins, an authorized participant may deposit cash with or receive cash from the Administrator, which will facilitate the purchase or sale of bitcoins through a liquidity provider on behalf of an authorized participant.[49]

According to the Sponsor, shares of the Trust are currently offered to accredited investors within the meaning of Regulation D under the Securities Act, and, once such investors have held their shares for the requisite holding period pursuant to Rule 144 under the Securities Act, they have the ability to resell them through transactions on the OTCQX Best Market (''OTCQX''), an over-the-counter (''OTC'') marketplace operated by OTC Markets Group that is not registered with the Commission as a national securities exchange.[50] The Sponsor states that these shares have been quoted on OTCQX since March 2015 and are available to investors through broker transactions.[51] The Sponsor also states that, in the twelve months ended October 31, 2021, trading in these shares accounted for the most transactions by dollar volume of any security traded on OTCQX.[52] The Sponsor further states that the Trust is the largest and most liquid bitcoin investment fund in the world and that the Sponsor is the world's largest digital currency asset manager, with more than $55 billion in assets under management as of October 29, 2021.[53]

III. Discussion

A. The Applicable Standard for Review

The Commission must consider whether NYSE Arca's proposal is consistent with the Exchange Act. Section 6(b)(5) of the Exchange Act requires, in relevant part, that the rules of a national securities exchange be designed ''to prevent fraudulent and manipulative acts and practices'' and ''to protect investors and the public interest.'' [54] Under the Commission's

Compliant Exchanges'' to describe Constituent Platforms that are ''compliant with applicable U.S. federal and state licensing requirements and practices regarding AML and KYC regulations.'' *Id.* at 28052 n.35. According to NYSE Arca, ''[a]ll Constituent [Platforms] are U.S.-Compliant Exchanges.'' *Id.*

[38] *See id.* at 28049. According to the Exchange, prior to February 1, 2022, the Trust valued its bitcoins for operational purposes by reference to the volume-weighted average Index Price (''Old Index Price''). The Old Index Price was calculated by applying a weighting algorithm to the price and trading volume data for the immediately preceding 24-hour period as of 4:00 p.m., New York time, derived from the Constituent Platforms reflected in the Index on such trade date, and overlaying an averaging mechanism to the price produced. Thus, whereas the Old Index Price reflected the price of a bitcoin at 4:00 p.m., New York time, calculated by taking the average of each price of a bitcoin produced by the Index over the preceding 24-hour period, as of February 1, 2022, the Index Price reflects the price of a bitcoin at 4:00 p.m., New York time, calculated based on the price and trading volume data of the Constituent Platforms over the preceding 24-hour period. According to the Exchange, the Index Price differs from the Old Index Price only in that it does not use an additional averaging mechanism; the Index Price otherwise uses the same methodology as the Old Index Price, and there has been no change to the Index used to determine the Index Price or the criteria used to select the Constituent Platforms. *See id.* at 28053 n.44.

[39] ''Incidental Rights'' are rights to acquire, or otherwise establish dominion and control over, any virtual currency or other asset or right, which rights are incident to the Trust's ownership of bitcoins and arise without any action of the Trust, or of the Sponsor or Trustee on behalf of the Trust. *See id.* at 28044 n.14.

[40] ''IR Virtual Currency'' is any virtual currency tokens, or other asset or right, acquired by the Trust through the exercise (subject to the applicable provisions of the Trust Agreement) of any Incidental Right. *See id.* at 28045 n.15.

[41] ''Additional Trust Expenses'' are any expenses incurred by the Trust in addition to the Sponsor's fee that are not Sponsor-paid expenses. *See id.* at 28045 n.16.

[42] *See id.* at 28045, 28047.

[43] The Exchange does not define the term ''Digital Asset Holdings'' in the proposed rule change. Additional information about the calculation of the Digital Asset Holdings can be found in Amendment No. 1. *See id.* at 28047. The Trust does not expect to take any Incidental Rights or IR Virtual Currency it may hold into account for purposes of determining the Trust's Digital Asset Holdings. *Id.*

[44] *See id.* at 28058.

[45] *Id.*

[46] *See id.* at 28055.

[47] *See id.* at 28056.

[48] *See id.* at 28056–57.

[49] *See id.* at 28055–57.

[50] *See* Grayscale Letter I, at 2.

[51] *See id.*

[52] *See id.*

[53] *See id.* at 4.

[54] 15 U.S.C. 78f(b)(5). Pursuant to Section 19(b)(2) of the Exchange Act, 15 U.S.C. 78s(b)(2), the Commission must disapprove a proposed rule change filed by a national securities exchange if it does not find that the proposed rule change is consistent with the applicable requirements of the Exchange Act. Exchange Act Section 6(b)(5) states that an exchange shall not be registered as a national securities exchange unless the Commission determines that ''[t]he rules of the exchange are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between

Continued

Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the rule change.'' [55]

The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[56] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations.[57] Moreover, ''unquestioning reliance'' on an SRO's representations in a proposed rule change is not sufficient to justify Commission approval of a proposed rule change.[58]

B. Whether NYSE Arca Has Met Its Burden to Demonstrate That the Proposal Is Designed to Prevent Fraudulent and Manipulative Acts and Practices

(1) Assertions That Other Means Besides Surveillance-Sharing Agreements Will Be Sufficient to Prevent Fraudulent and Manipulative Acts and Practices

(i) Assertions Regarding the Bitcoin Market

As stated above, the Commission has recognized that a listing exchange could demonstrate that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying bitcoin assets, including by demonstrating that the bitcoin market as a whole or the relevant underlying bitcoin market is uniquely and inherently resistant to fraud and manipulation.[59] Such resistance to fraud and manipulation, however, must be novel and beyond those protections that exist in traditional commodities or securities markets.[60]

(a) Representations Made and Comments Received

NYSE Arca asserts that ''the fundamental features of [b]itcoin's fungibility, transportability[,] and exchange tradability offer novel protections beyond those that exist in traditional commodity markets or equity markets when combined with other means.'' [61]

In addition, some commenters claim that the spot bitcoin market's size and depth of liquidity, as well as the diversity of market participants, limits its susceptibility to manipulation.[62] An affiliate of the Custodian, for example, states that bitcoin's average daily trading volume in 2021 was approximately $45 billion, which, according to this commenter, is significantly higher than that of the largest equity stocks.[63] This commenter also states that the spot bitcoin market is comparably as large and transparent as the silver, palladium, and platinum markets, for which the Commission has approved spot ETPs.[64] According to this commenter, ''[w]hen compared across key market dimensions—trading volume, capitalization, and number of active trading venues—the [b]itcoin spot market is more robust, a sign of lower likelihood of successful market manipulation.'' [65] Lastly, this commenter states that asset managers, hedge funds, and public companies participate in the bitcoin market and that interest from institutional investors continues to increase.[66]

Some commenters state that active participation by market makers and arbitrageurs across bitcoin-related markets serves to quickly close arbitrage opportunities, including any that may be due to attempted price manipulation.[67] In support of this claim, the affiliate of the Custodian states that it has undertaken empirical research that shows that spot bitcoin prices do not deviate significantly across digital asset platforms.[68] According to this commenter, in a comparison of hour-end prices for bitcoin across the Constituent Platforms, the platforms showed less than 20 basis point deviation 97% of the time over a roughly three-year time horizon.[69] This commenter states that its observations and interpretations are consistent with those expressed previously by the Commission—that a strong convergence

customers, issuers, brokers, or dealers, or to regulate by virtue of any authority conferred by this title matters not related to the purposes of this title or the administration of the exchange.'' 15 U.S.C. 78f(b)(5).

[55] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[56] *See id.*

[57] *See id.*

[58] *Susquehanna Int'l Group, LLP* v. *Securities and Exchange Commission,* 866 F.3d 442, 447 (D.C. Cir. 2017) (''Susquehanna'').

[59] *See* USBT Order, 85 FR at 12597 n.23. The Commission is not applying a ''cannot be manipulated'' standard. Instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met. *See id.*

[60] *See id.* at 12597.

[61] Amendment No. 1, 87 FR at 28051.

[62] *See, e.g.,* Letter from Paul Grewal, Chief Legal Officer, Coinbase, dated Mar. 3, 2022 (''Coinbase Letter II''), at 2 (''the [b]itcoin markets exhibit characteristics and maturity commensurate with some of the deeply traded markets in commodities and U.S. equities. The liquidity and transparency of the [b]itcoin markets limits its susceptibility to manipulation . . . .''); Letter from Cassandra Lentchner, President and Chairman, BitGo Trust Company, Inc., dated Apr. 18, 2022 (''BitGo Letter''), at 2 (''Bitcoin is a widely-traded asset with a market capital of over $750B and trading volumes of tens of billions daily. The sheer size of this widely held market demonstrates the difficulty of manipulation.''); Letter from Mike Cammarata, dated Mar. 31, 2022 (''Cammarata Letter'') (''the size of the [b]itcoin market (around $1 Trillion USD) has now reached a level where price manipulation concerns are minor as any attempt at manipulation will simply be arbitraged away by the deep pool of robust market participants''); Letter from Kate McAllister and James Toes, Security Traders Association, dated Apr. 20, 2022 (''STA Letter''), at 2 (''the combination of liquid markets for [b]itcoin and the features within the ETF structure mitigate potential price manipulation''); Letter from Michael D. Moffitt, dated Feb. 7, 2022 (''Moffitt Letter I'') (stating that ''the [b]itcoin as of 2021/2022 are indeed sufficiently liquid and transparent for the purposes of an ETF'' and ''it is my belief that widespread manipulation is simply not possible in the same way that it might have been several years ago'').

[63] *See* Coinbase Letter II, at 3.

[64] *See id.* at 3, 8. *See also, e.g.,* Letter from Douglas Shultz (Feb. 14, 2022) (''Shultz Letter'') (''The cryptocurrency market has passed silver in terms of total market capitalization at various times. If silver can't be manipulated at these levels, neither can [b]itcoin.'').

[65] Coinbase Letter II, at 3.

[66] *See id.* at 3.

[67] *See, e.g.,* Coinbase Letter II, at 2; Letter from Douglas A. Cifu, Chief Executive Officer, Virtu Financial, Inc., dated Apr. 4, 2022 (''Virtu Letter''), at 3 (''we believe that the active participation by market makers across all of these linked markets—spot, futures, derivatives and ETP—can mitigate the risk of manipulation through competitive liquidity provision, arbitrage and creation/redemption transactions''); Letter from W. Graham Harper, Head of Public Policy and Market Structure, Cumberland, a subsidiary of DRW Trading Group, dated Apr. 1, 2022 (''Cumberland Letter''), at 2 (''[a]ny narrowly scoped attempt to manipulate the spot [b]itcoin market would be quickly counteracted by the collective activity of arbitrageurs and liquidity providers, ultimately facilitating orderly price discovery potentially causing artificial prices to be perpetuated across all [b]itcoin related products, but in any case, forcing the arbitrage relationships to remain intact'').

[68] *See* Coinbase Letter II, at 4.

[69] *See id.* According to this commenter, while there were instances where prices across Constituent Platforms experienced higher deviations than 20 bps, the vast majority (*e.g.,* 90% of deviations greater than 1%) were driven by a single platform's pricing with less than 5% of the trading volume. In the remaining instances, price differences quickly closed by intermarket trading, typically within one hour, with the exception of two price deviations that lasted three hours during the onset of the Covid–19 pandemic. *See id.*

of pricing across a broad market is present where spot markets are deep and liquid.[70] This commenter concludes that, given the spot bitcoin market's significant volume and efficiency of intermarket price correction, manipulating the price of the Shares by manipulating the spot bitcoin market would require a prohibitively large trading volume and coordination across several large trading platforms, and that activity on this scale would be readily detected via surveillance.[71]

A number of commenters, however, take the opposite view, arguing, among other things, that the price of bitcoin is subject to manipulation on the unregulated platforms, and approval of the proposal would invite additional manipulation.[72]

(b) Analysis

As with the previous proposals, the Commission here concludes that information in the record regarding the bitcoin market does not support a finding that the Exchange has established other means to prevent fraudulent and manipulative acts and practices sufficient to justify dispensing with the detection and deterrence of fraud and manipulation that is provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin. Likewise, the record does not support a finding that the Exchange has demonstrated that the bitcoin market as a whole or the relevant underlying bitcoin market is uniquely and inherently resistant to fraud and manipulation.

The Commission has identified in previous orders possible sources of fraud and manipulation in the spot bitcoin market, including: (1) ''wash'' trading; [73] (2) persons with a dominant position in bitcoin manipulating bitcoin pricing; (3) hacking of the bitcoin network and trading platforms; (4) malicious control of the bitcoin network; (5) trading based on material, non-public information (for example, plans of market participants to significantly increase or decrease their holdings in bitcoin, new sources of demand for bitcoin, or the decision of a bitcoin-based investment vehicle on how to respond to a ''fork'' in the bitcoin blockchain, which would create two different, non-interchangeable types of bitcoin) or based on the dissemination of false and misleading information; (6) manipulative activity involving purported ''stablecoins,'' including Tether (USDT); and (7) fraud and manipulation at bitcoin trading platforms.[74]

NYSE Arca concedes that neither bitcoin itself nor the global bitcoin markets are inherently resistant to fraud or manipulation.[75] NYSE Arca acknowledges in its proposal that ''fraud and manipulation may exist and that [b]itcoin trading on any given exchange may be no more uniquely resistant to fraud and manipulation than other commodity markets.'' [76] NYSE Arca also states that ''[b]itcoin is not itself inherently resistant to fraud and manipulation'' [77] and concedes that ''the global exchange market for the trading of [b]itcoins''—which NYSE Arca says consists of transactions on the ''electronic marketplace where exchange participants may trade, buy and sell [b]itcoins based on bid-ask trading''—also ''is not inherently resistant to fraud and manipulation.'' [78]

Moreover, the Trust's Registration Statement acknowledges that ''[d]ue to the unregulated nature and lack of transparency surrounding the operations of [bitcoin trading platforms], they may experience fraud, security failures or operational problems, which may adversely affect the value of [b]itcoin and, consequently, the value of the Shares''; that the bitcoin network is currently vulnerable to a ''51% attack,'' in which a bad actor or botnet that controls a majority of the processing power dedicated to mining on the bitcoin network may be able to gain full control of the network and the ability to manipulate the bitcoin blockchain; that ''in 2019 there were reports claiming that 80–95% of [b]itcoin trading volume on [bitcoin platforms] was false or non-economic in nature''; and that ''[o]ver the past several years, some [bitcoin trading platforms] have been closed due to fraud and manipulative activity, business failure or security breaches.'' [79]

NYSE Arca asserts that bitcoin's fungibility, transportability, and exchange tradability, ''when combined with other means,'' offer novel protections beyond those that exist in traditional commodity markets or equity markets.[80] The Exchange, however, does not explain how bitcoin is fungible, transportable, or tradable; or how bitcoin's fungibility, transportability, and tradability offer novel protections or help to detect and deter potential fraud and manipulation. As stated above, ''unquestioning reliance'' on an SRO's representations in a proposed rule change is not sufficient to justify the

[70] *See id.* (citing to Securities Exchange Act Release No. 50603 (Oct. 28, 2004), 69 FR 64614 (Nov. 5, 2004) (SR–NYSE–2004–22) (Order Granting Approval of Proposed Rule Change by the New York Stock Exchange, Inc. Regarding Listing and Trading of streetTRACKS® Gold Shares).

[71] *See id.* at 4–5.

[72] *See, e.g.,* Letters from David Rosenthal (Apr. 20, 2022); David Golumbia (Apr. 18, 2022); Elliot Kleinfelder (Apr. 19, 2022) (''Kleinfelder Letter''); Scott S. (Feb. 20, 2022); John Carvalho (Feb. 22, 2022); JRL Innovations (Feb. 14, 2022); Anonymous (Feb. 17, 2022); Adan (Feb. 8, 2022). Some commenters that support approval of the proposal nevertheless state that the spot bitcoin market is subject to manipulation. *See, e.g.,* Letter from Noah Dreyfuss, CIO, Dreyfuss Capital Management, dated Feb. 21, 2022 (''Dreyfuss Letter''), at 1 (''Frankly, one would find great difficulty in claiming that the spot [b]itcoin market is free of manipulation.''); Letter from Jonas M. Grant (Feb. 6, 2022) (''the [b]itcoin market is no doubt susceptible to some manipulation'').

[73] *See also CFTC* v. *Gemini Trust Co., LLC,* No. 22–cv–4563 (S.D.N.Y. filed June 2, 2022) (alleging, among other things, failure by Gemini personnel to disclose to the CFTC that Gemini customers could and did engage in collusive or wash trading).

[74] *See* USBT Order, 85 FR at 12600–01 & nn.66–67 (discussing J. Griffin & A. Shams, *Is Bitcoin Really Untethered?* (Oct. 28, 2019), *available at https://ssrn.com/abstract=3195066* and published in 75 J. Finance 1913 (2020)); Winklevoss Order, 83 FR at 37585–86; WisdomTree Order, 86 FR at 69326; Global X Order, 87 FR at 14916; ARK 21Shares Order, 87 FR at 20019; One River Order, 87 FR at 33554.

[75] *See* Amendment No. 1, 87 FR at 28050–51 (where the Exchange states that ''[t]he Commission has expressed legitimate concerns about the underlying [spot bitcoin market] due to the potential for fraud and manipulation'' and discusses previous Commission orders finding ''evidence of potential and actual fraud and manipulation in the historical trading of [b]itcoin on certain marketplaces such as (1) 'wash' trading, (2) trading based on material, non-public information, including the dissemination of false and misleading information, (3) manipulative activity involving Tether, and (4) fraud and manipulation''). *See also id.* at 28049 (where the Exchange asserts that the proposal's use of the Index mitigates the effects of wash trading and order book spoofing).

[76] *Id.* at 28051.

[77] *Id.* at 28054.

[78] *Id.* at 28059 (the ''Digital Asset Exchange Market is not inherently resistant to fraud and manipulation''). In its filing, the Exchange uses the term ''Digital Asset Exchange Market'' as ''the global exchange market for the trading of [b]itcoins, which consists of transactions on electronic Digital Asset Exchanges.'' A ''Digital Asset Exchange'' is defined by NYSE Arca as ''an electronic marketplace where exchange participants may trade, buy and sell [b]itcoins based on bid-ask trading.'' *Id.* at 28045 n.18.

[79] *See* Exhibit 99.1 of the Registration Statement, at 13–14, 17–18. *See also* 2021 10–K, at 13, 50; *Are Blockchains Decentralized? Unintended Centralities in Distributed Ledgers,* prepared by Trail of Bits based upon work supported by the Defense Advanced Research Projects Agency, June 2022, *available at: https://assets-global.website-files.com/5fd11235b3950c2c1a3b6df4/62af6c641a672b3329b9a480_Unintended_Centralities_in_Distributed_Ledgers.pdf.*

[80] *See* Amendment No. 1, 87 FR at 28051. The Exchange does not explicitly tie the asserted novel aspects of bitcoin to an argument that such market provides sufficient means besides surveillance-sharing agreements to prevent fraud and manipulation.

Commission's approval of a proposed rule change.[81]

Further, contrary to the Exchange's assertion, fungibility, transportability, and tradability are not a novel protection beyond those that exist in traditional commodity or equity markets. Fungible, ''transportable,'' exchange-traded assets, such as securities and exchange-traded derivatives, trade subject to substantial regulatory oversight and surveillance-sharing agreements that would be unnecessary if fungibility, transportability, and tradability were sufficient protection against fraud and manipulation. Moreover, manipulation of asset prices can occur through trading activity, including activity that creates a false impression of supply and demand.[82] Therefore, the Exchange's assertions about fungibility, transportability, and tradability do not inform the Commission's view with respect to the necessity that a listing exchange have the abilities to detect and deter fraud and manipulation that are provided by entering into a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin.[83]

Likewise, the Commission is not persuaded by commenters' assertions that the bitcoin market's size, liquidity, market participation, or arbitrage, either individually or together, sufficiently address concerns regarding fraud and manipulation.[84] Although commenters recite various metrics, including market capitalization and average daily trading volume, or make observations concerning the growth of the bitcoin market, including increasing institutional participation, they offer no evidence or analysis of how these metrics or observations serve to detect and deter potential fraud and manipulation. Further, even if the record demonstrates that the bitcoin market's size, liquidity, market participation, or arbitrage makes manipulation more difficult or costly, as the Commission has stated in prior orders with respect to similar arguments, these attributes speak to providing some resistance to manipulation, rather than establishing a *unique* resistance to manipulation that would justify dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin.[85]

Moreover, commenters do not explain how the bitcoin market's diversity of market participants, widely held nature, or increase in institutional participation help mitigate concerns about fraud and manipulation such that a surveillance-sharing agreement is unnecessary. In addition, commenters' assertions about the diverse, broad, and institutional nature of bitcoin's investor base do not provide any information on the concentration of bitcoin ownership within or among market participants, or take into account that a market participant with a dominant ownership position may not find it prohibitively expensive to overcome the liquidity supplied by arbitrageurs and could use dominant market share to engage in manipulation.[86] Indeed, the Sponsor's own statements cast doubt on assertions that the bitcoin market's attributes sufficiently address concerns about fraud and manipulation. According to the Sponsor, ''[a]s of December 31, 2021, the largest 100 [b]itcoin wallets held approximately 15% of the [b]itcoins in circulation. Moreover, it is possible that other persons or entities control multiple wallets that collectively hold a significant number of [b]itcoins, even if they individually only hold a small amount, and it is possible that some of these wallets are controlled by the same person or entity. As a result of this concentration of ownership, large sales or distributions by such holders could have an adverse effect on the market price of [b]itcoin.'' [87]

The Custodian affiliate's comparison of the spot bitcoin market to the silver, palladium, and platinum markets also does not support the finding that other means to prevent fraudulent and manipulative acts and practices are sufficient to justify dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin. As discussed above,[88] for the commodity-trust ETPs approved to date for listing and trading, including where the underlying commodity is silver, palladium, or platinum, there has been in *every* case at least one significant, regulated market for trading futures on the underlying commodity, and the ETP listing exchange has entered into surveillance-sharing agreements with, or held ISG membership in common with, that market.

The Commission is also not persuaded by commenters' assertion that efficiency of intermarket price correction in the spot bitcoin markets would make manipulating the spot market prohibitively expensive and readily detectable. The affiliate of the Custodian provides various statistics which purport to show that bitcoin prices are closely and increasingly aligned across markets and that any price disparities are quickly arbitraged away. However, such statistics are based on hour-end bitcoin prices and do not capture intra-hour price disparities or provide intra-hour information on how long price disparities persist. Nor do this commenter's statistics or its assertions provide any insight into what size or duration of price disparities would be needed for a would-be manipulator to have an opportunity to make a profit.[89]

In any event, as the Commission has explained, efficient price arbitrage is not sufficient to support the finding that a market is uniquely or inherently resistant to manipulation such that the Commission can dispense with surveillance-sharing agreements.[90] The Commission has stated, for example,

[81] *See supra* note 58.

[82] *See* Winklevoss Order, 83 FR at 37585.

[83] Further, transportation and storage costs for bitcoin are not zero, as bitcoin mining and recording transactions to the blockchain have costs. Bitcoin mining involves significant costs for electrical power and computer hardware. Moreover, bitcoin trading is subject to transaction fees charged by trading platforms, withdrawal fees, expenses for custody arrangements, and other factors that impose frictions on trading.

[84] Although a commenter claims that ''transparency'' of the bitcoin market assists arbitrage and limits bitcoin's susceptibility to manipulation, the commenter does not explain what is meant by ''transparency,'' how the bitcoin markets are transparent, or why such transparency limits manipulation. *See* Coinbase Letter II, at 2–4.

[85] *See* USBT Order, 85 FR at 12601; Kryptoin Order, 86 FR at 74171; Global X Order, 87 FR at 14916; Wise Origin Order, 87 FR at 5531.

[86] *See, e.g.,* Winklevoss Order, 83 FR at 37584; USBT Order, 85 FR at 12600–01; WisdomTree Order, 86 FR at 69325; Valkyrie Order, 86 FR at 74160; Kryptoin Order, 86 FR at 74170; SkyBridge Order, 87 FR at 3783–84; Wise Origin Order, 87 FR at 5531; ARK 21Shares Order, 87 FR at 20019.

[87] 2021 10–K, at 46.

[88] *See supra* note 23 and accompanying text.

[89] *See* Coinbase Letter II, at 4–5. In addition, the Registration Statement states: ''As corresponding increases in throughput lag behind growth in the use of digital asset networks, average fees and settlement times may increase considerably. For example, the Bitcoin Network has been, at times, at capacity, which has led to increased transaction fees . . . . Increased fees and decreased settlement speeds could . . . adversely impact the value of the Shares.'' Exhibit 99.1 of the Registration Statement, at 13. *See also* 2021 10–K, at 46. The affiliate of the Custodian does not provide data or analysis to address, among other things, whether such risks of increased fees and bitcoin transaction settlement times may affect whether arbitrage is as effective as the commenter asserts. And without such data or analysis, the Commission cannot agree with this commenter's assertions. *See* Susquehanna, 866 F.3d at 447. *See also* ARK 21Shares Order, 87 FR at 20019 n.68.

[90] *See* Winklevoss Order, 83 FR at 37586; SolidX Order, 82 FR at 16256–57; USBT Order, 85 FR at 12601; WisdomTree Order, 86 FR at 69325; Valkyrie Order, 86 FR at 74159–60; Kryptoin Order, 86 FR at 74170; Wise Origin Order, 87 FR at 5531; ARK 21Shares Order, 87 FR at 20019.

that even for equity options based on securities listed on national securities exchanges, the Commission relies on surveillance-sharing agreements to detect and deter fraud and manipulation.[91] Equities that underlie such options trade on U.S. equity markets that are deep, liquid, highly interconnected, and almost entirely automated and operate at high speeds measured in microseconds and even nanoseconds.[92] Here, the affiliate of the Custodian and other commenters provide insufficient evidence to support their assertion of efficient price arbitrage across bitcoin-related platforms, let alone any evidence that price arbitrage in the bitcoin market is novel and beyond those protections that exist in traditional commodity markets or securities markets so as to warrant the Commission dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin.

Additionally, even assuming that efficiency of intermarket price correction in the spot bitcoin markets results in bitcoin prices increasingly aligned across markets, such alignment is not sufficient to support the finding that a market is uniquely or inherently resistant to manipulation such that the Commission can dispense with surveillance-sharing agreements.[93] As stated above, as a general matter, the manipulation of asset prices can occur simply through trading activity that creates a false impression of supply and demand, notwithstanding the presence of linkages among markets, whether these linkages be formal (such as those with consolidated quotations or routing requirements) or informal (such as in the context of the global bitcoin markets).[94]

[91] *See, e.g.,* USBT Order, 85 FR at 12601; WisdomTree Order, 86 FR at 69329; Valkyrie Order, 86 FR at 74160; Kryptoin Order, 86 FR at 74170; Wise Origin Order, 87 FR at 5531; ARK 21Shares Order, 87 FR at 20019.

[92] *See* SEC Staff Report on Algorithmic Trading in U.S. Capital Markets (Aug. 5, 2020), *available at: https://www.sec.gov/files/Algo_Trading_Report_2020.pdf;* Market Data Infrastructure Proposing Release, Securities Exchange Act Release No. 88216 (Feb. 14, 2020), 85 FR 16726, 16728 (Mar. 24, 2020). *See also* ARK 21Shares Order, 87 FR at 20019 n.70.

[93] *See* WisdomTree Order, 86 FR at 69325–26; Kryptoin Order, 86 FR at 74170; SkyBridge Order, 87 FR at 3783–84; Wise Origin Order, 87 FR at 5531; ARK 21Shares Order, 87 FR at 20019.

[94] *See* Winklevoss Order, 83 FR at 37585; ARK 21Shares Order, 87 FR at 20019.

(ii) Assertions Regarding the Index

(a) Representations Made and Comments Received

NYSE Arca asserts that the Index used by the Trust to determine the value of its bitcoin assets ''represents an effective alternative means to prevent fraud and manipulation[,] and the Trust's reliance on the Index addresses the Commission's concerns with respect to potential fraud and manipulation.'' [95] It states that the Trust ''has used the Index to price the Shares for more than six years, and the Index has proven its ability to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity from impacting the [b]itcoin reference rate, (ii) provide a real-time, volume-weighted fair value of bitcoin and (iii) appropriately handle and adjust[ ] for non-market related events, such that efforts to manipulate the price of [b]itcoin would have had a negligible effect on the pricing of the Trust, due to the controls embedded in the structure of the Index.'' [96]

First, NYSE Arca argues that the Index's use of Constituent Platforms that are compliant with applicable U.S. federal and state licensing requirements and practices regarding anti-money laundering (''AML'') and know-your-customer (''KYC'') regulations reduces the risk of fraud, manipulation, and other anomalous trading activity from impacting the Index. NYSE Arca also states that Constituent Platforms are considered to be Money Services Businesses (''MSBs'') and thus subject to certain requirements such as reporting suspicious activities to the U.S. Department of the Treasury's FinCEN division, having customer identification through KYC procedures, and establishing a formal AML policy.[97] In addition, the Constituent Platforms that are regulated by the New York State Department of Financial Services (''NYSDFS'') under the BitLicense program have regulatory requirements (1) to implement measures designed to effectively detect, prevent, and respond to fraud, attempted fraud, market manipulation, and similar wrongdoing; and (2) to monitor, control, investigate, and report back to the NYSDFS regarding any wrongdoing.[98] And according to NYSE Arca, the other non-NYSDFS regulated Constituent Platforms have voluntarily implemented measures to protect against common forms of market manipulation.[99] Moreover, according to NYSE Arca, the Commodity Futures Trading Commission (''CFTC'') has the authority to police fraud and manipulation on Constituent Platforms.[100] In addition, certain of the Index's Constituent Platforms ''have or have begun to implement market surveillance infrastructure to further detect, prevent, and respond to fraud, attempted fraud, and similar wrongdoing, including market manipulation.'' [101]

[95] Amendment No. 1, 87 FR at 28053. A commenter also states that the ''Index is designed to (i) mitigate the effects of fraud, manipulation and other anomalous trading activity from impacting the bitcoin reference rate, (ii) provide a real-time, volume-weighted fair value of bitcoin and (iii) appropriately handle and adjust for non-market related events.'' Letter from Campbell R. Harvey, Professor of Finance, Duke University, dated Mar. 26, 2022 (''Harvey Letter''), at 3. Another commenter agrees with the Exchange that ''[h]aving the Index Price determined through a process in which trade data is cleansed and compiled will sufficiently mitigate the impact of manipulation.'' Letter from Robert Citrone, Founder, Discovery Capital Management, dated Feb. 23, 2022 (''Discovery Letter''), at 1. *See also, e.g.,* Moffitt Letter I (''the structure of this Index is robust enough to protect investors'').

[96] Amendment No. 1, 87 FR at 28059. *See also id.* at 28053 (''Since November 1, 2014, the Trust has consistently priced its Shares at 4:00 p.m., E.T. based on the Index Price. . . . While that pricing would be known to the market, the Sponsor believes that, even if efforts to manipulate the price of [b]itcoin at 4:00 p.m., E.T. were successful on any exchange, such activity would have had a negligible effect on the pricing of the Trust, due to the controls embedded in the structure of the Index.'').

[97] *See id.* at 28052.

[98] *See id.* The Exchange also states that these platforms have the following obligations: submission of audited financial statements; compliance with NYSDFS's capitalization requirements; prohibitions against the ''sale or encumbrance to protect the full reserves of custodian assets''; fingerprints and photographs of employees with access to customer funds; retention of a qualified Chief Information Security Officer and annual penetration testing/audits; documented business continuity and disaster recovery plan; and participation in an independent exam by NYSDFS. *See id.*

[99] *See id.* The Exchange states that, as of the date of the filing, two of the four Constituent Platforms (Bitstamp and Coinbase Pro) are regulated by NYSDFS. *See id.* at 28052 n.39.

[100] *See id.* at 28052. A commenter states that the CFTC has exercised its anti-manipulation and anti-fraud enforcement authority over spot bitcoin markets since 2014, which is three years longer than the CFTC has overseen bitcoin futures markets. *See* Letter from Kristin Smith, Executive Director, and Jake Chervinsky, Head of Policy, Blockchain Association, dated Nov. 29, 2021 (''Blockchain Association Letter''), at 3. Another commenter states that the Commission should rely on the CFTC to exercise its fraud authority to ensure the underlying bitcoin market is free of manipulation. *See* Letter from Michelle Bond, Chief Executive Officer, Association for Digital Asset Markets, dated Apr. 19, 2022 (''ADAM Letter''), at 6.

[101] Amendment No. 1, 87 FR at 28059–60. The affiliate of the Custodian that operates one of the Constituent Platforms states in a comment letter that it applies surveillance and monitoring measures for its spot digital asset trading platform that are designed to identify and address potential manipulative or fraudulent trading activity, and that it believes that the other Constituent Platforms also employ measures to counter potential fraudulent or manipulative trading. *See* Coinbase Letter II, at 5. This commenter states that, in

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Second, NYSE Arca asserts that other aspects of the methodology employed in constructing the Index mitigate the impact of fraud, manipulation, and other anomalous trading activity.[102] The Exchange states that the Index is calculated once every second according to a systematic methodology that relies on observed trading activity on the Constituent Platforms. The key elements of this proprietary methodology are as follows: (i) *volume weighting*—Constituent Platforms with greater liquidity receive a higher weighting in the Index; (ii) *price variance weighting*—the Index reflects data points that are weighted in proportion to their variance from the rest of the Constituent Platforms (*i.e.,* as the price at a particular platform diverges from the prices at the rest of the Constituent Platforms, its weight in the Index Price decreases.); (iii) *inactivity adjustment*—the Index algorithm penalizes stale activity from any given Constituent Platform; and (iv) *manipulation resistance*—the Index only includes executed trades in its calculation in order to mitigate the effects of wash trade and spoofing, and only includes Constituent Platforms that charge trading fees to its users in order to attach a real, quantifiable cost to any manipulation attempts.[103] In addition, the Exchange states that, by referencing multiple trading venues and weighting them based on trade activity, the Index mitigates the impact of any potential fraud, manipulation, or anomalous trading activity occurring on any single venue.[104] In other words, the effects of fraud, manipulation, or anomalous trading activity occurring on any single venue are de-weighted and consequently diluted by non-anomalous trading activity of other Constituent Platforms.[105]

Third, NYSE Arca asserts that the Index is constructed and maintained by an expert third-party index provider, which would allow for prudent handling of non-market-related events.[106] The Exchange states that in the event that a manual intervention with respect to the Index calculation is necessary in response to ''non-market-related events'' (*e.g.,* halting of deposits or withdrawals of funds, unannounced closure of platform operations, insolvency, compromise of user funds, etc.), the Index Provider would issue a public announcement.[107] NYSE Arca also asserts that the Index Provider reviews and periodically updates which bitcoin platforms are included in the Index by utilizing a methodology that is guided by the IOSCO principles for financial benchmarks.[108]

(b) Analysis

Based on the assertions made and the information provided with respect to the Index, the record is inadequate to conclude that NYSE Arca has articulated other means to prevent fraud and manipulation that are sufficient to justify dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin.

First, NYSE Arca argues that the Index's exclusive use of prices from particular spot bitcoin trading platforms (the Constituent Platforms), which are subject to FinCEN's AML/KYC regulations, as well as NYSDFS's BitLicense program for two Constituent Platforms, helps to reduce the impact of fraud and manipulation on the Index Price. The Exchange acknowledges, however, that it ''does not believe the inclusion'' of these platforms is ''in and of itself sufficient to prove that the Index is an alternative means to prevent fraud and manipulation such that surveillance sharing agreements are not required'' but rather that including only such platforms ''in the Index is one significant way in which the Index is protected from the potential impacts of fraud and manipulation.'' [109]

The Commission does not agree that the inclusion of only certain Constituent Platforms as described provides a significant protection against fraud and manipulation. Any oversight afforded by FinCEN and NYSDFS, including AML/KYC or BitLicense regulation, is not a substitute for a surveillance-sharing agreement between the Exchange and a *regulated* market of significant size related to the underlying bitcoin assets. AML and KYC regulation, for example, do not substitute for the sharing of information about market trading activity or clearing activity that a surveillance-sharing agreement would afford. And although some of the Constituent Platforms may be registered with FinCEN or NYSDFS, these spot bitcoin trading platforms are not comparable to a national securities exchange or futures exchange.[110] As the Commission has explained, there are substantial differences between NYSDFS and FinCEN regulation and the Commission's regulation of national securities exchanges.[111] The Commission's market oversight of national securities exchanges includes substantial requirements, including the requirement to have rules that are ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.'' [112] Moreover, national securities exchanges must file proposed

addition to its surveillance program, it employs measures similar to circuit breakers and trading limits used in traditional financial markets and participates in industry initiatives meant to facilitate cross-platform surveillance and bolster the integrity and efficiency of digital asset markets. *See id.* at 6.

[102] *See* Amendment No. 1, 87 FR at 28052–53; 28059. A commenter states that the Index Provider has published empirical evidence identifying a number of cases in which the Index methodology has successfully shielded the Index from anomalistic or manipulative pricing. *See* Harvey Letter, at 4 (citing to *https://tradeblock.com/blog/analysis-of-bitfinex-anomalies-and-xbx-performance; https://tradeblock.com/blog/bitfinex-flash-crash-analysis; https://tradeblock.com/blog/xbx-update-adding-okcoin-removing-btc-e-and-btcchina; https://tradeblock.com/blog/xbx-update-adding-coinbase-removing-kraken; https://tradeblock.com/blog/xbx-index-update-removing-okcoin; https://tradeblock.com/blog/updates-to-tradeblocks-ecx-and-xbx-indices-2; https://tradeblock.com/blog/bitfinex-bitcoin-premium-reaches-widest-level-in-two-years; https://tradeblock.com/blog/bitcoin-futures-flash-crash-occurs-as-exchanges-show-irregular-trading-activity, https://tradeblock.com/blog/updates-to-all-tradeblock-indices*). This commenter also states that ''this is the highest quality benchmark being used in a bitcoin ETP proposal and one that can substantially mitigate price manipulation to ensure a fair, orderly, and efficient market.'' *Id.*

[103] *See* Amendment No. 1, 87 FR at 28052–53.

[104] *See id.* at 28053. A commenter states that the Trust has ''created a robust approach to managing the risk of manipulation by relying on an index of [b]itcoin prices from various exchanges'' and that the Index's ''use of a 24-hour VWAP should make any attempt at manipulation prohibitively expensive.'' Letter from Peter L. Briger, Jr., Chief Executive Officer, Fortress Investment Group LLC, dated Apr. 25, 2022 (''Fortress Letter''), at 2–3. The Exchange states that the Index no longer utilizes a 24-hour VWAP in its methodology. *See supra* note 38.

[105] *See* Amendment No. 1, 87 FR at 28053.

[106] *See id.* at 28053, 28059.

[107] *See id.* at 28053.

[108] *See id.*

[109] *Id.* at 28052.

[110] *See* USBT Order, 85 FR at 12603–05 and n.101; VanEck Order, 86 FR at 64545 and n.89; WisdomTree Order, 86 FR at 69328 and n.95; Kryptoin Order, 86 FR at 74173 and n.98; ARK 21Shares Order, 87 FR at 20021–22 and n.107.

[111] FinCEN and NYSDFS regulation have been referenced in other bitcoin-based ETP proposals as a purportedly alternative means by which such ETPs would be uniquely resistant to manipulation. *See* USBT Order, 85 FR at 12603 n.101 and accompanying text. *See also, e.g.,* WisdomTree Order, 86 FR at 69328 n.95; Kryptoin Order, 86 FR at 74173 n.98; ARK 21Shares Order, 87 FR at 20022 n.107.

[112] 15 U.S.C. 78f(b)(5).

rules with the Commission regarding certain material aspects of their operations,[113] and the Commission has the authority to disapprove any such rule that is not consistent with the requirements of the Exchange Act.[114] Thus, national securities exchanges are subject to Commission oversight of, among other things, their governance, membership qualifications, trading rules, disciplinary procedures, recordkeeping, and fees.[115] The Constituent Platforms have none of these requirements—none are registered as a national securities exchange. In addition, NYSDFS's BitLicense program is ''guidance'' that is ''not intended to limit the scope or applicability of any law or regulation,'' including the Exchange Act.[116]

Further, neither the Constituent Platforms' voluntary adherence to the BitLicense program, nor the Custodian affiliate's adoption of various surveillance, monitoring, and other measures to address potential manipulative or fraudulent trading activity on its trading platform, is material to the Commission's analysis. The Exchange provides no supporting evidence to substantiate its claims that the Constituent Platforms have voluntarily implemented measures to protect against common forms of market manipulation and that some of the Constituent Platforms have begun to implement market surveillance infrastructure to further detect, prevent, and respond to fraud, attempted fraud, and similar wrongdoing. Moreover, even taken at face value, these measures, unlike the Exchange Act's requirements for national securities exchanges,[117] are entirely voluntary and therefore have no binding force. The Constituent Platforms, including the platform operated by an affiliate of the Custodian, could change or cease to administer such measures at any time.

NYSE Arca's assertions regarding the CFTC's authority with respect to the Constituent Platforms and the underlying bitcoin market also do not establish a level of oversight sufficient to dispense with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin.[118] While the Commission recognizes that the CFTC maintains some jurisdiction over the spot bitcoin market, under the Commodity Exchange Act, the CFTC does not have regulatory authority over spot bitcoin trading platforms, including the Constituent Platforms.[119] Except in certain limited circumstances, spot bitcoin trading platforms are not required to register with the CFTC,[120] and the CFTC does not set standards for, approve the rules of, examine, or otherwise regulate spot bitcoin markets.[121] As the CFTC itself stated, while the CFTC ''has an important role to play,'' U.S. law ''does not provide for direct, comprehensive Federal oversight of underlying Bitcoin or virtual currency spot markets.'' [122]

Second, the record does not demonstrate that the proposed methodology for calculating the Index would make the proposed ETP resistant to fraud or manipulation such that the ability to detect and deter fraud that is provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin is unnecessary. Specifically, NYSE Arca has not assessed the possible influence that spot platforms not included among the Constituent Platforms would have on bitcoin prices used to calculate the Index Price. As discussed above, NYSE Arca does not contest the presence of possible sources of fraud and manipulation in the spot bitcoin market generally.[123] Instead, NYSE Arca focuses its analysis on the attributes of the Constituent Platforms, as well as the Index methodology that calibrates the pricing input generated by the Constituent Platforms (such as volume and price-variance weighting and inactivity adjustment). What the Exchange ignores, however, is that to the extent that trading on spot bitcoin platforms not directly used to calculate the Index Price affects prices on the Constituent Platforms, the activities on those other platforms—where various kinds of fraud and manipulation from a variety of sources may be present and persist—may affect whether the Index is resistant to manipulation. Importantly, the record does not demonstrate that these possible sources of fraud and manipulation in the broader spot bitcoin market do not affect the Constituent Platforms that represent a slice of the spot bitcoin market. To the extent that fraudulent and manipulative trading on the broader bitcoin market could influence prices or trading activity on the Constituent Platforms, the Constituent Platforms (and thus the Index) would not be inherently resistant to manipulation.[124]

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[113] 17 CFR 240.19b–4(a)(6)(i).

[114] Section 6 of the Exchange Act, 15 U.S.C. 78f, requires national securities exchanges to register with the Commission and requires an exchange's registration to be approved by the Commission, and Section 19(b) of the Exchange Act, 15 U.S.C. 78s(b), requires national securities exchanges to file proposed rule changes with the Commission and provides the Commission with the authority to disapprove proposed rule changes that are not consistent with the Exchange Act. Designated contract markets (''DCMs'') (commonly called ''futures markets'') registered with and regulated by the CFTC must comply with, among other things, a similarly comprehensive range of regulatory principles and must file rule changes with the CFTC. *See, e.g.,* Designated Contract Markets (DCMs), CFTC, *available at http://www.cftc.gov/IndustryOversight/TradingOrganizations/DCMs/index.htm.*

[115] *See* Winklevoss Order, 83 FR at 37597.

[116] Maria T. Vullo, Superintendent of Financial Services, NYSDFS, *Guidance on Prevention of Market Manipulation and Other Wrongful Activity* (Feb. 7, 2018), *available at https://www.dfs.ny.gov/system/files/documents/2020/03/il180207.pdf. See also, e.g.,* WisdomTree Order, 86 FR at 69328 n.95; Kryptoin Order, 86 FR at 74173 n.98; ARK 21Shares Order, 87 FR at 20022 n.107.

[117] *See* 15 U.S.C. 78e, 78f.

[118] *See* Valkyrie Order, 86 FR at 74162.

[119] *See* USBT Order, 85 FR at 12604.

[120] *See* Winklevoss Order, 83 FR at 37599 (''Spot bitcoin markets are not required to register with the CFTC, unless they offer leveraged, margined, or financed trading to retail customers.''). *See* Commodity Exchange Act Sections 2(c)(2)(D), 7 U.S.C. 2(c)(2)(D), and 2(c)(2)(A)(i), 7 U.S.C. 2(c)(2)(A)(i) (defining CFTC jurisdiction to specifically cover contracts of sale of a commodity for future delivery (or options on such contracts), or an option on a commodity (other than foreign currency or a security or a group or index of securities), that is executed or traded on an organized exchange). *See also* Winklevoss Order, 83 FR at 37599 n.286.

[121] *See* USBT Order, 85 FR at 12604; SolidX Order, 82 FR at 16256 (concluding that there is nothing in the record to indicate that there is currently a regulatory framework in the United States for detecting and deterring manipulation in the spot bitcoin markets and that ''[a]lthough the CFTC can bring enforcement actions against manipulative conduct in spot markets for a commodity, spot markets are not required to register with the CFTC unless they offer leveraged, margined, or financed trading to retail customers. . . . In all other cases, the CFTC does not set standards for, approve the rules of, examine, or otherwise regulate bitcoin spot markets.'').

[122] Winklevoss Order, 83 FR at 37599 (quoting CFTC Backgrounder on Oversight of and Approach to Virtual Currency Futures Markets (Jan. 4, 2018), at 1, *available at: http://www.cftc.gov/idc/groups/public/@newsroom/documents/file/backgrounder_virtualcurrency01.pdf*). *See also* Testimony of Rostin Behnam, Chair, CFTC, Before the Senate Committee on Agriculture, Nutrition, and Forestry (Feb. 9, 2022), *available at: https://www.agriculture.senate.gov/imo/media/doc/Testimony_Behnam_020920225.pdf* (''[W]hile the crystallization of our enforcement authority through judicial interpretation has proven an effective means of uncovering and addressing some of the regulatory gaps presented by innovation and evolution in the financial markets with respect to digital and related assets, it cannot be viewed as a viable substitute for a functional regulatory oversight regime for the cash digital asset market. . . . In fact, there is no one regulator, either state or federal, with sufficient visibility into digital asset commodity trading activity to fully police conflicts of interest and deceptive trading practices impacting retail customers.'').

[123] *See supra* notes 75–78 and accompanying text.

[124] *See* USBT Order, 85 FR at 12601; WisdomTree Order, 86 FR at 69327; Kryptoin Order, 86 FR at 74172; Valkyrie Order, 86 FR at 74161; SkyBridge Order, 87 FR at 3873.

In addition, while NYSE Arca asserts that aspects of the Index methodology mitigate the impact of fraud and manipulation on the Shares, the Commission can find no basis to conclude that the Index methodology constitutes a novel means beyond the protections utilized by traditional commodity or securities markets to prevent fraud and manipulation that is sufficient to justify dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin. For example, while the Index methodology uses an algorithm to discount prices that deviate from the average (*i.e.,* price variance weighting), this automatic discounting could attenuate, but would not eliminate, the effect of manipulative activity on one of the Constituent Platforms—just as it could attenuate, but would not eliminate, the effect of bona fide liquidity demand on one of those platforms.[125]

Moreover, NYSE Arca's assertions that the Trust's use of the Index helps make the Shares resistant to manipulation conflict with the Registration Statement. Specifically, the Registration Statement represents, among other things, that the market price of bitcoin may be subject to ''[m]anipulative trading activity on bitcoin [trading platforms], which are largely unregulated,'' and that, ''[d]ue to the unregulated nature and lack of transparency surrounding the operations of bitcoin [trading platforms], they may experience fraud, security failures or operational problems, which may adversely affect the value of [b]itcoin and, consequently, the value of the Shares.'' [126] Constituent Platforms are a subset of the bitcoin trading platforms that the Registration Statement describes.[127] The Registration Statement also states, specifically with respect to the Index, that ''[t]he Index has a limited history and a failure of the [Index Price] could adversely affect the value of the Shares.'' [128] Although the Sponsor raises concerns regarding fraud on and the security of bitcoin platforms, as well as concerns specific to the Index, the Exchange does not explain how or why such concerns are consistent with its assertion that the Index is resistant to fraud and manipulation.

Third, although NYSE Arca asserts that the Index Provider's oversight of the Index, which includes updating the Constituent Platforms from time to time and handling non-market-related events, mitigates fraud and manipulation in calculation of the Index, the record does not suggest that the purported oversight represents a unique measure to resist or prevent fraud or manipulation beyond protections that exist in traditional securities or commodities markets.[129] Rather, the oversight performed by the Index Provider appears to be for the purpose of ensuring the accuracy and integrity of the Index. Such Index accuracy and integrity oversight serves a fundamentally different purpose as compared to the regulation of national securities exchanges and the requirements of the Exchange Act. While the Commission recognizes that this may be an important function in ensuring the integrity of the Index, such requirements do not imbue the Index Provider with regulatory authority similar to that which the Exchange Act confers upon SROs such as national securities exchanges.[130] Furthermore, other commodity-based ETPs approved by the Commission for listing and trading utilize reference rates or indices administered by similar benchmark administrators,[131] and the Commission has not, in those instances, dispensed with the need for a surveillance-sharing agreement with a significant regulated market.

Finally, NYSE Arca does not explain the significance of the Index's purported resistance to manipulation to the overall analysis of whether the proposal to list and trade the Shares is designed to prevent fraud and manipulation.[132] Even assuming that NYSE Arca's argument is that the price of the Trust's Shares would be resistant to manipulation if the Index is resistant to manipulation, NYSE Arca has not established in the record a basis for this conclusion because NYSE Arca has not established a link between the price of the Shares and the Index Price, either in the primary or secondary market. While the Index is used by the Trust to value its bitcoin, the Trust will create or redeem Baskets only upon the receipt or distribution of bitcoins from/to authorized participants, and only for the amount of bitcoin represented by the Shares in such Baskets, without reference to the value of such bitcoin as determined by the Index or otherwise. Furthermore, the Shares would trade in the secondary market at market-based prices, not the Index Price. The Exchange provides no information on the relationship between the Index and secondary market prices generally,[133] or how the use of the Index would mitigate fraud and manipulation of the Shares in the secondary market.[134]

(2) Assertions That NYSE Arca Has Entered Into a Comprehensive Surveillance-Sharing Agreement With a Regulated Market of Significant Size Related to the Underlying Bitcoin Assets

As NYSE Arca has not demonstrated that other means besides surveillance-sharing agreements will be sufficient to prevent fraudulent and manipulative acts and practices, the Commission next examines whether the record supports the conclusion that NYSE Arca has entered into a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying bitcoin assets. In this context, the term ''market of

[125] *See* SolidX Order, 82 FR at 16257.

[126] Exhibit 99.1 of the Registration Statement, at 16–17. *See also* 2021 10–K, at 50.

[127] *See* Exhibit 99.1 of the Registration Statement, at 42–43. *See also* 2021 10–K, at 10.

[128] Exhibit 99.1 of the Registration Statement, at 18. *See also* 2021 10–K, at 51.

[129] *See, e.g.,* Valkyrie Order, 86 FR at 74162.

[130] *See* WisdomTree Order, 86 FR at 69329; One River Order, 87 FR at 33556.

[131] *See, e.g.,* Securities Exchange Act Release Nos. 80840 (June 1, 2017) 82 FR 26534 (June 7, 2017) (SR–NYSEArca–2017–33) (approving the listing and trading of shares of certain trusts seeking to track the Solactive GLD EUR Gold Index, Solactive GLD GBP Gold Index, and the Solactive GLD JPY Gold Index).

[132] The Commission has previously considered and rejected similar arguments about the valuation of bitcoin according to a benchmark or reference price. *See, e.g.,* SolidX Order, 82 FR at 16258; Winklevoss Order, 83 FR at 37587–90; USBT Order, 85 FR at 12599–601; Valkyrie Order, 86 FR at 74162; ARK 21Shares Order, 87 FR at 20022.

[133] For example, as currently traded OTC, the Shares do not reflect the value of the Index but rather trade at a significant discount (or at other times, a significant premium). *See* Exhibit 99.1 of the Registration Statement, at 23 (''the value of the Shares of the Trust may not approximate, and the Shares may trade at a substantial premium over, or substantial discount to, the value of the Trust's Bitcoin Holdings per Share''); 2021 10–K, at 2 (''from May 5, 2015 to December 31, 2021, the maximum premium of the closing price of the Shares quoted on OTCQX over the value of the Trust's Digital Asset Holdings per Share was 142% . . . and the average premium was 37% . . ., and the maximum discount of the closing price of the Shares quoted on OTCQX below the value of the Trust's Digital Asset Holdings was 21% . . . and the average discount was 13% . . . . As of December 31, 2021, the Trust's Shares were quoted on OTCQX at a discount of 20% . . . to the Trust's Digital Asset Holdings per Share.''); Grayscale Letter I, at 2 n.11 (''From May 5, 2015 to October 31, 2021, the maximum single-day premium of the closing price of BTC shares quoted on OTCQX over the value of its Bitcoin holdings was 142% and the average of all daily premiums was 37%; the maximum single-day discount below the value of its Bitcoin holdings was 21% and the average of all daily discounts was 12%; and the average of all single-day premiums and discounts was a premium of 32%.''); Coinbase Letter I, at 2 (''GBTC has traded over-the-counter at a premium to its net-asset value that has ranged as high as 142% and a discount to its net-asset value of 21%'').

[134] *See* WisdomTree Order, 86 FR at 69329 and n.108; Valkyrie Order, 86 FR at 74162; ARK 21Shares Order, 87 FR at 20022.

significant size'' includes a market (or group of markets) as to which (i) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (ii) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[135]

As the Commission has explained, it considers two markets that are members of the ISG to have a comprehensive surveillance-sharing agreement with one another, even if they do not have a separate bilateral surveillance-sharing agreement.[136] Accordingly, based on the common membership of NYSE Arca and the CME in the ISG,[137] NYSE Arca has the equivalent of a comprehensive surveillance-sharing agreement with the CME. However, while the Commission recognizes that the CFTC regulates the CME futures market,[138] including the CME bitcoin futures market, and thus such market is ''regulated,'' in the context of the proposed ETP, the record does not, as explained further below, establish that the CME bitcoin futures market is a ''market of significant size'' related to spot bitcoin, the underlying bitcoin assets that would be held by the Trust.

(i) Whether There is a Reasonable Likelihood That a Person Attempting To Manipulate the ETP Would Also Have To Trade on the CME Bitcoin Futures Market to Successfully Manipulate the ETP

The first prong in establishing whether the CME bitcoin futures market constitutes a ''market of significant size'' related to spot bitcoin is the determination that there is a reasonable likelihood that a person attempting to manipulate the ETP would have to trade on the CME bitcoin futures market to successfully manipulate the ETP. In previous Commission orders, the Commission explained that the lead/lag relationship between the bitcoin futures market and the spot market is ''central'' to understanding this first prong.[139]

(a) Assertions Made and Comments Received

The Exchange asserts in its proposal that the CME bitcoin futures market is a ''large, surveilled and regulated market that is closely connected with the spot market for [b]itcoin and through which the Exchange could obtain information to assist in detecting and deterring potential fraud or manipulation.'' [140] The Exchange, however, concedes that the Sponsor did not find a significant lead/lag relationship between the spot and the CME bitcoin futures markets. Specifically, according to NYSE Arca, the Sponsor ''conducted a lead/lag analysis of per minute data comparing the [b]itcoin futures market, as represented by the CME futures market, to the [b]itcoin spot market, as represented by the Index.'' However, for the period of November 1, 2019, to August 31, 2021, the analysis showed that ''there does not appear to be a significant lead/lag relationship between the two instruments.'' [141] The Sponsor's analysis notwithstanding, NYSE Arca states that ''other studies prior to and since such date have found that the CME futures market does lead the [b]itcoin spot market.'' [142]

NYSE Arca goes on to assert that, ''[a]lthough there have been mixed findings regarding the lead/lag relationship between the CME futures and [b]itcoin spot markets, . . . the CME futures market represents a large, surveilled[,] and regulated market.'' [143] As evidence of its assertion that the CME constitutes a market of significant size related to spot bitcoin, the Exchange states that, from November 1, 2019, to August 31, 2021, the CME futures market trading volume was over $432 billion, compared to $624 billion in trading volume across the Constituent Platforms included in the Index.[144] The Exchange also points to the CME futures market trading volume from November 1, 2019, to August 31, 2021, which it states was approximately 50% of the trading volume of certain U.S. dollar-denominated spot bitcoin platforms, including Binance, Coinbase Pro, Bitfinex, Kraken, Bitstamp, BitFlyer, Poloniex, Bittrex, and itBit.[145] The Exchange, therefore, concludes that, ''[g]iven the significant size of the CME futures markets, . . . there is a

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[135] *See* Winklevoss Order, 83 FR at 37594.

[136] *See id.* at 37580 n.19.

[137] *See* Amendment No. 1, 87 FR at 28054.

[138] While the Commission recognizes that the CFTC regulates the CME, the CFTC is not responsible for direct, comprehensive regulation of the underlying spot bitcoin market. *See* Winklevoss Order, 83 FR at 37587, 37599. *See also* WisdomTree Order, 86 FR at 69330 n.118; Kryptoin Order, 86 FR at 74174 n.119; SkyBridge Order, 87 FR at 3874 n.80; Wise Origin Order, 87 FR at 5534 n.93; ARK 21Shares Order, 87 FR at 20023 n.121.

[139] *See, e.g.,* USBT Order, 85 FR at 12612 (''[E]stablishing a lead-lag relationship between the bitcoin futures market and the spot market is central to understanding whether it is reasonably likely that a would-be manipulator of the ETP would need to trade on the bitcoin futures market to successfully manipulate prices on those spot platforms that feed into the proposed ETP's pricing mechanism. In particular, if the spot market leads the futures market, this would indicate that it would not be necessary to trade on the futures market to manipulate the proposed ETP, even if arbitrage worked efficiently, because the futures price would move to meet the spot price.''). When considering past proposals for spot bitcoin ETPs, the Commission has discussed whether there is a lead/lag relationship between the regulated market (*e.g.,* the CME) and the market on which the assets held by the ETP would have traded (*i.e.,* spot bitcoin platforms), as part of an analysis of whether a would-be manipulator of the spot bitcoin ETP would need to trade on the regulated market to effect such manipulation. *See, e.g.,* USBT Order, 85 FR at 12612. *See also* VanEck Order, 86 FR at 64547; WisdomTree Order, 86 FR at 69330–31; Kryptoin Order, 86 FR at 74176 n.144; SkyBridge Order, 87 FR at 3876 n.101; Wise Origin Order, 87 FR at 5535 n.107; ARK 21Shares Order, 87 FR at 20024 n.138.

[140] Amendment No. 1, 87 FR at 28060. A commenter also states its belief that the Trust ''has strong links to a regulated market of significant size (*i.e.,* the CME).'' Fortress Letter, at 2. Based on arguments articulated in the proposal, the Commission understands that the Exchange is arguing that CME is the regulated market of significant size with which it has the relevant surveillance-sharing agreement.

[141] Amendment No. 1, 87 FR at 28054.

[142] *Id.* at 28054 and n.50 (citing Memorandum to File from Neel Maitra, Senior Special Counsel (Fintech & Crypto Specialist), Division of Trading and Markets, U.S. Securities and Exchange Commission re: Meeting with Representatives from Fidelity Digital Assets, et al. and attachment (SR–CboeBZX–2021–039) (Sept. 8, 2021), *available at: https://www.sec.gov/comments/sr-cboebzx-2021-039/srcboebzx2021039-250110.pdf*; Letter from Bitwise Asset Management, Inc. re: File Number SR–NYSEArca–2021–89 (Feb. 25, 2022), *available at: https://www.sec.gov/comments/sr-nysearca-2021-89/srnysearca202189-20117902-270822.pdf*; Letter from Wilson Sonsini Goodrich and Rosati, P.C. and Chapman and Cutler LLP, on behalf of Bitwise Asset Management, Inc. re: File No. SR–NYSEArca–2021–89 (Mar. 7, 2022), *available at: https://www.sec.gov/comments/sr-nysearca-2021-89/srnysearca202189-20118794-271630.pdf*). *See also* Submission by the Sponsor to the Commission in connection with a meeting between representatives of the Sponsor, the Sponsor's counsel, Davis Polk & Wardwell LLP, and Commission staff on April 26, 2022 (''Grayscale Submission''), at 21–22, *available at: https://www.sec.gov/comments/sr-nysearca-2021-90/srnysearca202190-20128860-294707.pdf*). A commenter states that ''there is ample historical data to demonstrate how closely the CME futures contracts track the spot market (and in fact as BitWise's research has shown, lead the spot market a majority of the time.).'' Letter from Ben Davenport, dated Feb. 10, 2022 (''Davenport Letter'').

[143] Amendment No. 1, 87 FR at 28054.

[144] *See id.*

[145] *See id.* at 28054 and n.51. *See also* Grayscale Submission, at 16, citing to *https://www.bitcointradingvolume.com/* (''CME represents >50% of all [b]itcoin trading volume''). *But see* Letter from Robert E. Whaley, Professor of Management (Finance), Director, Financial Markets Research Center, Vanderbilt University Owen Graduate School of Management, dated May 25, 2022 (''Whaley Letter''), at 2 (''In terms of USD value, the market cap in the CME's bitcoin futures market averages less than one-quarter of one percent of the bitcoin spot market.''). This commenter nonetheless concludes that, ''[s]ince the Commission is comfortable with the viability of futures-based ETF investing in an environment in which the spot market dominates (in terms of both dollar value and trading volume), it follows logically that spot-based ETPs are warranted.'' Whaley Letter, at 2.

reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, since arbitrage between the derivative and spot markets would tend to counter an attempt to manipulate the spot market alone.'' [146]

Similar to the Sponsor's analysis, a commenter concludes that the relationship between spot and futures prices is ''complex and interrelated with no clear winner.'' [147] According to the commenter, the ''results of the test of which market is leading depends on the time period of testing.'' [148] Despite the commenter's lead/lag conclusion, the commenter argues that a would-be manipulator would be unable to manipulate the proposed ETP without also trading in the CME bitcoin futures market, ''[g]iven the relative size of trading volumes of bitcoin futures relative to spot, the strong dependence of spot prices on futures prices and vice versa, and the inefficiency of attempting to manipulate the [proposed] ETP through offshore trading.'' [149] Regarding the relative size of trading volumes, the commenter states that it examined Bloomberg trading data for the 365 days ended February 4, 2022, across all spot bitcoin trading venues and all CME bitcoin futures contract maturities, and found that the aggregate futures volume ($579 billion) was 31% higher than aggregate spot volume ($442 billion), a result that the commenter found to be statistically significant.[150] Regarding offshore trading, the commenter states that they believe it unlikely ''a bad actor would attempt to manipulate the [proposed] ETP through trading on offshore cryptocurrency trading venues'' because ''offshore trading venues generally do not support fiat trading and instead only support trading between different cryptocurrencies.'' [151] The commenter further states that ''offshore trading venues generally offer trading in bitcoin derivatives such as quarterly futures and perpetual futures; however, both would be poor choices for a bad actor seeking to manipulate the [proposed] ETP because both are known to deviate from the bitcoin spot price much more than CME futures,'' and thus any actor seeking to manipulate the proposed ETP ''would risk expanding or contracting the premium of the derivative being used as a manipulation tool rather than influencing bitcoin spot prices.'' [152]

(b) Analysis

The record does not demonstrate that there is a reasonable likelihood that a person attempting to manipulate the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP. The Exchange's and commenters' assertions about the size of the CME bitcoin futures market in comparison to the Constituent Platforms in particular and/or spot bitcoin markets in general do not establish that the CME bitcoin futures market is of significant size related to spot bitcoin. As the Commission has previously stated, the interpretation of the term ''market of significant size'' or ''significant market'' depends on the interrelationship between the market with which the listing exchange has a surveillance-sharing agreement and the proposed ETP.[153] Recitations of data reflecting the size of the CME bitcoin futures market and the size of the spot bitcoin market are not sufficient to establish an interrelationship between the CME bitcoin futures market and the proposed ETP.[154]

NYSE Arca asserts that there is a reasonable likelihood that a person would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP, because ''arbitrage between the derivative and spot markets would tend to counter an attempt to manipulate the spot market alone.'' [155] However, the record does not demonstrate the existence of efficient price arbitrage across bitcoin-related platforms, either generally or specifically as it relates to the bitcoin derivative and spot markets.[156] The Exchange also does not provide any additional data or analysis to support its conclusion that the arbitrage that may exist between the bitcoin derivatives markets and spot markets would counter an attempt to manipulate the spot market alone, or to demonstrate that such arbitrage would occur quickly enough to prevent a would-be manipulator of the proposed ETP from profiting off of movements in the spot price. Moreover, even assuming that the Commission concurred with the Exchange's premise that efficient arbitrage exists between the bitcoin derivatives markets and spot markets, the Exchange does not explain why the presence of efficient arbitrage implies that a would-be manipulator would be reasonably likely to trade specifically on *the CME* bitcoin futures market rather than on unregulated bitcoin futures markets or other bitcoin derivatives markets.[157]

In addition, while a commenter asserts that it is unlikely a would-be manipulator would use offshore bitcoin futures as their manipulation tool,[158] this commenter has not sufficiently explained or supported its assertions. The commenter provides no data or other evidence to support its assertions that, because Tether often trades at a premium or discount to USD, it is not ''economically practical''—and therefore ''unlikely''—for a bad actor to manipulate the proposed ETP using Tether-denominated bitcoin prices. The commenter also does not provide any data regarding the deviation of offshore futures prices from spot bitcoin prices, or on how much (or how long) attempted manipulation of offshore futures affects this deviation, that would allow for assessment of whether offshore futures would be a ''poor choice'' for a manipulation tool.

Finally, the econometric evidence in the record for the proposal does not support the conclusion that an interrelationship exists between the CME bitcoin futures market and the spot bitcoin market such that it is reasonably likely that a person attempting to manipulate the proposed ETP would also have to trade on the CME bitcoin futures market.[159] As the Commission

[146] Amendment No. 1, 87 FR at 28054. A commenter also states its belief that ''any attempt to manipulate the price of [the Trust] would likely also require manipulation of the CME futures markets''; that ''arbitrage between the spot and derivative markets would quickly counteract the attempted manipulation''; and that ''the CME would undoubtedly assist in monitoring and stopping the misconduct.'' Fortress Letter, at 3.

[147] Letter from Hunting Hill Global Capital, LLC, dated Mar. 3, 2022 (''Hunting Hill Letter''), at 2. The commenter makes this conclusion based on its own lead/lag analysis, ''using minute-by-minute last-price data over the [365 days ended February 4, 2022], converted to percentage price changes, based on the first lagged term for both markets.'' *Id.*

[148] *Id.*

[149] *Id.* at 3.

[150] *See id.* at 1–2. Although the observed time periods are different, the Commission observes that the relative trading volume data provided by this commenter is significantly different than the relative trading volume data provided by the Exchange. *See supra* notes 144–145 and accompanying text.

[151] Hunting Hill Letter, at 2–3. To the extent some offshore trading venues allow for bitcoin to be exchanged to Tether, the commenter states that ''it would not be economically practical for a bad actor to manipulate the [proposed] ETP using Tether-denominated bitcoin prices'' because ''manipulation in the bitcoin/USD exchange pair would likely result in a widening of Tether premiums and discounts.'' *Id.*

[152] *Id.* at 3.

[153] *See* USBT Order, 85 FR at 12611.

[154] *See id.* at 12612; Wise Origin Order, 87 FR at 5534–35.

[155] Amendment No. 1, 87 FR at 28054.

[156] *See also supra* note 89 and accompanying text.

[157] *See* WisdomTree Order, 86 FR at 69332; NYDIG Order, 87 FR at 14939.

[158] *See supra* notes 151–152 and accompanying text.

[159] *See* USBT Order, 85 FR at 12611; Wise Origin Order, 87 FR at 5535; NYDIG Order, 87 FR at 14938;

has stated in previous orders, if the spot market leads the futures market, this would indicate that it would not be necessary to trade on the futures market to manipulate the proposed ETP.[160] But as NYSE Arca concedes, there have been ''mixed'' findings regarding the lead/lag relationship between the CME futures and spot bitcoin markets.[161] Moreover, based on the Sponsor's own analysis—the data, methodology, results, and statistical significance of which were not described in the filing—''there does not appear to be a significant lead/lag relationship between'' the CME bitcoin futures market and the spot bitcoin market.[162] In addition, a commenter's lead/lag analysis purportedly finds ''no clear winner'' and a bi-directional relationship between spot bitcoin prices and CME futures prices.[163] And while the Exchange and the Sponsor highlight previous papers and analyses submitted to the Commission in connection with other proposals to list and trade spot bitcoin ETPs to support the premise that the CME bitcoin futures market leads the spot bitcoin market,[164] the Commission disapproved the proposals related to these submissions, and the Commission raised issues and criticisms with respect to these submissions that the Exchange does not address. The Exchange does not provide any additional evidence of an interrelationship between the CME bitcoin futures market, which is the regulated market, and spot bitcoin platforms, which are the markets on which the assets held by the proposed ETP would trade. As in previous disapprovals, because the lead/lag analysis regarding whether the CME bitcoin futures market leads the spot market remains inconclusive,[165] the Commission determines that the evidence in the record is inadequate to conclude that an interrelationship exists between the CME bitcoin futures market and the spot bitcoin market such that it is reasonably likely that a person attempting to manipulate the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP.

The Commission thus concludes that the information that NYSE Arca provides is not sufficient to support a determination that it is reasonably likely that a would-be manipulator of the proposed ETP would have to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP. Therefore, the information in the record also does not establish that the CME bitcoin futures market is a ''market of significant size'' related to the assets to be held by the proposed ETP.

(ii) Whether It Is Unlikely That Trading in the Proposed ETP Would Be the Predominant Influence on Prices in the CME Bitcoin Futures Market

The second prong in establishing whether the CME bitcoin futures market constitutes a ''market of significant size'' related to spot bitcoin is the determination that it is unlikely that trading in the proposed ETP would be the predominant influence on prices in the CME bitcoin futures market.[166]

(a) Assertions Made and Comments Received

NYSE Arca asserts that ''it is unlikely that the ETP would become the predominant influence on prices in the market.'' [167] In support, NYSE Arca states that the Sponsor examined the change in ''market capitalization of bitcoin'' with net inflows into the Trust, which currently trades OTC,[168] and found that from November 1, 2019, to August 31, 2021, the market capitalization of bitcoin grew by $721 billion, while the Trust experienced $6.6 billion of inflows over the same period.[169] The Exchange states that the cumulative inflow into the Trust over the stated time period was only 0.9% of the aggregate growth of bitcoin's market capitalization.[170] The Exchange also states that ''the Trust experienced approximately $98.5 billion of trading volume from November 1, 2019[,] to August 31, 2021, only 23% of the CME futures market and 16% of the Index over the same period.'' [171]

(b) Analysis

The record does not demonstrate that it is unlikely that trading in the proposed ETP would be the predominant influence on prices in the CME bitcoin futures market. First, the Sponsor's comparison of the Trust's historical inflows to the growth of bitcoin's market capitalization misapplies the second prong of the Commission's analysis. As stated above, the second prong in establishing whether the CME bitcoin futures market constitutes a ''market of significant size'' is the determination that it is unlikely that trading in the proposed ETP would be the predominant influence on *prices* in the *CME bitcoin futures market.* The Sponsor's analysis of the Trust's historical inflows vis-à-vis the *capitalization* of the *spot* bitcoin market considers neither the CME bitcoin futures market nor the CME bitcoin futures market's prices. Accordingly, such statistics, without more, are not relevant to the Commission's consideration of whether trading in the ETP would be the predominant influence on prices in the CME bitcoin futures market.

Second, putting aside the question of the spot bitcoin market's relevance to the second prong of the analysis, neither the Sponsor nor the Exchange has adequately explained why *historical* inflows into *the OTC* Trust is an appropriate proxy for trading in what would be exchange-listed Shares. There is no limit on the amount of mined bitcoins that the Trust may hold. Yet the Sponsor relies on the Trust's historical inflows and does not provide any information on the expected growth in the size of the Trust if the proposal is approved and the resultant increase in

Global X Order, 87 FR at 14920; ARK 21Shares, 87 FR at 20024.

[160] *See, e.g.,* USBT Order, 85 FR at 12612.

[161] *See* Amendment No. 1, 87 FR at 28054.

[162] *Id.*

[163] *See* Hunting Hill Letter, at 2. The Commission considers the lead/lag relationship between the CME bitcoin futures market and the spot bitcoin market to be central to understanding whether it is reasonably likely that a would-be manipulator of a spot bitcoin ETP would need to trade on the CME bitcoin futures market to successfully manipulate the proposed ETP. *See* USBT Order, 85 FR at 12612. This commenter, however, does not explain its data, methodology (such as why using only the first lag for each time series was the appropriate model specification), or results to an extent that can be assessed and/or verified. The commenter also argues that the Commission should not require that the CME bitcoin futures market ''always'' lead the spot market, as the commenter believes that would be ''tantamount to requiring that an obvious statistical arbitrage opportunity exists between two highly liquid and automated markets'' from which any trader could ''profit immensely,'' and would ''be the same as a declaration that bitcoin ETPs will never be approved in the United States.'' *See* Hunting Hill Letter, at 2. The Commission disagrees. A lead/lag statistical result that CME bitcoin futures prices ''lead'' spot prices does *not* mean that CME bitcoin futures prices ''always'' move before spot prices—which would be the ''obvious'' and exploitable arbitrage opportunity—or that there would never be a situation where the spot price moves before the CME bitcoin futures price.

[164] *See supra* note *142.*

[165] As the academic literature and listing exchanges' analyses pertaining to the pricing relationship between the CME bitcoin futures market and spot bitcoin market have developed, the Commission has critically reviewed those materials. *See* ARK 21Shares Order, 87 FR at 20024; Global X Order, 87 FR at 14920; Wise Origin Order, 87 FR at 5535–36, 5539–40; Kryptoin Order, 86 FR at 74176; WisdomTree Order, 86 FR at 69330–32; VanEck Order, 86 FR at 64547–48; USBT Order, 85 FR at 12613.

[166] *See* Winklevoss Order, 83 FR at 37594; USBT Order, 85 FR at 12596–97.

[167] Amendment No. 1, 87 FR at 28054.

[168] The Exchange states that, compared with global commodity ETPs, the Trust would rank fourth among global commodity ETPs in assets under management and seventh in notional trading volume for the period from November 1, 2019, to October 31, 2020. *See id.* at 28054 n.52.

[169] *See id.* at 28054.

[170] *See id.*

[171] *Id.*

the amount of bitcoin that may be held by the Trust over time, or on the overall expected number, size, and frequency of creations and redemptions—or how any of the foregoing could (if at all) influence prices in the CME bitcoin futures market. Moreover, the Trust's trading volume cited by the Exchange only relates to the Trust *as it trades OTC* and does not contemplate what may happen if the Trust converts to an ETP.[172] Commenters state that approval of a spot bitcoin ETP would provide a simpler, safer, and more efficient way to obtain exposure to bitcoin than the products that are currently available to retail investors; [173] and converting the Trust into an ETP would allow for daily creations and redemptions.[174] Further, the Sponsor itself acknowledges that converting the Trust into an ETP would allow the Shares to better track the Trust's net asset value (''NAV'') and reduce discounts and premiums.[175] Therefore, the Sponsor's use of historical inflow data is questionable as a way to approximate trading that may ensue in the proposed ETP.

Third, NYSE Arca's assertions are general and conclusory. While NYSE Arca recites data relating to the market capitalization of bitcoin and inflows to the Trust, and trading volume of the Trust as compared to the CME bitcoin futures market and the Constituent Platforms, NYSE Arca provides no meaningful analysis of such data to support its conclusion. For example, setting aside the issues with the relevance of the data that the Sponsor chose to consider, the analysis performed on such data is merely a comparison of the size of one data point (*e.g.,* change in market capitalization) to the size of another (*e.g.,* net inflows). Such an analysis is, at best, a simple correlation between the two data points; it provides no information relating to the *impact* of one on the other—*e.g.,* no information on the impact of the Trust's historical inflows on market capitalization, or of the Trust's trading volume on the CME bitcoin futures market (let alone, on the CME bitcoin futures market's prices). In short, the analysis performed provides no information on the *influence* that is central to the second prong.

Fourth, the data that NYSE Arca provides indicate that the Trust's trading volume from November 1, 2019, to August 31, 2021, was ''only'' 23% of that of the CME bitcoin futures market.[176] Even assuming that this historical data is an accurate predictor of the future percentage, neither the Sponsor nor the Exchange directly addresses why a *single* bitcoin ETP with trading volume close to one-quarter that of the CME bitcoin futures market is not likely to be the predominant influence on prices in that market. Moreover, the Sponsor describes the Trust, as of April 26, 2022, as holding approximately $30 billion in bitcoin, an amount that constitutes 3.4% of all outstanding bitcoin [177] and that far exceeds the value of all open interest in CME bitcoin futures contracts.[178] Yet neither the Sponsor nor the Exchange directly addresses why a spot bitcoin ETP whose assets under management would similarly exceed the value of all open interest in CME bitcoin futures contracts is not likely to be the predominant influence on prices in that market.

Thus, the Commission cannot conclude, based on the assertions in the filing and absent sufficient evidence or analysis in support of these assertions, that it is unlikely that trading in the proposed ETP would be the predominant influence on prices in the CME bitcoin futures market.[179]

Therefore, because NYSE Arca has not provided sufficient information to establish both prongs of the ''market of significant size'' determination, the Commission cannot conclude that the CME bitcoin futures market is a ''market of significant size'' related to spot bitcoin such that NYSE Arca would be able to rely on a surveillance-sharing agreement with the CME to provide sufficient protection against fraudulent and manipulative acts and practices.

(3) Assertions That the Proposed Spot Bitcoin ETP Is Comparable to Bitcoin Futures-Based ETFs and ETPs

(i) Assertions Made and Comments Received

The Exchange and the Sponsor argue that it would be inconsistent for the Commission to allow the listing and trading of ETFs and ETPs that provide exposure to bitcoin through CME bitcoin futures while disapproving the current proposal.[180]

The Sponsor asserts that CME bitcoin futures ETFs and ETPs and spot bitcoin ETPs ''are the same in all relevant respects.'' [181] In support of this assertion, the Sponsor claims that CME bitcoin futures ETFs and ETPs are ''priced according to the CME CF Bitcoin Reference Rate'' (''BRR''), which, ''in turn, is determined according to pricing data collected from digital asset trading platforms that include all but one of those currently incorporated into [the Index].'' [182] NYSE Arca also states that spot bitcoin ETPs, including the Trust, ''would be priced by referencing [spot bitcoin platforms] included in the BRR, such as through the Index.'' [183]

The Sponsor further asserts that, because the BRR is based upon ''substantially the same [b]itcoin pricing data'' as the Index, both CME bitcoin futures ETFs and ETPs and spot bitcoin ETPs are exposed to the ''same risks relating to pricing data quality'' (''same data, same risks'').[184] Moreover, because of the ''almost complete overlap'' in the platforms underlying the BRR and the Index, the Sponsor claims that ''the risks of fraud and manipulation in the [b]itcoin market impacting spot [b]itcoin ETPs are indistinguishable from those same risks impacting futures [b]itcoin ETPs.'' [185] The Exchange also asserts

[172] In addition, neither the Exchange nor the Sponsor addresses the likely impact, if any, of the conversion itself on CME bitcoin futures prices, such as whether there may be rapid inflows into, or outflows from, the Trust upon conversion, and how long any such impacts are expected to last.

[173] *See infra* note 237.

[174] *See infra* note 245 and accompanying text.

[175] *See infra* notes 245–246 and accompanying text.

[176] *See* Amendment No. 1, 87 FR at 28054.

[177] *See* Grayscale Submission, at 2.

[178] As of May 31, 2022, the value of open interest in the front two month CME BTC contracts was approximately $1.7 billion (source: CME Group).

[179] *See* VanEck Order, 86 FR at 64548–59; WisdomTree Order, 86 FR at 69332–33; Kryptoin Order, 86 FR at 74177; SkyBridge Order, 87 FR at 3879; Wise Origin Order, 87 FR at 5537; ARK 21Shares Order, 87 FR at 20025.

[180] *See* Amendment No. 1, 87 FR at 28055; Grayscale Letter I, at 7–13; Letter from Davis Polk & Wardwell LLP, on behalf of the Sponsor, dated Apr. 18, 2022 (''Grayscale Letter II'').

[181] Grayscale Letter I, at 4.

[182] *Id.* at 7. *See also* Amendment No. 1, 87 FR at 28055; Grayscale Letter II, at 2; Grayscale Submission, at 13–14; STA Letter, at 2 (''both types of products use similar processes for determining price on the underlying spot cash [b]itcoin markets'').

[183] Amendment No. 1, 87 FR at 28055. *See also* Grayscale Letter I, at 7; Grayscale Letter II, at 2; Grayscale Submission, at 13; Fortress Letter, at 2; Virtu Letter, at 3; Letter from Adam Kornfield, dated Feb. 15, 2022 (''Kornfield Letter''), at 1; Letter from Hashem Dezhbakhsh, Narasimhan Jegadeesh, and Juan Rubio-Ramirez, Emory University, dated April 24, 2022, at 2 (''Emory Letter''). The Sponsor states that the BRR and the Index have significant overlap in constituents, resulting in prices that track each other closely, with an average daily price difference over trailing 12 months of 0.04%. *See* Grayscale Submission, at 13. *See also* Whaley Letter, at 2–3 (presenting summary data relating to the Index and the BRR and concluding that ''XBX and BRR are near perfect substitutes'').

[184] *See* Grayscale Letter I, at 7. *See also, e.g.,* Letter from Paul Grewal, Chief Legal Officer, Coinbase, dated Dec. 14, 2021 (''Coinbase Letter I''), at 4 (''the reference rate used to price [b]itcoin contracts underlying futures-based ETPs is subject to the same pricing quality risks as the index used to price spot [b]itcoin and calculate net-asset value in spot ETPs.''); Letter from James J. Angel, Associate Professor of Finance, Georgetown University, dated Apr. 17, 2022 (''Angel Letter I''), at 6; Blockchain Association Letter, at 3.

[185] Grayscale Letter I, at 9.

that, because of this overlap, any potential fraud or manipulation in the underlying spot bitcoin market would impact both CME bitcoin futures ETFs and ETPs and spot bitcoin ETPs.[186] The Sponsor goes further, asserting that ''any'' fraud or manipulation in the underlying market ''will affect both products in the same way.'' [187]

Moreover, the Sponsor states that the Commission itself has recognized that ''the CME bitcoin futures market is not insulated from potential risks of fraud and manipulation in the underlying [b]itcoin market.'' [188] The Sponsor even asserts that, ''[i]f anything, derivatives markets present additional opportunities for manipulation on top of spot markets—which is why the derivatives markets have an additional layer of federal regulation to begin with.'' [189] According to the Sponsor, the Commission has never found there to be any meaningful difference in the risk of fraud or manipulation between spot bitcoin and bitcoin futures markets.[190] The Sponsor further asserts that, ''[e]ven with regulation by the CFTC, limiting ETP exposure to [b]itcoin futures does not address the risk of manipulation of underlying [b]itcoin spot market prices—unless the Commission's view is that CFTC regulation is adequate for all [b]itcoin spot markets, including those in which [the Trust] invests.'' [191]

Given that CME bitcoin futures ETFs currently trade, the Sponsor believes that the Commission's disapproval of the proposal would violate Section 6(b)(5) of the Exchange Act's prohibition against unfair discrimination among issuers, and would constitute an arbitrary and capricious administrative action in violation of the Administrative Procedure Act (''APA'').[192] According to the Sponsor, ''[t]he Commission has not offered any meaningful explanation for its differential treatment of these competing products.'' [193] The Sponsor argues that regulation of bitcoin futures ETFs under the 1940 Act offers no protections against fraudulent and manipulative trading in the underlying bitcoin market and provides no basis for treating bitcoin futures ETFs and spot bitcoin ETPs registered under the Securities Act differently.[194]

The Sponsor also argues that the Commission's standard violates the APA because it is illusory and cannot be satisfied.[195] According to the Sponsor, the framework that the Commission has articulated for assessing whether a proposal to list and trade any bitcoin-based ETP complies with the requirements of Exchange Act Section 6(b)(5) is ''so ill-defined and unachievable as to be arbitrary.'' [196] The Sponsor continues to state that ''[t]he Commission has never quantified a 'significant market' or 'market of significant size.' '' [197] Moreover, according to the Sponsor, the Commission ''has never defined or specified what would actually constitute 'unique resistance to manipulation' that is 'beyond the protections of the traditional commodities and equities markets,' nor has the Commission explained what it

[186] *See* Amendment No. 1, 87 FR at 28055. *See also* Grayscale Submission, at 14. Some commenters agree that bitcoin futures ETFs and ETPs pose identical risks of fraud and manipulation as spot bitcoin ETPs given their views that both products are priced based on the spot bitcoin price. *See, e.g.,* Blockchain Association Letter, at 2; Coinbase Letter I, at 3; Coinbase Letter II, at 7; Virtu Letter, at 3; Angel Letter I, at 5; BitGo Letter, at 2; Cumberland Letter, at 2; Letter from Carol R. Goforth, University Professor and Clayton N. Little Professor of Law, University of Arkansas, dated May 3, 2022 (''Goforth Letter''), at 1; Kornfield Letter, at 2; Letters from Brandon Gunderson (Feb. 4, 2022) (''Gunderson Letter''), at 2; Kenneth L. Keiffer, dated May 3, 2022 (''Keiffer Letter''), at 1; Robert L. DiLonardo and Donna S. DiLonardo, dated May 3, 2022 (''DiLonardo Letter''); Bridget Metzger (May 9, 2022) (''Metzger Letter''); Emory Letter, at 2; Letter from Sigal Mandelker and Jessi Brooks, Ribbit Capital, dated June 20, 2022 (''Ribbit Capital Letter''), at 5. An affiliate of the Custodian also states that prices and volumes in the bitcoin futures and spot bitcoin markets ''are highly correlated, indicating very similar market dynamics between the futures market, for which the Commission has approved a [CME bitcoin futures ETF], and the spot market.'' Coinbase Letter II, at 3.

[187] Grayscale Letter II, at 2.

[188] *Id.* (referring to the Teucrium Order, *supra* note 11). *See also* Grayscale Submission, at 14.

[189] *See* Grayscale Letter I, at 11. Some commenters make similar arguments. For example, a commenter states that ''spot markets may be less prone to manipulation given their daily notional volumes in the range of $35 billion, with futures volumes in the range of $1 billion daily notional.'' Virtu Letter, at 3. Another commenter states that an ETP that actually holds bitcoin would be less vulnerable to manipulation than an ETP that holds futures contracts because, with respect to bitcoin futures, there is the possibility of manipulation on the CME itself in addition to the spot bitcoin trading platforms. *See* Angel Letter I, at 6. Another commenter states that having a bitcoin futures ETF actually makes the derivatives markets more liquid and easy to manipulate than the spot market. *See* Dreyfuss Letter, at 2. *See also, e.g.,* Letter from Mary L. Holsinger, dated May 8, 2022.

[190] *See* Grayscale Letter I, at 11–12; Grayscale Letter II, at 2 (''The Commission's prior disapprovals of spot bitcoin ETPs have not identified any distinct and significant additional risk of fraud and manipulation that is somehow specific to spot [b]itcoin ETPs, and none exists.''). *See also, e.g.,* Blockchain Association Letter, at 3.

[191] Grayscale Letter I, at 11. *See also, e.g.,* Blockchain Association Letter, at 3; Coinbase Letter I, at 3; Ribbit Capital Letter, at 5.

[192] *See* Grayscale Letter I, at 8–9; 12–13; Grayscale Submission, at 23; Grayscale Letter II, at 2–4 (stating, among other things, that if the proposal ''were disapproved based on the 'significant market' test, without an independent evaluation of the proposal's compliance with Section 6(b)(5) in light of the [Teucrium Order], we believe the action would be inconsistent with the requirements of both the Exchange Act and the [APA]''). Some commenters agree that the Commission's disparate treatment of bitcoin futures ETFs and ETPs and spot bitcoin ETPs results in unfair discrimination amongst issuers in contravention of the Exchange Act and/or is arbitrary and capricious in violation of the APA. *See, e.g.,* Blockchain Association Letter, at 3–4, Coinbase Letter I, at 4; Virtu Letter, at 3; Angel Letter I, at 5; Fortress Letter, at 3; Kornfield Letter; Keiffer Letter; Metzger Letter; Goforth Letter, at 2; DiLonardo Letter; Letter from Michael D. Moffitt, dated Mar. 13, 2022 (''Moffitt Letter II) (citing transcript of Joseph Grundfest, former SEC Commissioner); Davenport Letter; Letter from John Carlson, dated Feb. 22, 2022; Ribbit Capital Letter, at 6; Letter from Alan J. Lane, Chief Executive Officer, Silvergate Capital Corporation, dated June 21, 2022. *See also, e.g.,* ADAM Letter, at 6 (''a disapproval of Arca's proposal would lead to the Commission picking winners based on its preferential treatment of one product over another''). A commenter asserts that ''it is not within [the Commission's mandate to regulate the spot commodity markets upon which ETPs are based[,]'' that ''Section 6(b)(5) neither mentions underlying markets, nor an exchange's obligations with respect to fraud within them[,]'' and ''[t]he Commission's apparent position that an exchange must mitigate fraud and manipulation in an underlying market, or be prohibited from listing a product based on a commodity in an underlying market subject to fraud and manipulation not in the exchange's control, stretches the Commission's authority beyond existing statutory language.'' *See* Ribbit Capital Letter, at 5.

[193] Grayscale Letter I, at 8. Some commenters agree that the Commission has not articulated a valid justification for treating bitcoin futures ETFs and ETPs and spot bitcoin ETPs differently. *See, e.g.,* Blockchain Association Letter, at 3–4; Coinbase Letter I, at 4; Cumberland Letter, at 2; STA Letter, at 2; Moffitt Letter II (citing transcript of Joseph Grundfest, former SEC Commissioner); Kornfield Letter; Goforth Letter; Chilson Letter, at 4.

[194] *See* Grayscale Letter I, at 9–11; Grayscale Submission, at 14. *See also, e.g.,* Blockchain Association Letter, at 3; Coinbase Letter I, at 5 n.11. The Sponsor states that the Commission's recent approval of bitcoin futures ETPs registered under the Securities Act ''confirms that 1940 Act registration is not a basis for the Commission to approve one product and reject another.'' *See* Grayscale Letter II, at 1 (referring to the Teucrium Order, *supra* note 11). *See also* Amendment No. 1, 87 FR at 28055; Goforth Letter, at 1–2.

[195] *See* Grayscale Letter I, at 12–13.

[196] *See id.* at 12. For a summary of the Commission's approach to considering proposals to list bitcoin-based ETPs, *see supra* notes 11–27 and accompanying text. Some commenters agree that the Commission's evaluation of spot bitcoin ETPs and bitcoin futures ETFs and ETPs is ambiguous and inconsistent. *See, e.g.,* Coinbase Letter I, at 4 (''when market participants compare the Commission's evaluation and approval of a futures-based [b]itcoin ETP to its treatment of spot [bitcoin] ETP proposals, they will see a lack of well-defined criteria and inconsistent application of the criteria''); Fortress Letter, at 2 (''While the Commission has stated that it considered each [spot bitcoin ETP] rule application 'on its own merits and under the standards applicable to it', the Commission has itself devised those standards ambiguously and inconsistently.'').

[197] Grayscale Letter I, at 12. *See also* Grayscale Letter II, at 3 (''the Commission's reluctance to quantify the size a market must achieve to be 'significant,' and its reluctance to articulate discernible standards for determining whether the market has the requisite linkage to the ETP's assets, renders this test subjective, arbitrary and effectively unachievable'').

means for resistance to be 'inherent' or 'novel' in this context.'' [198]

(ii) Analysis

The Commission disagrees with these assertions and conclusions. The proposed rule change does not relate to the same underlying holdings as either ETFs regulated under the 1940 Act that provide exposure to bitcoin through CME bitcoin futures, or CME bitcoin futures-based ETPs registered under the Securities Act but not regulated under the 1940 Act. The Commission considers the proposed rule change on its own merits and under the standards applicable to it. Namely, with respect to this proposed rule change, the Commission must apply the standards as provided by Section 6(b)(5) of the Exchange Act, which it has applied in connection with its orders considering previous proposals to list bitcoin-based commodity trusts and bitcoin-based trust issued receipts.[199]

In asserting that, for purposes of making a determination to approve or disapprove proposals to list and trade bitcoin futures and spot bitcoin ETPs, the Commission is drawing a distinction about the potential for fraud and manipulation in the CME bitcoin futures market vis-à-vis the spot bitcoin markets, the Exchange, Sponsor, and commenters mischaracterize the framework that the Commission has articulated in the Winklevoss Order. As stated in the Winklevoss Order, the Commission is not applying a ''cannot be manipulated'' standard—either on the CME bitcoin futures market or the spot bitcoin markets. Rather, as the Commission has repeatedly emphasized, and also summarized above, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, is placing the burden on NYSE Arca to demonstrate the validity of its contentions that bitcoin markets ''offer novel protections beyond those that exist in traditional commodity markets or equity markets'' such that the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin is unnecessary,[200] or to establish that it has entered into such a surveillance-sharing agreement.[201]

Consistent with this approach, contrary to the Exchange's, the Sponsor's, and some commenters' assertions, the Commission's consideration (and approval) of proposals to list and trade CME bitcoin futures ETPs, as well as the Commission's consideration (and thus far, disapproval) of proposals to list and trade spot bitcoin ETPs, does not focus on an assessment of the overall risk of fraud and manipulation in the spot bitcoin or futures markets, or on the extent to which such risks are similar.[202] Rather, the Commission's focus has been consistently on whether the listing exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying bitcoin assets of the ETP under consideration, so that it would have the necessary ability to detect and deter manipulative activity. For reasons articulated in the orders approving proposals to list and trade CME bitcoin futures-based ETPs (*i.e.,* the Teucrium Order and the Valkyrie XBTO Order), the Commission found that in each such case the listing exchange has entered into such a surveillance-sharing agreement.[203] Making the same assessment with respect to this proposed spot bitcoin ETP, however, as discussed and explained above, the Commission finds that NYSE Arca has not.

Specifically, for the CME bitcoin futures ETPs under consideration in the Teucrium Order and the Valkyrie XBTO Order, the proposed ''significant'' regulated market (*i.e.,* the CME) with which the listing exchange has a surveillance-sharing agreement is the *same* market on which the underlying bitcoin assets (*i.e.,* CME bitcoin futures contracts) trade. As explained in those Orders, the CME's surveillance can reasonably be relied upon to capture the effects on the CME bitcoin futures market caused by a person attempting to manipulate the CME bitcoin futures ETP by manipulating the price of CME bitcoin futures contracts, whether that attempt is made by directly trading on the CME bitcoin futures market or indirectly by trading outside of the CME bitcoin futures market.[204] Regarding the approved Teucrium Bitcoin Futures Fund in the Teucrium Order (''Fund''), for example, when the CME shares its surveillance information with NYSE Arca (the listing exchange for the Fund), the information would assist in detecting and deterring fraudulent or manipulative misconduct related to the non-cash assets held by the Fund.[205] Accordingly, the Commission explains in the Teucrium Order and the Valkyrie XBTO Order that it is unnecessary for a listing exchange to establish a

[198] Grayscale Letter I, at 13.

[199] *See supra* note 11 and accompanying text. The Sponsor also mischaracterizes the Teucrium Order. For example, the Sponsor states that the Teucrium Order ''reflects plainly the Commission's recognition that the CME bitcoin futures market is not insulated from potential risks of fraud and manipulation in the underlying [b]itcoin market,'' and that ''the Commission took pains to 'disagree[ ] with much of [NYSE] Arca's reasoning' about the [b]itcoin futures market's separation from the underlying [b]itcoin market.'' Grayscale Letter II, at 2. However, this discussion in the Teucrium Order addresses whether NYSE Arca had supported its claim that it is reasonably likely that a would-be manipulator of the CME bitcoin futures ETP that was the subject of the Teucrium Order would have to trade on the CME to manipulate that ETP. *See* Teucrium Order, 87 FR at 21679. In that context, NYSE Arca had not sufficiently supported its statements that the CME bitcoin futures market ''stands alone'' or that ''[b]itcoin futures prices are not specifically materially influenced by other [b]itcoin markets'' for the Commission to be persuaded by such statements. *See id.* at 21680.

[200] *See supra* note 60 and accompanying text.

[201] Although the Sponsor claims that the Commission has never defined or specified what would constitute ''unique resistance to manipulation'' that is ''beyond the protections of the traditional commodities and equities markets,'' or explained what it means for resistance to be ''inherent'' or ''novel,'' the Sponsor mischaracterizes the premise of its own argument. Listing exchanges, not the Commission, have argued that other means besides surveillance-sharing agreements may be sufficient to prevent fraudulent and manipulative acts and practices, including by asserting that the bitcoin market as a whole or the relevant underlying bitcoin market is ''uniquely'' and ''inherently'' resistant to fraud and manipulation. In response, the Commission has agreed with listing exchanges' posited hypothetical: that, *if* a listing exchange could establish that the underlying market inherently possesses a unique resistance to manipulation beyond the protections that are utilized by traditional commodity or securities markets—for which surveillance-sharing agreements in the context of listing derivative securities products have been consistently present—the exchange would not necessarily need to enter into a surveillance-sharing agreement with a regulated significant market related to the underlying bitcoin assets. *See* Winklevoss Order, 83 FR at 37580, 37582–91 (addressing assertions that ''bitcoin and bitcoin [spot] markets'' generally, as well as one bitcoin trading platform specifically, have unique resistance to fraud and manipulation). *See also* USBT Order, 85 FR at 12597. Furthermore, a listing exchange need not substantiate its claim that the underlying bitcoin market is uniquely and inherently resistant to fraud *in addition to* demonstrating that the listing exchange has a surveillance-sharing agreement with a regulated significant market related to the underlying bitcoin assets.

[202] The Commission's general discussion on the risk of fraud and manipulation in the spot bitcoin or futures markets is only in response to arguments raised by the proposing listing exchanges (or commenters) that mitigating factors against fraud and manipulation in the spot bitcoin or futures markets should compel the Commission to dispense with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying bitcoin assets. But even in such instance, the central issue is about the necessity of such a surveillance-sharing agreement, not the overall risk of fraud and manipulation in the spot bitcoin or futures markets, or the extent to which such risks are similar.

[203] *See* Teucrium Order, 87 FR at 21678–81; Valkyrie XBTO Order, 87 FR at 28850–53.

[204] *See* Teucrium Order, 87 FR at 21679; Valkyrie XBTO Order, 87 FR at 28851.

[205] *See* Teucrium Order, 87 FR at 21679.

reasonable likelihood that a would-be manipulator would have to trade on the CME itself to manipulate a proposed ETP whose only non-cash holdings would be CME bitcoin futures contracts.[206]

However, as the Commission also states in those Orders, this reasoning does not extend to spot bitcoin ETPs. Spot bitcoin markets are not currently ''regulated.'' [207] If an exchange seeking to list a spot bitcoin ETP relies on the CME as the regulated market with which it has a comprehensive surveillance-sharing agreement, the assets held by the spot bitcoin ETP would not be traded on the CME. Because of this significant difference, with respect to a spot bitcoin ETP, there would be reason to question whether a surveillance-sharing agreement with the CME would, in fact, assist in detecting and deterring fraudulent and manipulative misconduct affecting the price of the spot bitcoin held by that ETP. If, however, an exchange proposing to list and trade a spot bitcoin ETP identifies the CME as the regulated market with which it has a comprehensive surveillance-sharing agreement, the exchange could overcome the Commission's concern by demonstrating that there is a reasonable likelihood that a person attempting to manipulate the spot bitcoin ETP would have to trade on the CME in order to manipulate the ETP, because such demonstration would help establish that the exchange's surveillance-sharing agreement with the CME would have the intended effect of aiding in the detection and deterrence of fraudulent and manipulative misconduct related to the spot bitcoin held by the ETP.[208]

Because, here, NYSE Arca is seeking to list a spot bitcoin ETP that relies on the CME as the purported ''significant'' regulated market with which it has a comprehensive surveillance-sharing agreement, the assets held by the proposed ETP would *not* be traded on the CME. Thus there is reason to question whether a surveillance-sharing agreement with the CME would, in fact, assist in detecting and deterring fraudulent and manipulative misconduct affecting the price of the spot bitcoin held by the proposed ETP.[209] The Exchange could have overcome this concern by demonstrating that there is a reasonable likelihood that a person attempting to manipulate the proposed ETP would have to trade *on the CME* in order to manipulate the ETP because such demonstration would help establish that the Exchange's surveillance-sharing agreement with the CME would have the intended effect of aiding in the detection and deterrence of fraudulent and manipulative misconduct related to the spot bitcoin held by the proposed ETP.[210] As discussed and explained above,[211] the Commission finds that NYSE Arca has not made such demonstration.

To the extent that the Sponsor—by way of claiming that, ''[b]ecause both spot and futures-based [b]itcoin products face exposure to the same underlying [b]itcoin market, any fraud or manipulation in the underlying market will affect both products in the same way'' [212]—is arguing that the CME's surveillance would, in fact, assist in detecting and deterring fraudulent and manipulative misconduct that impacts spot bitcoin ETPs in the same way as it would for misconduct that impacts the CME bitcoin futures ETFs/ETPs, the information in the record for this filing does not support such a claim. Specifically, the Sponsor claims that (i) CME bitcoin futures ETFs/ETPs are ''priced according to the [BRR];'' (ii) the proposed spot bitcoin ETP would be priced based on the Index; and (iii) because of the ''almost complete overlap'' between the spot platforms whose prices are used to calculate the BRR and the Index, bitcoin futures ETFs/ETPs and the proposed ETP are subject to the ''same risks relating to pricing data quality.'' [213] This logic, however, is flawed for the following reasons.

First, there is no evidence in the record that CME bitcoin futures ETFs/ETPs are ''priced according to the [BRR].'' The BRR is a once-a-day reference rate of the U.S. dollar price of one bitcoin as of 4 p.m., London time.[214] The BRR aggregates the trade flow of its constituent spot bitcoin platforms—Coinbase, Gemini, LMAX Digital, itBit, Kraken, and Bitstamp [215]—during a specific one-hour calculation window.[216] While the BRR is used to value the final cash settlement of CME bitcoin futures contracts, it is not generally used for daily cash settlement of such contracts,[217] nor is it claimed to be used for any intra-day trading of such contracts. In addition, CME bitcoin futures ETFs/ETPs do not hold their CME bitcoin futures contracts to final cash settlement; rather, the contracts are rolled prior to their settlement dates. Moreover, the shares of CME bitcoin futures ETFs/ETPs trade in secondary markets, and there is no evidence in the record for this filing that such intra-day, secondary market trading prices are determined by the BRR.

Second, there is no evidence in the record that the Shares' prices would be determined by the Index. The Index is a U.S. dollar-denominated composite reference rate for the price of bitcoin calculated at 4:00 p.m. New York time.[218] As described above, the Index applies an algorithm to the price of bitcoin on the Constituent Platforms—Coinbase Pro, LMAX Digital, Kraken, and Bitstamp—calculated on a per second basis over a 24-hour period. While the Index is used daily to value the bitcoins held by the Trust,[219] as discussed above,[220] the Index would not be used for the creation or redemption of Shares, nor is the Index claimed to be used for any intra-day secondary market trading of the Shares, either currently on the OTC market or in the future on the Exchange. Rather, the Share price is discovered through continuous intra-day, secondary market interactions of buy and sell interests.[221]

[206] *See id.*

[207] *See* Teucrium Order, 87 FR at 21679 n.46 (citing USBT Order, 85 FR at 12604; NYDIG Order, 87 FR at 14936 nn.65–67). *See also* Valkyrie XBTO Order, 87 FR at 28851 n.42.

[208] *See* Teucrium Order, 87 FR at 21679 n.46; Valkyrie XBTO Order, 87 FR at 28851 n.42.

[209] *See* Teucrium Order, 87 FR at 21679 n.46; Valkyrie XBTO Order, 87 FR at 28851 n.42. There is reason to question whether the CME's surveillance would capture manipulation of spot bitcoin that occurs off of the CME, if, for example, off-CME manipulation of spot bitcoin does not also similarly impact CME bitcoin futures contracts. As discussed further below, *see infra* notes 224–225 and accompanying text, the information in the record for this filing does not sufficiently demonstrate that attempted manipulation of spot bitcoin would also similarly impact CME bitcoin futures contracts.

[210] *See* Teucrium Order, 87 FR at 21679 n.46; Valkyrie XBTO Order, 87 FR at 28851 n.42.

[211] *See* Section III.B.2.i, *supra.*

[212] Grayscale Letter II, at 2.

[213] *See id.* at 7, 9.

[214] *See https://docs-cfbenchmarks.s3.amazonaws.com/CME+CF+Reference+Rates+Methodology.pdf.*

[215] *See https://docs-cfbenchmarks.s3.amazonaws.com/CME+CF+Constituent+Exchanges.pdf.*

[216] *See https://www.cmegroup.com/education/courses/introduction-to-bitcoin/introduction-to-bitcoin-reference-rate.html.* This one-hour window is partitioned into 12, five-minute intervals, where the BRR is calculated as the equally-weighted average of the volume-weighted medians of all 12 partitions. *See id.*

[217] Under normal procedures, daily cash settlements are generally based on the volume-weighted average price of trading activity on CME Globex between 2:59 p.m. and 3:00 p.m., Central Time). *See https://www.cmegroup.com/confluence/display/EPICSANDBOX/Bitcoin* for a description of CME bitcoin futures daily settlement procedures.

[218] *See* Amendment No. 1, 87 FR at 28047.

[219] *See id.* at 28047, 28049.

[220] *See supra* notes 132–133 and accompanying text.

[221] As discussed above, the use of the Index by the Trust to determine the value of its bitcoin does not support the finding that the Exchange has established other means to prevent fraud and manipulation that are sufficient to justify

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Third, despite the Sponsor's claim of ''almost complete overlap'' between the spot platforms whose prices are used to calculate the BRR and those platforms whose prices are used for the Index, the BRR includes trade flow from Gemini and itBit, neither of which are included as Constituent Platforms of the Index.[222]

In short, and importantly, although the Exchange and the Sponsor focus heavily on the similarities between the BRR and the Index, there is no evidence in the record that the shares of any CME bitcoin futures ETF/ETP, or the Shares of the proposed spot bitcoin ETP, would trade in the secondary market at a price related to (or informed by) the BRR or the Index.[223]

Fourth, the Commission's determination in the Teucrium Order and the Valkyrie XBTO Order to approve the listing and trading of the relevant CME bitcoin futures ETPs was not based on the ETPs' use—or lack of use—of the BRR (or any other similar pricing mechanism) for the calculation of NAV, or on the fact that the BRR is used for the final cash settlement of CME bitcoin futures contracts. Rather, as discussed above, the Commission approved the listing and trading of such CME bitcoin futures ETPs, not because of the BRR, but because the Commission found that the listing exchanges satisfy the requirement pertaining to a surveillance-sharing agreement with a regulated market of significant size related to the underlying bitcoin assets—which for such ETPs are CME bitcoin futures contracts, not spot bitcoin.

Fifth, even if the Exchange or the Sponsor had demonstrated a link between the BRR and/or the Index and the prices of CME bitcoin futures ETFs/ETPs and/or the proposed ETP, which they have not, it does not necessarily follow that the CME's surveillance would, in fact, assist in detecting and deterring fraudulent and manipulative misconduct that impacts spot bitcoin ETPs in the same way as it would for misconduct that impacts the CME bitcoin futures ETFs/ETPs—particularly when such misconduct occurs off of the CME itself.[224] For example, even assuming, for the sake of argument, that the BRR and/or the Index is a potential link between prices on certain spot bitcoin platforms and CME bitcoin futures prices, it does not—absent supporting data—necessarily follow that *any* manipulation that impacts spot bitcoin *also similarly* impacts CME bitcoin futures contracts. Neither the Sponsor nor the Exchange has provided any analysis or data that assesses the reaction (if any) of CME bitcoin futures contracts to instances of fraud and manipulation in spot bitcoin markets. Indeed, the only analysis that the Sponsor itself provides is a summary of its lead/lag analysis comparing CME bitcoin futures prices with the Index, from which the Sponsor concludes that ''there does not appear to be a significant lead/lag relationship between the two instruments.'' [225]

In addition, the disapproval of the proposal would not violate the requirement in Section 6(b)(5) of the Exchange Act [226] that the rules of an exchange not be designed to permit unfair discrimination between issuers, nor would it constitute an arbitrary and capricious administrative action in violation of the APA.[227] Importantly, the issuers are not similarly situated. The issuers of CME bitcoin futures-based ETPs propose to hold only CME bitcoin futures contracts (which are traded on the CME itself) as their only non-cash holdings, and the Trust proposes to hold only spot bitcoin (which is not traded on the CME). As explained in detail above and in the Teucrium Order and the Valkyrie XBTO Order, because of this important difference, for a spot bitcoin ETP, there is reason to question whether a surveillance-sharing agreement with the CME would, in fact, assist in detecting and deterring fraudulent and manipulative misconduct affecting the price of the spot bitcoin held by that ETP.[228] And as discussed above, neither the Exchange, nor the Sponsor, nor any other evidence in the record for this filing, sufficiently demonstrates that the CME's surveillance can be reasonably relied upon to capture the effects of manipulation of the *spot* bitcoin assets underlying the proposed ETP when such manipulation is not attempted on the CME itself.

Moreover, the analytical framework for assessing compliance with the requirements of Exchange Act Section 6(b)(5) that the Commission applies here (*i.e.,* comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying bitcoin assets) is the same one that the Commission has applied in each of its orders considering previous proposals to list bitcoin-based

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dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin. *See* Section III.B.1.ii, *supra*. Likewise, the Commission has previously rejected arguments by listing exchanges that the use of a reference rate similar to the BRR to value bitcoin held by proposed spot bitcoin ETPs provides other means to prevent fraud and manipulation that are sufficient to justify dispensing with the detection and deterrence of fraud and manipulation provided by a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin. *See* Wise Origin Order, 87 FR at 5532–33; SkyBridge Order, 87 FR at 3877. Accordingly, the Index and the BRR, and the similarities between the BRR and the Index, are not informative in the Commission's determination of whether the Exchange has established other means to prevent fraud and manipulation.

[222] Although the Sponsor states that the BRR is ''determined according to pricing data collected from digital asset trading platforms that include all but one of those currently incorporated into [the Index]'' (Grayscale Letter I, at 7), based on information provided on the CME's website, the Sponsor's statement does not appear to be correct. *See https://www.cmegroup.com/markets/cryptocurrencies/cme-cf-cryptocurrency-benchmarks.html?redirect=/trading/cryptocurrency-indices/cf-bitcoin-reference-rate.html*. It is also unclear from the record whether Coinbase (used by the BRR) and Coinbase Pro (used by the Index) are the same platform. Based on recent press articles, it appears that Coinbase Pro will be discontinued. *See, e.g., https://cointelegraph.com/news/coinbase-to-shut-down-coinbase-pro-to-merge-trading-services; https://www.forbesindia.com/article/crypto-made-easy/coinbase-to-shut-down-coinbase-pro-to-merge-trading-services/77585/1#:~:text=Coinbase%20Pro%2C%20the%20professional,them%20into%20a%20single%20platform.*

[223] A commenter provides a correlation analysis, using daily price information between November 2021 and February 2022, which purports to show high correlation (99.9%) between the price of CME bitcoin futures contracts and a Coinbase spot price. *See* Coinbase Letter II, at 7 and Figure 6. The same commenter also provides correlation analysis, using daily price information between December 2021 and February 2022, which purports to show high correlation between the prices of various non-U.S. spot bitcoin ETPs and a Coinbase spot price. *See id.* at 8–9 and Figures 11–16. The commenter, however, does not provide evidence with respect to price correlation between shares of CME bitcoin futures ETFs and the BRR or between the prices of various non-U.S. spot bitcoin ETPs and the Index. Nor does correlation analysis, at daily intervals, provide evidence of the causal economic relationship of interest: namely, whether fraud or manipulation that impacts spot bitcoin would also similarly impact CME bitcoin futures contracts. *See infra* notes 224–225 and accompanying text.

[224] *See also supra* note 209.

[225] *See* Amendment No. 1, 87 FR at 28054.

[226] 15 U.S.C. 78f(b)(5).

[227] The Sponsor argues that disapproval of the proposal would constitute merit regulation, which is not authorized under the Exchange Act. *See* Grayscale Letter I at 14–15. In addition, the affiliate of the Custodian states that ''the Commission's role is not to evaluate the characteristics and quality of the underlying [b]itcoin market but instead to evaluate the [proposed] ETP, and the role that [NYSE] Arca would play in monitoring trading in [the Shares].'' Coinbase Letter I, at 5. *See also, e.g.,* ADAM Letter, at 6; Ribbit Capital Letter, at 5. As previously stated, the Commission is disapproving this proposed rule change because NYSE Arca has not met its burden to demonstrate that its proposal is consistent with the requirements of Exchange Act Section 6(b)(5). The Commission's disapproval of this proposed rule change does not rest on an evaluation of the relative investment quality of a product holding spot bitcoin versus a product holding CME bitcoin futures, or an assessment of whether bitcoin, or blockchain technology more generally, has utility or value as an innovation or an investment. *See, e.g.,* Winklevoss Order, 83 FR at 37580; USBT Order, 85 FR at 12597; One River Order, 87 FR at 33550.

[228] *See supra* notes 208–209 and accompanying text.

commodity trusts and trust issued receipts.[229] The Commission has applied this framework to each proposal by analyzing the evidence presented by the listing exchange and statements made by commenters.[230] Although the Sponsor states that the Commission's approach to assessing compliance with Section 6(b)(5) has created a standard that cannot be satisfied and therefore violates the APA, the Commission has in fact recently approved proposals by the Exchange and the Nasdaq Stock Market to list and trade shares of ETPs holding CME bitcoin futures as their only non-cash holdings.[231] And in the orders approving these CME bitcoin futures-based ETPs, the Commission explicitly discussed how an exchange seeking to list and trade a spot bitcoin ETP could overcome the lack of a one-to-one relationship between the regulated market with which it has a surveillance-sharing agreement and the market(s) on which the assets held by a spot bitcoin ETP could be traded: by demonstrating that there is a reasonable likelihood that a person attempting to manipulate the spot bitcoin ETP would have to trade on the regulated market (*i.e.,* on the CME) to manipulate the spot bitcoin ETP.[232]

When considering past proposals for spot bitcoin ETPs, the Commission has, in particular, reviewed the econometric and/or statistical evidence in the record to determine whether the listing exchange's proposal has met the applicable standard.[233] The Commission's assessment fundamentally presents quantitative, empirical questions, but, as discussed above, the Exchange has not provided evidence sufficient to support its arguments. Instead, the Exchange and the Sponsor make various assertions that are not supported by the limited data in the record regarding, among other things, trading volume and bitcoin market capitalization, or the relationship between spot bitcoin prices and CME bitcoin futures prices (including the lead/lag relationship between the spot market and the CME bitcoin futures market), and the record contains insufficient empirical analysis or quantitative evidence of any such data to support the Exchange's conclusions.[234]

The requirements of Section 6(b)(5) of the Exchange Act apply to the rules of national securities exchanges. Accordingly, the relevant obligation to have a comprehensive surveillance-sharing agreement with a regulated market of significant size related to spot bitcoin, or other means to prevent fraudulent and manipulative acts and practices that are sufficient to justify dispensing with such a surveillance-sharing agreement, resides with the listing exchange. Because there is insufficient evidence in the record demonstrating that NYSE Arca has satisfied this obligation, the Commission cannot approve the proposed ETP for listing and trading on NYSE Arca.

C. Whether NYSE Arca Has Met Its Burden to Demonstrate That the Proposal Is Designed to Protect Investors and the Public Interest

NYSE Arca contends that, if approved, the proposed ETP would protect investors and the public interest. However, the Commission must consider these potential benefits in the broader context of whether the proposal meets each of the applicable requirements of the Exchange Act.[235] Because NYSE Arca has not demonstrated that its proposed rule change is designed to prevent fraudulent and manipulative acts and practices, the Commission must disapprove the proposal.

(1) Assertions Made and Comments Received

Commenters argue that the Commission should approve the proposal because doing so would satisfy investor demand for a U.S. regulated investment vehicle with direct exposure to bitcoin.[236] Commenters state that approval of a spot bitcoin ETP would provide a simpler, safer, and more efficient way to obtain exposure to bitcoin than the products that are currently available to retail investors, such as holding spot bitcoin, OTC bitcoin funds, bitcoin futures funds, or foreign bitcoin funds.[237] Some commenters state that approving a spot bitcoin ETP would reduce the custody and cybersecurity risks to investors of holding physical bitcoin.[238]

Several commenters argue that a spot bitcoin ETP would provide lower costs and less risk than bitcoin futures ETPs.[239] The Sponsor and some

[229] *See supra* notes 11–24 and accompanying text.

[230] *See supra* note 11.

[231] *See* Teucrium Order and Valkyrie XBTO Order, *supra* note 11.

[232] *See supra* note 208 and accompanying text.

[233] *See, e.g.,* USBT Order, 85 FR at 12612–13; VanEck Order, 86 FR at 64547–48; WisdomTree Order, 86 FR at 69330–32; Kryptoin Order, 86 FR at 74175–76; NYDIG Order, 87 FR at 14938–39; Wise Origin Order, 87 FR at 5534–36; Global X Order, 87 FR at 14919–20; ARK 21Shares Order, 87 FR at 20023–24.

[234] *See* Sections III.B.1 & III.B.2, *supra.*

[235] *See* Winklevoss Order, 83 FR at 37602. *See also* GraniteShares Order, 83 FR at 43931; ProShares Order, 83 FR at 43941; USBT Order, 85 FR at 12615; WisdomTree Order, 86 FR at 69333; Valkyrie Order, 86 FR at 74163; Kryptoin Order, 86 FR at 74178; SkyBridge Order, 87 FR at 3880; Wise Origin Order, 87 FR at 5537.

[236] *See, e.g.,* Blockchain Association Letter, at 1–2; Virtu Letter, at 2–4; BitGo Letter, at 1–2; STA Letter, at 2–3; ADAM Letter, at 3–4; Harvey Letter, at 1–3; Shultz Letter; Letter from Neil Chilson and Jonathan M. Zalewski, dated May 31, 2022 (''Chilson Letter''), at 3; Letter from Jody Cryder, dated Apr. 25, 2022; Letter from Rich Seils, dated Apr. 25, 2022 (''Seils Letter''); Letter from Grant Johnson, dated Mar. 4, 2022 (''Johnson Letter''); Letter from Evelyne Dandurand, dated Feb. 18, 2022; Letter from David Brown, dated Apr. 19, 2022; Letter from Mark Reid, dated Feb. 28, 2022; Letter from William McPherson, dated Mar. 1, 2022; Letter from Jalen Rose, dated Mar. 2, 2022; Letter from Brandon Gillet, dated Feb. 22, 2022; Letter from Clint Jasperson, dated Feb. 18, 2022; Letter from Jason Miller, dated Feb. 17, 2022 (''Miller Letter''); Letter from Michael Bielik, dated Feb. 18, 2022; Letter from Joseph DeFilippis, dated Feb. 15, 2022; Letter from Peter C., dated Feb. 15, 2022; Letter from James P. Scofield, dated Feb. 14, 2022; Letter from Chris Smalley, dated Feb. 10, 2022; Letter from Nico Peruzzi, dated Feb. 5, 2022; Letter from Matt Robins, dated May 10, 2022. *See also* Grayscale Submission, at 10.

[237] *See, e.g.,* ADAM Letter, at 3–4; Harvey Letter, at 1–3; BitGo Letter, at 1–2; Discovery Letter, at 2; Angel Letter, at 6–7; Johnson Letter; Letter from Logan Kane, Writer, Seeking Alpha, dated Feb. 19, 2022 (''Kane Letter''); Letter from Michael Falk, dated Feb. 15, 2022; Letter from Andrew Farinelli, dated Feb. 10, 2022 (''Farinelli Letter''); Letter from Boris Hristov, dated May 18, 2022; Letter from Paul Smith, dated Feb. 28, 2022; Letter from Luke Groom, dated Feb. 22, 2022; Emory Letter, at 2. In addition, some commenters state that a spot bitcoin ETP would be just as, or less risky than, other investments already trading in the U.S. *See, e.g.,* Dreyfuss Letter; Miller Letter; Letter from Derek Serlet, dated Apr. 27, 2022; Letter from Monty Henry, dated Feb. 7, 2022 (''Henry Letter''); Letter from Alexander, dated Feb. 22, 2022; Letter from Martin Baer, dated Feb. 15, 2022; Letter from Gage Gorda, dated Feb. 14, 2022; Letter from Branon White, dated Feb. 10, 2022; Letter from Nikolas Garcia, dated Mar. 4, 2022 (''Garcia Letter'').

[238] *See, e.g.,* Angel Letter I, at 8; ADAM Letter; Kane Letter; Henry Letter; Letter from Tim Crick, dated Mar. 21, 2022; Letter from Michael David Spadaccini, dated Feb. 7, 2022; Letter from Michael A. Rheintgen, dated Feb. 24, 2022; Letter from Richard Arrett, dated Feb. 22, 2022 (''Arrett Letter''); Letter from Brian Boerner, dated Feb. 14, 2022; Letter from William Perez, dated Feb. 12, 2022 (''Perez Letter''); Letter from Henry Chen, dated Feb. 26, 2022 (''Chen Letter'').

[239] *See, e.g.,* Blockchain Association Letter, at 2 (''while bitcoin futures ETPs have certain useful features, they are inferior investment products for many Americans due to their relatively higher cost and risk profile''); Angel Letter I, at 6–7 (stating that ''[a] physical-based product in which the fund actually holds the bitcoin is far less vulnerable to manipulation than the futures contracts'' and that CME futures contracts experience roll costs, lack liquidity, and have wide bid-ask spreads); Letter from Murray Stahl, Chief Investment Officer, Horizon Kinetics Asset Management LLC, dated Apr. 8, 2022 (''Horizon Kinetics Letter''), at 1–2 (stating that a futures-based bitcoin ETP is not suitable for long-term investors since the performance deviates greatly from the underlying asset and that a spot bitcoin ETP would eliminate such a tracking error); Fortress Letter, at 2–3 (''Futures ETFs present investors with a more costly and complex means of gaining exposure to [b]itcoin while reflecting only a small portion of the actual market for the digital asset''); Letter from Benjamin

Continued

commenters assert that disapproving spot bitcoin ETPs after approving bitcoin futures ETFs and ETPs harms investors.[240] In addition, the Sponsor states that bitcoin futures ETPs present certain structural disadvantages over spot bitcoin ETPs, such as monthly roll-costs [241] and risks due to position limits.[242]

Commenters also emphasize that conversion of the existing Trust to an ETP structure would be beneficial to its investors. The Sponsor, for example, states that the Trust has grown to become the largest publicly-traded digital asset fund in the world [243] and that approving the Trust to operate as an ETP traded on a national securities exchange ''will provide investors with the additional protections of [the Commission] and [NYSE Arca] while unlocking billions of value for investors.'' [244] Moreover, according to the Sponsor, converting the Trust into an ETP would allow the Shares to better track the Trust's NAV and reduce discounts and premiums, thereby unlocking approximately $8 billion in value for investors.[245] Similarly, commenters state that the proposal would protect investors and help maintain fair and orderly markets by reducing premium and discount volatility with respect to the Shares, thereby allowing investors to gain access to bitcoin through an ETP structure at trading prices that are more closely aligned with spot bitcoin trading prices.[246] Moreover, other commenters state that approving the proposal and allowing the Trust to convert into an ETP would protect investors by, among other things, lowering fees and providing heightened regulation of the Shares.[247]

Several commenters further state that approval of a spot bitcoin ETP would enhance the liquidity, price discovery, and efficiency of the underlying bitcoin markets.[248] The affiliate of the Custodian states that the introduction of a spot bitcoin ETP with a robust create and redeem arbitrage process can improve the price efficiency of an underlying asset and thus further increase the resilience of bitcoin trading in the spot market.[249] This commenter believes the presence of a spot bitcoin ETP ''may bolster and stabilize the broader [b]itcoin derivatives market by encouraging a . . . greater volume of activity and easier arbitrage between the two markets.'' [250]

Finally, some commenters argue that the proposal should be approved because doing so would enhance investor choice,[251] improve market structure and competition for the benefit of investors,[252] and facilitate capital formation.[253]

T. Fulton, CEO, Elkhorn Consulting, LLC, dated Apr. 27, 2022 (''Elkhorn Letter''), at 2–3; Harvey Letter, at 3; Whaley Letter, at 3–7; Letter from Charles Hwang, Jason Albanese, Jock Percy, General Partners, Lightning Capital, dated Mar. 21, 2022 (''Lightning Capital Letter''), at 2–3; Discovery Letter, at 2 (''a spot [b]itcoin ETP would provide a much better vehicle for investors due to the vast liquidity, lower cost, and transparent Index pricing than the current [f]utures based ETPs''); Kane Letter; Letter from Ryan Wilday, dated Feb. 17, 2022; Letter from Michael Douglas Magee, dated Apr. 19, 2022; Letter from Bryan Kelley, dated May 10, 2022.

[240] *See, e.g.,* Grayscale Letter I, at 13–14 (''Continued disparate treatment of [b]itcoin futures ETPs and spot [b]itcoin ETPs would harm—rather than protect—investors by limiting their choices without a reasoned basis.''); Cumberland Letter, at 1–2; Harvey Letter, at 2–3; Lightning Capital Letter, at 1–3; ADAM Letter, at 6; Fortress Letter, at 2; Letter from Justin Valdata, dated Apr. 22, 2022 (''Valdata Letter''). A commenter argues that such disparate treatment may undermine confidence in the Commission and stifle innovation in the bitcoin and securities markets. *See* Coinbase Letter I, at 4.

[241] *See* Grayscale Letter I, at 14. The Sponsor states that one analysis showed that over the last year, a bitcoin futures ETP would have lost 28% of its value just on roll costs (effectively, fees and expenses being equal, a spot ETP would have performed around 28% better). *See id.* (citing Michael J. Casey, Why a Bitcoin Futures ETF is Bad for Investors, CoinDesk (last updated Oct. 22, 2021 at 4:29 p.m.), *https://www.coindesk.com/policy/2021/10/22/why-a-bitcoin-futures-etf-is-bad-for-investors/*). *See also, e.g.,* Blockchain Association Letter, at 2; Angel Letter I, at 7; Harvey Letter, at 3; Elkhorn Letter, at 2; Fortress Letter, at 1–2; BitGo Letter, at 1–2; Horizon Kinetics Letter, at 1–2.

[242] *See* Grayscale Letter I, at 14. According to the Sponsor, position limits can cause a bitcoin futures ETP to experience liquidity problems or losses, or have to halt new creations or increase its fixed-income portfolio, thereby introducing tracking error by diluting its exposure to bitcoin. The Sponsor states that, alternatively, the CME may have to raise position limits to accommodate increased demand in the absence of a spot bitcoin ETP alternative, potentially increasing the concentration of economic power of a few large market participants in the bitcoin futures markets and reducing the resiliency of those markets against manipulation. The Sponsor states that ''[t]hese risks—that [b]itcoin futures ETPs could be constrained by position limits and that the CME may raise those limits—are not purely speculative; indeed, both have already occurred since the first [b]itcoin futures ETP began trading.'' *Id. See also, e.g.,* Blockchain Association Letter, at 2 (''Futures ETPs are also subject to additional, unique risks related to position limits, limited liquidity, dilution and other factors.'').

[243] *See* Grayscale Submission, at 2.

[244] *Id.* at 17.

[245] *See id.* at 9. The Sponsor states that, because the Shares are not currently listed on a national securities exchange and the Trust is therefore not permitted to operate an ongoing creation and redemption program, arbitrage opportunities resulting from differences between the price of the Shares and the price of bitcoin are not available to keep the price of the Shares closely linked to the Index Price for bitcoin. As a result, the Shares are usually quoted at a premium over, or discount to, the value of the Trust's bitcoin holdings. *See* Grayscale Letter I, at 5. *See also* Coinbase Letter I, at 2.

[246] *See, e.g.,* Coinbase Letter I, at 2–3; Virtu Letter, at 2; Angel Letter I, at 7–8; BitGo Letter, at 1; ADAM Letter, at 4–5; Cumberland Letter, at 1; Lightning Capital Letter, at 1–2; Gunderson Letter; Discovery Letter, at 1; Henry Letter; Keiffer Letter; Perez Letter; DiLonardo Letter; Kornfield Letter; Garcia Letter; Johnson Letter; Arrett Letter; Emory Letter, at 2; Letter from Richard Leo, dated Apr. 22, 2022; Letter from Joseph McDevitt, dated Apr. 22, 2022; Letter from Mitchell J. Brodie, dated Apr. 22, 2022; Letter from Steve Axel, dated Feb. 18, 2022; Letter from Brent Zeigler, dated Feb. 19, 2022; Letter from Jonas Lippuner, dated Apr. 21, 2022; Letter from David Lynch, dated Mar. 3, 2022; Letter from David New, dated Feb. 23, 2022; Letter from Roger A. Rector, dated Feb. 22, 2022; Letter from Michael Charles, dated Feb. 19, 2022; Letter from Scott Egon Roge, dated Feb. 15, 2022; Letter from Ozeir Nassery, dated Feb. 11, 2022; Letter from Raj Lakkundi, dated Feb. 11, 2022. The affiliate of the Custodian states that the performance of spot bitcoin ETPs in other countries confirms the ability of a spot bitcoin ETP to appropriately reflect the underlying bitcoin market. *See* Coinbase Letter II, at 3, 8. *See also* Virtu Letter, at 2 (''In our experience as a market maker and AP in spot cryptocurrency ETPs in Canada, we have observed the positive impact of these dynamics—as spot cryptocurrency ETP spreads to NAV are compressed to levels observed for non-crypto ETPs.'').

[247] *See, e.g.,* Angel Letter I, at 7–8; Horizon Kinetics Letter, at 2–3; Shultz Letter; Johnson Letter; Arret Letter; Roge Letter; Perez Letter; Letter from Keith Arvidson, dated Apr. 5, 2022; Letter from Rick Parker, dated Feb. 22, 2022; Letter from Michael J. Sheslow, dated Feb. 22, 2022; Letter from Omid Jafari, dated Feb. 18, 2022; Letter from Richard Payne, dated Feb. 19, 2022; Letter from Sunjeev Konduru, dated Mar. 16, 2022 (''Konduru Letter'').

[248] *See, e.g.,* Cammarata Letter, Coinbase Letter I, at 3; Coinbase Letter II, at 7; Fortress Letter, at 3; Harvey Letter, at 5 (stating ''financial derivatives, including ETPs, can generally serve to enhance the liquidity and efficiency of the markets for many asset classes and currencies, including bitcoins'' and ''[i]t is difficult to imagine a scenario in which approval of [the Trust] as a bona fide ETP on the NYSE Arca would not increase the number of market participants, dollar-denominated liquidity, and other competitive forces that would lead to more efficient price discovery than currently exists in a semi-fragmented, global bitcoin spot market that lacks a regulated, centralized trading venue or order book''); Fortress Letter, at 3 (stating that the Trust can serve an important price discovery purpose and that, because of its size, the Trust will create additional liquidity and will allow for greater transparency and efficiency in the bitcoin market); Dreyfuss Letter, at 2 (stating that ''increasing the liquidity of [the spot bitcoin] markets would actually reduce the influence of predatory forces by encouraging long term ownership across a broader spectrum of investors'').

[249] *See* Coinbase Letter I, at 3.

[250] Coinbase Letter II, at 7.

[251] *See, e.g.,* Blockchain Association Letter, at 1; Letter from David Noble, Director, The Werth Institute, University of Connecticut, dated Apr. 26, 2022 (''Noble Letter''); Letter from John Shinkunas, dated Apr. 10, 2022; Letter from Karl J. Randall, dated Feb. 28, 2022; Letter from Reginald M. Browne, Principal, GTS Securities, LLC, dated June 10, 2022 (''GTS Letter''), at 2.

[252] *See, e.g.,* BitGo Letter, at 1;Virtu Letter, at 3–4; Groom Letter; Egan Letter; Angel Letter I; Chilson Letter; GTS Letter, at 2.

[253] *See, e.g.,* Harvey Letter, at 5 (''as an ETP on the NYSE Arca, [the Trust] would continue to serve as a liquid, but even more regulated conduit for capital formation within the bitcoin ecosystem''); ADAM Letter, at 5 (stating that approval of the proposal would facilitate the Commission's mission of promoting capital formation); GTS Letter, at 2; Emory Letter, at 1–2 (stating that disapproval of the proposal would be ''contrary to the goal of equitable access to means of wealth generation'').

(2) Analysis

The Commission disagrees. Here, even if it were true that, compared to trading in unregulated spot bitcoin markets or OTC bitcoin funds, trading a spot bitcoin-based ETP on a national securities exchange could provide some additional protection to investors, or that the Shares would provide more efficient exposure to bitcoin than other products on the market such as bitcoin futures ETPs, or that approval of a spot bitcoin ETP could enhance competition or strengthen the underlying spot bitcoin and derivatives markets, the Commission must consider this potential benefit in the broader context of whether the proposal meets each of the applicable requirements of the Exchange Act.[254] Pursuant to Section 19(b)(2) of the Exchange Act, the Commission must approve a proposed rule change filed by a national securities exchange if it finds that the proposed rule change is consistent with the applicable requirements of the Exchange Act—including the requirement under Section 6(b)(5) that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices—and it must disapprove the filing if it does not make such a finding.[255] Thus, even if a proposed rule change purports to protect investors from a particular type of investment risk—such as experiencing a potentially high premium/discount by investing in an OTC bitcoin fund or roll costs by investing in bitcoin futures ETPs—or purports to provide benefits to investors and the public interest—such as enhancing competition and bolstering resiliency in the underlying commodity or futures markets—the proposed rule change may still fail to meet the requirements under the Exchange Act.[256]

For the reasons discussed above, NYSE Arca has not met its burden of demonstrating an adequate basis in the record for the Commission to find that the proposal is consistent with Exchange Act Section 6(b)(5),[257] and, accordingly, the Commission must disapprove the proposal.[258]

D. Other Comments

Comment letters also address, among other things, the general nature and uses of bitcoin and blockchain technology; [259] the state of development of bitcoin as an investment asset; [260] beneficial tax consequences of approval of a spot bitcoin ETP; [261] the merits of an investment in bitcoin; [262] the nature and state of the bitcoin mining network; [263] the current failure, and potential promotion of, U.S. competitiveness in the global marketplace relating to bitcoin; [264] suggestions for improving regulation of bitcoin and other digital assets markets and related market participants and criticisms of the current regulatory approach; [265] increasing education relating to, and accessibility of, bitcoin; [266] the merits of the Sponsor; [267] and specific concerns relating to the Sponsor and its management of the Trust.[268] Ultimately, however, additional discussion of these topics is unnecessary, as they do not bear on the basis for the Commission's decision to disapprove the proposal.

IV. Conclusion

For the reasons set forth above, the Commission does not find, pursuant to Section 19(b)(2) of the Exchange Act, that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, with Section 6(b)(5) of the Exchange Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act, that proposed rule change SR–NYSEArca-2021–90, as modified by Amendment No. 1, be, and hereby is, disapproved.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

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[254] *See supra* note 235.

[255] *See* Exchange Act Section 19(b)(2)(C), 15 U.S.C. 78s(b)(2)(C). *See also Affiliated Ute Citizens of Utah* v. *United States,* 406 U.S. 128, 151 (1972) (Congress enacted the Exchange Act largely ''for the purpose of avoiding frauds''); *Gabelli* v. *SEC,* 568 U.S. 442, 451 (2013) (The ''SEC's very purpose'' is to detect and mitigate fraud.).

[256] *See* SolidX Order, 82 FR at 16259; VanEck Order, 86 FR at 54550–51; WisdomTree Order, 86 FR at 69344; Kryptoin Order, 86 FR at 74179; Valkyrie Order, 86 FR at 74163; SkyBridge Order, 87 FR at 3881; Wise Origin Order, 87 FR at 5538; ARK 21Shares Order, 87 FR at 20026–27.

[257] 15 U.S.C. 78f(b)(5).

[258] In disapproving the proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f). Some commenters state that approval of the proposal would enhance market efficiency and facilitate competition and capital formation. *See supra* notes 248–253 and accompanying text. For the reasons discussed throughout, however (*see supra* notes 56–57), the Commission is disapproving the proposed rule change because it does not find that the proposed rule change is consistent with the Exchange Act. *See also* USBT Order, 85 FR at 12615.

[259] *See, e.g.,* Angel Letter I, at 2–4, Letter from Thomas M. Wynne, dated Apr. 9, 2022 (''Wynne Letter''); Chilson Letter, at 1.

[260] *See, e.g.,* Moffitt Letter I; Letter from Patric Berger, dated Feb. 23, 2022; Letter from Sundeep Bollineni, dated Feb. 22, 2022; Chilson Letter; Letter from James McClave, Jane Street Capital, LLC, dated June 16, 2022.

[261] *See, e.g.,* Chen Letter; Letter from John Berggren, dated Feb. 14, 2022.

[262] *See, e.g.,* Seils Letter; Konduru Letter; Emory Letter.

[263] *See, e.g.,* Letters from David Bush, dated Feb. 22, 2022 (''Bush Letter''); Joseph D. Camp, Ph.D., Professor, Southern Methodist University, dated Feb. 14, 2022.

[264] *See, e.g.,* Elkhorn Letter; Johnson Letter; Valdata Letter; Bush Letter; Letter from Milton W., dated Feb. 23, 2022; Letter from Aaron Fenker, dated Feb. 23, 2022; Letter from Anil Gorania, dated Feb. 18, 2022; Letter from Nirav Trivedi, dated Feb. 11, 2022; Letter from Enrique Rea, Jr., dated Apr. 22, 2022; Chilson Letter, at 3; GTS Letter, at 2; Emory Letter, at 2. The Sponsor states that the U.S. lags global markets with respect to providing bitcoin and other digital asset ETPs and argues that approval of the proposal would support the White House Executive Order on Ensuring Responsible Development of Digital Assets by further bringing bitcoin into the regulatory perimeter. *See* Grayscale Submission, at 11–12. A commenter states that, ''as a global firm, it is concerning to observe the U.S. lagging far behind such foreign capital market competitors in offering regulated products for an emerging technology like Blockchain.'' Fortress Letter, at 3.

[265] *See, e.g.,* Angel Letter I, at 9–40; ADAM Letter, at 5; Dreyfuss Letter; Kane Letter; Boyer Letter; Letter from James J. Angel, Associate Professor of Finance, Georgetown University, dated May 6, 2022 (''Angel Letter II''); Chilson Letter, at 1–2.

[266] *See, e.g.,* Noble Letter; Letter from Julian Rogers, dated Apr. 7, 2022.

[267] *See, e.g.,* Wynne Letter; Henry Letter.

[268] *See, e.g.,* Letter from David B. Hennes, Ropes & Gray LLP, dated March 3, 2022 (expressing concern, on behalf of an unnamed ''interested investor,'' about the Sponsor's potential windfall if the Trust were to be allowed to convert to an ETP); Kleinfelder Letter.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95174; File No. SR–BOX–2022–19]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing of Proposed Rule Change To Amend Article 4 of the Exchange's Bylaws To Establish a Staggered Board

June 29, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 17, 2022, BOX Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Article 4 of the Exchange's Bylaws to establish a staggered board. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *http://boxoptions.com.*

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Bylaws to establish a staggered Board. Specifically, the Exchange proposes to amend Section 4.03 (Term of Directors) of the Exchange Bylaws to provide that Exchange Directors shall be divided into three classes, designated Class I, Class II and Class III, which shall be as nearly equal in number and classification as the total number of such Directors then serving on the Board permits.[3] Section 4.03 of the Bylaws would further provide that each class of newly elected Directors shall serve staggered three-year terms, with the term of office of one class expiring each year.[4]

In order to commence such staggered three-year terms, the Exchange proposes to amend Section 4.03 of the Bylaws to provide that Class I Directors serving when amended Section 4.03 is adopted shall serve until the first annual meeting of Members following the adoption of amended Section 4.03; Class II Directors serving when amended Section 4.03 is adopted shall serve until the second annual meeting of Members following the adoption of amended Section 4.03; and Class III Directors serving when amended Section 4.03 is adopted shall serve until the third annual meeting of Members following the adoption of amended Section 4.03. The 2022 annual meeting of the Members of the Exchange has not yet occurred. Accordingly, if this proposed rule change is approved before the 2022 annual meeting of Members, the term of Class I Directors would end at the 2022 annual meeting of Members, a new slate of Class I Directors would be nominated and selected in 2022 in accordance with the Bylaws.[5]

The Exchange also proposes to amend Section 4.03 of the Bylaws to provide that, in the case of any new Director as contemplated by Article IV, Section 4.02, such Director shall be added to a class, as determined by the Board at the time of such Director's initial election or appointment, and shall have an initial term expiring at the same time as the term of the class to which such Director has been added. In making such determinations, the Board shall balance the categories of Directors (*e.g.* Non-Industry, Public, Participant and Facility Directors) among the classes to the extent possible. Pursuant to Section 4.02 of the Bylaws, the total number of Directors is determined by the Board and must be between five and eleven directors. Accordingly, the Exchange is adding this provision to specify that if a new Director is added to the Board, the term of that Director shall correspond to the class to which that Director is assigned at the time of election or appointment.

In addition, the Exchange proposes to amend Section 4.02 to specify that no decrease in the number of Directors shall have the effect of shortening the term of any incumbent Director.[6] The purpose of this provision is to provide that, in the event that the Board determines to reduce the number of overall Directors, the term of any incumbent Director will not be cut short because of such determination. The Exchange could not, for example, determine to reduce the size of the Board by eliminating the Director seat for a Director who had two years of his or her term remaining.

The Exchange also proposes to make certain other conforming edits to other provisions of the Bylaws to clarify the responsibilities of the Board's Nominating Committee and to address Director vacancies that may arise. Specifically, the Exchange proposes to amend Section 4.06 (Nominating Committee) of the Bylaws to specify that the Board's Nominating Committee will nominate individuals in advance of each annual meeting of the Members to begin service as Directors ''for the applicable class term then expiring (*i.e.,* Class I, Class II or Class III)'' at such annual meeting of the Members.[7] The Exchange also proposes to amend Section 4.06(d) (Selection of Directors) of the Bylaws to provide that, prior to each annual meeting of the Members, the Nominating Committee shall select nominees for each Director position ''for the class with its term then expiring'' to begin service as Directors.[8] Finally, the Exchange proposes to amend Section 4.10 (Vacancies) by deleting the language ''until the next annual meeting or until his or her successor is elected and qualified'' and inserting the language ''for the remainder of the applicable class term'' to provide that a Director who is elected by the Board to fill a vacancy (*e.g.,* as a result of the death, resignation, removal or increase in the authorized number of Directors), shall serve for the remainder of the applicable class term. For example, if a Director in Class II resigns, the Director elected to fill the vacancy would serve for the remainder of the term of Class II Directors.[9]

[3] The current Exchange Board expects to initially designate: in Class I, one Non-Industry Director and one Participant Director; in Class II, two Non-Industry Directors, one of which is a Public Director; and in Class III, one Non-Industry Director and one Participant Director. These initial class designations are intended to balance, to the extent possible, the various categories of Directors among the three classes. Board actions are taken by majority vote in accordance with Section 4.11(j) of the Exchange Bylaws.

[4] Currently under the Exchange's Bylaws, Directors serve one-year terms and all Directors are nominated and begin serving each year at the annual meeting of Members. This provision in Section 4.03 of the Exchange Bylaws is proposed to be changed to delete ''Directors shall serve terms of one year each beginning each year at the annual meeting of the Members.''

[5] In this circumstance, the term of Class II and Class III directors would end at the Members annual meeting in 2023 and 2024, respectively.

[6] This provision is substantially similar to a comparable provision in the bylaws of another national securities exchange that provides for a staggered board. *See* Amended and Restated By-Laws of Miami International Securities Exchange LLC, Section 2.2(a).

[7] Similarly, the Exchange also proposes to amend the final sentence of Section 4.06 to specify that at each annual meeting of the Members, the individuals selected ''for the applicable class term'' pursuant to Section 4.06 of the Bylaws shall begin serving as Directors.

[8] The Exchange proposes to amend Section 4.06(d)(i) to include the same conforming edits to specify that the Nominating Committee shall meet for the purposes of selecting proposed Director nominees ''for the class then expiring'' and that the Nominating Committee shall provide the names of all proposed Director nominees ''for the class then expiring'' to the Exchange's Secretary not later than sixty days prior to the date of the annual meeting of the Members.

[9] With respect to a vacancy arising from an increase in the number of authorized Directors, pursuant to proposed Section 4.03 of the Bylaws,

The Exchange notes that it is not proposing any change to the composition of the Board, such as the requirement that 20% of Directors must be a Participant Directors or that a majority of Directors must be Non-Industry Directors.[10] All nominations and elections of Directors under the proposed staggered Board structure must be consistent with the existing composition requirements in the Bylaws. In addition, consistent with the existing Bylaws, Directors may serve consecutive terms.[11]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of the Exchange Act,[12] in general, and furthers the objective of Section 6(b)(5) of the Exchange Act,[13] in particular, because it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, or to regulate by virtue of any authority conferred by this Exchange Act matters not related to the purposes of the Exchange Act or the administration of the Exchange.

Specifically, the Exchange believes that the governance and administration of the Exchange would benefit from a Board structure in which Directors each serve staggered three-year terms in at least two ways. First, the Exchange believes that shifting from one-year terms for Exchange Directors to staggered three-year terms will help preserve institutional knowledge among Exchange Directors. Under the Exchange's current Bylaws, an entirely new set of Directors can be selected each year, which can potentially disrupt ongoing initiatives by the Exchange or result in a complete loss of institutional knowledge if all of the new Directors have no prior experience serving on the Exchange's Board. The Exchange believes that it benefits from the previous experience of those who have previously served as Exchange Directors and that ensuring some continuity among Directors promotes fair and orderly transitions to new Board leadership. By increasing the term length of each Director from one to three years, the Exchange can eliminate the possibility that an entirely new slate of Directors with no prior experience as a Director occurs. And, by staggering the election of Directors by dividing Directors into three classes with only one class elected each year, the Exchange can preserve institutional knowledge among a majority of the Directors over time. This change will ensue that at the time of every annual meeting of the Members, there will remain veteran leadership on the Board. In turn, the Exchange believes that these changes will help to improve the administration of the Exchange by fostering cooperation and coordination with persons, such as Directors, engaged in regulating and facilitating transactions in securities and removes impediments to and perfects the mechanism of a free and open market and a national market system, consistent with Section 6(b)(5) of the Exchange Act.[14] The Exchange also believes, consistent with Section 6(b)(5) of the Exchange Act, that these changes will also further the protection of investors and the public interest, which benefit from a governance structure that is designed to preserve institutional knowledge gained by incumbent Directors and through orderly transitions to new leadership among Directors.[15]

Second, the Exchange believes that the proposed staggered Board structure would help prevent any one Member or group of Members acting in coordination from exercising an undue influence over the Board through the election of Board Directors. As noted, currently the entire Board of Directors can be replaced each year. As a result, although no one Member has more than a 20% voting interest in the election of Directors, two or more Members acting in coordination could potentially exercise an outsized influence in the selection of Directors. Establishing a staggered Board would make it more difficult for such Members to take control of the Board, and therefore control of the Exchange, through a single election of the Board. By reducing the risk of coordinated Members taking control of the Board, the Board will be better positioned to address difficult, longer-term considerations related to management of the Exchange, rather than focusing on shorter-term considerations of certain Members. For example, a coordinated group of Members might seek to elect a slate of Directors that are more heavily focused on increasing Exchange profits without appropriate consideration of the longer-term growth of the Exchange. A staggered Board structure would make it more challenging for such Members to effect such a directional change by preventing the replacement of the entire Board of Directors in a given year. In turn, the Exchange believes that this would, consistent with Section 6(b)(5) of the Exchange Act, further the protection of investors and the public interest who are likely to benefit from an Exchange that is able to focus on longer-term goals rather than shorter-term interests of certain Members.[16]

In addition, the Exchange notes that, consistent with Section 6(b)(5), the proposed rule change is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.[17] The existing composition requirements related to Directors would remain the same under the proposed rule change, so there would not be, for example, any reduction in the representation of Exchange Participants on the Board. Moreover, all Directors would be subject to the same requirements under the proposed rule change (*i.e.,* all Directors, regardless of type, would be divided into one of three classes, each serving three-year terms).

The Exchange notes that, in order to commence the operation of the staggered Board, Directors assigned by the Board to Class I would serve for only one year following the adoption of this proposed rule change while Class II and Class III Directors would serve for two and three years respectively. While this could potentially be viewed as unfairly discriminatory against Class I and Class II Directors whose tenure would have a shorter duration than a Class III Director, these differing tenures are unavoidable to establish a staggered Board. Directors may also be re-elected and serve consecutive terms. As a result, although a Director assigned to Class I may have an initially shorter tenure, if re-elected at the time of the first annual meeting of Members following the adoption of this proposed rule change, such Director would then serve a three-year term.

Finally, the Exchange notes that the proposed staggered Board structure is substantially similar to the staggered board structure of at least two

the Director filling such vacancy would be assigned to a class by the Board and would have an initial term expiring at the same time as the term of the class to which such Director has been added.

[10] *See* Section 4.02 of the Bylaws.

[11] *See* Section 4.03 of the Bylaws.

[12] 15 U.S.C. 78a *et seq.*

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(5).

[15] *Id.*

[16] *Id.*

[17] *Id.*

exchanges.[18] Other exchanges have historically also operated with a substantially similar staggered board structure, including the BATS Exchange Inc. and EDGX Exchange Inc. and EDGA Exchange Inc. prior to their business combination with CBOE Holdings Inc.,[19] as well as International Securities Exchange, LLC prior to 2013.[20] Accordingly, the Exchange's proposed staggered Board structure does not present any novel considerations that the Commission has not previously considered.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.[21] The proposed rule change is concerned only with the governance structure and internal administration of the Exchange Board and would establish a staggered Board structure that is substantially similar to the existing board structure of other exchanges and self-regulatory organizations. As a result, the Exchange does not believe that the proposed rule change would result in any burden on competition or other competition-related considerations between or among Exchange Participants or between different exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

[18] *See* Amended and Restated By-Laws of Miami International Securities Exchange LLC (''MIAX''), Section 2.02(a) *and* First Amended and Restated Bylaws of Long-Term Stock Exchange, Inc. (''LTSE''), Section 3.3(b). The bylaws of The Options Clearing Corporation (''OCC''), another self-regulatory organization, also provide for a similar staggered board consisting of three classes. *See* OCC By-Laws, Article III, Section 3.

[19] *See* Exchange Act Release No. 57322 (File No. 10–182), Exhibit A.3 of the BATS Exchange Inc. Form 1 Application, as modified by Amendment No. 1, (Amended and Restated By-Laws of BATS Exchange Inc. at Section 3(b)) (February 13, 2008), *available at https://www.sec.gov/rules/other/2008/34-57322_application.htm#exhibit-a, and* Exchange Act Release No. 60651 (File No. 10–193), Exhibit A.3 of the EDGX Exchange Inc. Form 1 Application, as modified by Amendment No. 1 (Amended and Restated Bylaws of EDGX Exchange Inc. at Section 3(b)) (September 11, 2009), *available at https://www.sec.gov/rules/other/2009/edgx-f1-application.htm#exhibit-a.*

[20] *See* Exchange Act Release No. 69164, 78 FR 17727 (March 22, 2013) (SR–ISE–2013–07).

[21] 15 U.S.C. 78f(b)(8).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2022–19 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–BOX–2022–19. 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–BOX–2022–19, and should be submitted on or before July 27, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–14289 Filed 7–5–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95177; File No. SR–EMERALD–2022–22]

Self-Regulatory Organizations: MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 1900, Registration Requirements, Exchange Rule 1903, Continuing Education Requirements, and Exchange Rule 1904, Electronic Filing Requirements for Uniform Forms

June 29, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 28, 2022, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I 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 Exchange Rule 1903, Continuing Education Requirements. The proposed rule change also makes conforming amendments to Exchange Rule 1900, Registration Requirements. Among other changes, the proposed rule change requires that the Regulatory Element of continuing education be completed annually rather than every three years

[22] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

and provide a path through continuing education for individuals to maintain their qualification following the termination of a registration. The Exchange also proposes to amend its manual signature requirements in Exchange Rule 1904, Electronic Filing Requirements for Uniform Forms.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald,* at MIAX Emerald's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rules 1900 and 1903. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. (''FINRA'') [3] and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.[4] The Exchange also proposes to amend its manual signature requirements in Exchange Rule 1904, Electronic Filing Requirements for Uniform Forms, to align with changes FINRA has made to similar rules.[5] Each change is discussed in detail below.

The proposed changes are based on the changes filed with the Commission in SR–FINRA–2021–003 and SR–FINRA–2021–015.[6] The Exchange proposes to adopt such changes substantially in the same form as proposed by FINRA, with only minor changes necessary to conform to the Exchange's existing rules such as to remove cross-references and rules that are applicable to FINRA members but not to Exchange Members.[7]

Continuing Education Rules

i. Background

The continuing education program for registered persons of broker-dealers (''CE Program'') currently requires registered persons to complete continuing education consisting of a Regulatory Element and a Firm Element. The Regulatory Element, which is administered by FINRA on behalf of the Exchange, focuses on regulatory requirements and industry standards, while the Firm Element is provided by each firm and focuses on securities products, services, and strategies the firm offers, firm policies, and industry trends. The CE Program is codified under the rules of the self-regulatory organizations (''SROs''). The CE Program for registered persons of Exchange Members is codified under Exchange Rules 1900 and 1903.[8]

a. Regulatory Element

Exchange Rule 1903(a), Regulatory Element, currently requires a registered person to complete the applicable Regulatory Element initially within 120 days after the person's second registration anniversary date, and thereafter, within 120 days after every third registration anniversary date.[9] The Exchange may extend these time frames for good cause shown.[10] Registered persons who have not completed the Regulatory Element within the prescribed time frames will have their Exchange registrations deemed inactive and will be designated as ''CE inactive'' in the CRD system until the requirements of the Regulatory Element have been satisfied.[11] A CE inactive person is prohibited from performing, or being compensated for, any activities requiring Exchange registration, including supervision. Moreover, if registered persons remain CE inactive for two consecutive years, they must requalify by retaking required examinations (or obtain a waiver of the applicable qualification examinations).[12]

The Regulatory Element consists of a subprogram for registered persons generally, and a subprogram for principals and supervisors.[13] While some of the current Regulatory Element content is unique to particular registration categories, most of the content has broad application to both representatives and principals.[14]

The Regulatory Element was originally designed at a time when most

[3] *See* Securities Exchange Act Release Nos. 92183 (June 15, 2021), 86 FR 33427 (June 24, 2021) (SR–FINRA–2021–15); *and* 93097 (September 21, 2021), 86 FR 53358 (September 27, 2021) (SR–FINRA–2021–15).

[4] *See, e.g.,* Securities Exchange Act Release Nos. 94400 (March 11, 2022), 87 FR 15286 (March 17, 2022) (SR–NASDAQ–2022–021); 92562 (August 4, 2021), 86 FR 143701 (August 10, 2021) (SR–CBOE–2021–043); 94794 (April 26, 2022), 87 FR 25683 (May 2, 2022) (SR–BOX–2022–016); 94429 (March 16, 2022), 87 FR 16268 (March 22, 2022) (SR–MEMX–2022–05); *and* 95140 (June 22, 2022) (SR–MIAX–2022–23).

[5] *See* Securities Exchange Act Release No. 91262 (March 5, 2021), 86 FR 13935 (March 11, 2021) (SR–FINRA–2021–003).

[6] *See supra* notes 3 and 5.

[7] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[8] *See* Exchange Rules 1900 and 1903.

[9] *See* Exchange Rule 1903(a)(1). An individual's registration anniversary date is generally the date they initially registered with the Exchange in the Central Registration Depository (''CRD®'') system. However, an individual's registration anniversary date would be reset if the individual has been out of the industry for two or more years and is required to requalify by examination, or obtain an examination waiver, in order to reregister. An individual's registration anniversary date would also be reset if the individual obtains a conditional examination waiver that requires them to complete the Regulatory Element by a specified date. Non-registered individuals who are participating in the waiver program under Exchange Rule 1900, Interpretation and Policy .09, Waiver of Examinations for Individuals Working for a Financial Services Industry Affiliate of a Member, (''FSAWP participants'') are also subject to the Regulatory Element. *See also* Exchange Rule 1903(a)(5), Definition of Covered Person. The Regulatory Element for FSAWP participants correlates to their most recent registration(s), and it must be completed based on the same cycle had they remained registered. FSAWP participants are eligible for a single, fixed seven-year waiver period from the date of their initial designation, subject to specified conditions. Registered persons who become subject to a significant disciplinary action, as specified in Exchange Rule 1903(a)(3), Disciplinary Actions, may be required to retake the Regulatory Element within 120 days of the effective date of the disciplinary action, if they remain registered. Further, their cycle for participation in the Regulatory Element may be adjusted to reflect the effective date of the disciplinary action rather than their registration anniversary date.

[10] *See* Exchange Rule 1903(a)(2).

[11] *See id.* Individuals must complete the entire Regulatory Element session to be considered to have ''completed'' the Regulatory Element; partial completion is the same as non-completion.

[12] This CE inactive two-year period is calculated from the date such persons become CE inactive, and it continues to run regardless of whether they terminate their registrations before the end of the two-year period. Therefore, if registered persons terminate their registrations while in a CE inactive status, they must satisfy all outstanding Regulatory Element prior to the end of the CE inactive two-year period in order to reregister with a Member without having to requalify by examination or having to obtain an examination waiver.

[13] The S101 (General Program for Registered Persons) and the S201 (Registered Principals and Supervisors). For more information on both subprograms, *see* Content Outline for the S101 Regulatory Element Program, available at *https://www.finra.org/sites/default/files/S101P_Outline.pdf and* Content Outline for the S201 Regulatory Element Program, available at *https://www.finra.org/sites/default/files/2020-11/s201.pdf.*

[14] The current content is presented in a single format leading individuals through a case that provides a story depicting situations that they may encounter in the course of their work.

individuals had to complete the Regulatory Element at a test center, and its design was shaped by the limitations of the test center-based delivery model. In 2015, FINRA transitioned the delivery of the Regulatory Element to an online platform (''CE Online''), which allows individuals to complete the content online at a location of their choosing, including their private residence. This online delivery provides FINRA with much greater flexibility in updating content in a timelier fashion, developing content tailored to each registration category and presenting the material in an optimal learning format.

b. Firm Element

Exchange Rule 1903(b), Firm Element, currently requires each firm to develop and administer an annual Firm Element training program for covered registered persons.[15] The rule requires firms to conduct an annual needs analysis to determine the appropriate training.[16] Currently, at a minimum, the Firm Element must cover training in ethics and professional responsibility as well as the following items concerning securities products, services, and strategies offered by the Member: (1) general investment features and associated risk factors; (2) suitability and sales practices considerations; and (3) applicable regulatory requirements.[17]

A firm, consistent with its needs analysis, may determine to apply toward the Firm Element other required training. The current rule does not expressly recognize other required training, such as training relating to the anti-money laundering (''AML'') compliance program,[18] for purposes of satisfying Firm Element training.

c. Termination of a Registration

Currently, individuals whose registrations as representatives or principals have been terminated for two or more years may reregister as representatives or principals only if they requalify by retaking and passing the applicable representative- or principal-level examination or if they obtain a waiver of such examination(s) (the ''two-year qualification period'').[19] The two-year qualification period was adopted prior to the creation of the CE Program and was intended to ensure that individuals who reregister are relatively currently on their regulatory and securities knowledge.

ii. Proposed Rule Change

After extensive work with the Securities Industry/Regulatory Council on Continuing Education (''CE Council'') and discussions with stakeholders, including industry participants and the North American Securities Administrators Association (''NASAA''), FINRA adopted the following changes to the CE Program under its rules.[20] In order to promote uniform standards across the securities industry, the Exchange now proposes to adopt the same changes to its continuing education rules.

a. Transition to Annual Regulatory Element for Each Registration Category

As noted above, currently, the Regulatory Element generally must be completed every three years, and the content is broad in nature. Based on changes in technology and learning theory, the Regulatory Element content can be updated and delivered in a timelier fashion and tailored to each registration category, which would further the goals of the Regulatory Element.[21] Therefore, to provide registered persons with more timely and relevant training on significant regulatory developments, the Exchange proposes to amend Exchange Rule 1903(a) to require registered persons to complete the Regulatory Element annually by December 31.[22] The proposed amendment would also require registered persons to complete the Regulatory Element content for each representative or principal registration category that they hold, which would also further the goals of the Regulatory Element.[23]

Under the proposed rule change, firms would have the flexibility to require their registered persons to complete the Regulatory Element sooner than December 31, which would allow firms to coordinate the timing of the Regulatory Element with other training requirements, including the Firm Element.[24] For example, a firm could require its registered persons to complete both their Regulatory Element and Firm Element by October 1 of each year.

Individuals who would be registering as a representative or principal for the first time on or after the implementation date of the proposed rule change would be required to complete their initial

[15] ''Covered registered persons'' means any person registered with the Exchange pursuant to Rule 1900, including any person who is permissively registered pursuant to Exchange Rule 1900, Interpretation and Policy .02, and any person who is designated as eligible for a waiver pursuant to Exchange Rule 1900, Interpretation and Policy .09. *See* Exchange Rule 1903(a)(5).

[16] *See* Exchange Rule 1903(b)(2), Standards for the Firm Element.

[17] *Id.*

[18] *See* MIAX Rule 315(e) (applicable to the Exchange by being incorporated into the Exchange Rules by reference).

[19] *See* Exchange Rule 1900, Interpretation and Policy .08. The two-year qualification period is calculated from the date individuals terminate their registration and the date the Exchange receives a new application for registration. The two-year qualification period does not apply to individuals who terminate a limited registration category that is a subset of a broader registration category for which they remain qualified. For instance, it would not apply to an individual who maintains his registration as a General Securities Representative but who terminates his registration as an Investment Company and Variable Contracts Products Representative. Such individuals have the option of reregistering in the more limited registration category without having to requalify by examination or obtain an examination waiver so long as they continue to remain qualified for the broader registration category. Further, the two-year qualification period only applies to the representative- and principal-level examinations; it does not extend to the Securities Industry Essentials (''SIE'') examination. The SIE examination is valid for four years, but having a valid SIE examination alone does not qualify an individual for registration as a representative or principal. Individuals whose registrations as representatives or principals have been revoked pursuant to MIAX Rule 1011, Judgment and Sanction (applicable to the Exchange by being incorporated into the Exchange Rules by reference), may only requalify by retaking the applicable representative- or principal-level examination in order to reregister as representatives or principals, in addition to satisfying the eligibility conditions for association with a firm. Waivers are granted either on a case-by-case basis under Exchange Rule 1900, Interpretation and Policy .03, Qualification Examinations and Waivers of Examinations, or as part of the waiver program under Exchange Rule 1900, Interpretation and Policy .09.

[20] *See supra* note 3. FINRA's changes are based on the CE Council's September 2019 recommendations to enhance the CE Program. *See* Recommended Enhancements for the Securities Industry Continuing Education Program, available at *http://cecouncil.org/media/266634/council-recommendations-final-.pdf.* The CE Council is composed of securities industry representatives and representatives of SROs. The CE Council was formed in 1995 upon a recommendation from the Securities Industry Task Force on Continuing Education and was tasked with facilitating the development of uniform continuing education requirements for registered persons of broker-dealers.

[21] When the CE Program was originally adopted in 1995, registered persons were required to complete the Regulatory Element on their second, fifth and tenth registration anniversary dates. *See* Securities Exchange Act Release No. 35341 (February 8, 1995), 60 FR 8426 (February 14, 1995) (Order Approving File Nos. SR–AMEX–94–59; SR–CBOE–94–49; SR–CHX–94–27; SR–MSRB–94–17; SR–NASD–94–72; SR–NYSE–94–43; SR–PSE–94–35; and SR–PHLX–94–52). The change to the current three-year cycle was made in 1998 to provide registered persons more timely and effective training, consistent with the overall purpose of the Regulatory Element. *See* Securities Exchange Act Release No. 39712 (March 3, 1998), 63 FR 11939 (March 11, 1998) (Order Approving File Nos. SR–CBOE–97–68; SR–MSRB–98–02; SR–NASD–98–03; and SR–NYSE–97–33).

[22] *See* proposed changes to Exchange Rules 1903(a)(1) and (a)(4).

[23] *See* proposed changes to Exchange Rules 1900, Interpretation and Policy .07, *and* 1903(a)(1).

[24] *See* proposed changes to Exchange Rules 1903(a)(1) and (a)(4).

Regulatory Element for that registration category in the next calendar year following their registration.[25] In addition, subject to specified conditions, individuals who would be reregistering as a representative or principal on or after the implementation date of the proposed rule change would also be required to complete their initial Regulatory Element for that registration category in the next calendar year following their reregistration.[26]

Consistent with current requirements, individuals who fail to complete their Regulatory Element within the prescribed period would be automatically designated as CE inactive.[27] However, the proposed rule change preserves the Exchange's ability to extend the time by which a registered person must complete the Regulatory Element for good cause shown.[28]

The Exchange also proposes to amend Exchange Rule 1903(a) to clarify that: (1) individuals who are designated as CE inactive would be required to complete all of their pending and upcoming annual Regulatory Element, including any annual Regulatory Element that becomes due during their CE inactive period, to return to active status; [29] (2) the two-year CE inactive period is calculated from the date individuals become CE inactive, and it continues to run regardless of whether individuals terminate their registrations; [30] (3) individuals who become subject to a significant disciplinary action may be required to complete assigned continuing education content as prescribed by the Exchange; [31] (4) individuals who have not completed any Regulatory Element content for a registration category in the calendar year(s) prior to reregistering would not be approved for registration for that category until they complete that Regulatory Element content, pass an examination for that registration category or obtain an unconditional examination waiver for that registration category, whichever is applicable; [32] and (5) the Regulatory Element requirements apply to individuals who are registered, or in the process of registering, as a representative or principal.[33] In addition, the Exchange proposed making conforming amendments to Exchange Rule 1900, Interpretation and Policy .07.

Under the proposed rule change, the amount of content that registered persons would be required to complete in a three-year, annual cycle for a particular registration category is expected to be comparable to what most registered persons are currently completing every three years. In some years, there may be more required content for some registration categories depending on the volume of rule changes and regulatory issues. In addition, an individual who holds multiple registrations may be required to complete additional content compared to an individual who holds a single registration because, as noted above, individuals would be required to complete content specific to each registration category that they hold.[34] However, individuals with multiple registrations would not be subject to duplicative regulatory content in any given year. The more common registration combinations would likely share much of their relevant regulatory content each year. For example, individuals registered as General Securities Representatives and General Securities Principals would receive the same content as individuals solely registered as General Securities Representatives, supplemented with a likely smaller amount of supervisory-specific content on the same topics. The less common registration combinations may result in less topic overlap and more content overall.

b. Recognition of Other Training Requirements for Firm Element and Extension of Firm Element to All Registered Persons

To better align the Exchange's Rulebook with FINRA's Rulebook, and, in addition, to better align the Firm Element requirement with other required training, the Exchange proposes amending Rule 1903(b) to expressly allow firms to consider training relating to the AML compliance program and the annual compliance meeting toward satisfying an individual's annual Firm Element requirement.[35] The Exchange also proposes to amend the rule to extend the Firm Element requirement to all registered persons, including individuals who maintain solely a permissive registration consistent with Exchange Rule 1900, Interpretation and Policy .02, Permissive Registrations, thereby further aligning the Firm Element requirement with other broadly-based training requirements.[36] In conjunction with this proposed change, the Exchange proposes modifying the current minimum training criteria under Exchange Rule 1903(b) to instead provide that the training must cover topics related to the role, activities, or responsibilities of the registered person and to professional responsibility.[37]

c. Maintenance of Qualification After Termination of Registration

The Exchange proposes adopting paragraph (c) under Exchange Rule 1903 and Interpretation and Policies .01 and .02 to Exchange Rule 1903 to provide eligible individuals who terminate any of their representative or principal registrations the option of maintaining their qualification for any of the terminated registrations by completing continuing education.[38] The proposed rule change would not eliminate the two-year qualification period. Rather, it would provide such individuals as alternative means of staying current on their regulatory and securities knowledge following the termination of a registration(s). Eligible individuals who elect not to participate in the proposed continuing education program would continue to be subject to the current two-year qualification period. The proposed rule change is generally

[25] *See* proposed changes to Exchange Rule 1903(a)(1).

[26] *See* proposed changes to Exchange Rule 1903(a)(4).

[27] *See* proposed changes to Exchange Rule 1903(a)(2).

[28] *See id.* The proposed rule change clarifies that the request for an extension of time must be in writing and include supporting documentation, which is consistent with current practice.

[29] *Id.*

[30] *Id.*

[31] *See* proposed changes to Exchange Rule 1903(a)(3). As previously noted, Exchange Rule 1903(a)(3) currently provides that such individuals may be required to retake the Regulatory Element. *See supra* note 9.

[32] *See* proposed changes to Exchange Rule 1903(a)(4).

[33] *See* proposed changes to Exchange Rule 1903(a)(5).

[34] As discussed in the Economic Impact Assessment section in the FINRA Rule Change, *supra* note 3, individuals with multiple registrations represent a small percentage of the population of registered persons.

[35] *See* proposed Exchange Rule 1903(b)(2)(iv).

[36] *See* proposed changes to Exchange Rule 1903(b)(1). As noted earlier, the current requirement only applies to ''covered registered persons'' and not all registered persons.

[37] *See* proposed changes to Exchange Rule 1903(b)(2)(ii).

[38] The proposed option would also be available to individuals who terminate any permissive registrations as provided under Exchange Rule 1900, Interpretation and Policy .02. However, the proposed option would not be available to individuals who terminate a limited registration category that is a subset of a broader registration category for which they remain qualified. As previously noted, such individuals currently have the option of reregistering in the more limited registration category without having to requalify by examination or obtain an examination waiver so long as they continue to remain qualified for the broader registration category. In addition, the proposed option would not be available to individuals who are maintaining an eliminated registration category, such as the category for Corporate Securities Representative, or individuals who have solely passed the Securities Industry Essentials examination, which does not, in and of itself, confer registration.

aligned with other professional continuing education programs that allow individuals to maintain their qualification to work in their respective fields during a period of absence from their careers (including an absence of more than two years) by satisfying continuing education requirements for their credential.

The proposed rule change would impose the following conditions and limitations:

- Individuals would be required to be registered in the terminated registration category for at least one year immediately prior to the termination of that category; [39]
- Individuals could elect to participate when they terminate a registration or within two years from the termination of a registration; [40]
- Individuals would be required to complete annually all prescribed continuing education; [41]
- Individuals would have a maximum of five years in which to reregister; [42]
- Individuals who have been CE inactive for two consecutive years, or who become CE inactive for two consecutive years during their participation, would not be eligible to participate or continue; [43] and
- Individuals who are subject to a statutory disqualification, or who become subject to a statutory disqualification following the termination of their registration or during their participation, would not be eligible to participate or continue.[44]

The proposed rule change also includes a look-back provision that would, subject to specified conditions, extend the proposed option to individuals who have been registered as a representative or principal within two years immediately prior to the implementation date of the proposed rule change and individuals who have been FSAWP participants immediately prior to the implementation date of the proposed rule change.[45]

In addition, the proposed rule change includes a re-eligibility provision that would allow individuals to regain eligibility to participate each time they reregister with a firm for a period of at least one year and subsequently terminate their registration, provided that they satisfy the other participation conditions and limitations.[46] Finally, the Exchange proposes making conforming amendments to Exchange Rule 1900, including adding references to proposed Exchange Rule 1903(c) and Interpretation and Policy .08 to Exchange Rule 1900.

The proposed rule change will have several important benefits. It will provide individuals with flexibility to address life and career events and necessary absences from registered functions without having to requalify each time. It will also incentivize them to stay current on their respective securities industry knowledge following the termination of any of their registrations. The continuing education under the proposed option will be as rigorous as the continuing education of registered persons, which promotes investor protection. Further, the proposed rule change will enhance diversity and inclusion in the securities industry by attracting and retaining a broader and diverse group of professionals.

Significantly, the proposed rule change will be of particular value to women, who continue to be the primary caregivers for children and aging family members and, as a result, are likely to be absent from the industry for longer periods.[47] In addition, the proposed rule change will provide longer-term relief for women, individuals with low incomes and other populations, including older workers, who are at a higher risk of a job loss during certain economic downturns and who are likely to remain unemployed for longer periods.[48]

[39] *See* proposed Exchange Rule 1903(c)(1).

[40] *See* proposed Exchange Rule 1903(c)(2). Individuals who elect to participate at the later date would be required to complete, within two years from the termination of their registration, any continuing education that becomes due between the time of their Form U5 (Uniform Termination Notice for Securities Industry Registration) submission and the date that they commence their participation. In addition, FINRA would enhance its systems to notify individuals of their eligibility to participate, enable them to affirmatively opt in, and notify them of their annual continuing education requirement if they opt in.

[41] *See* proposed Exchange Rule 1903(c)(3). However, upon a participant's request and for good cause shown, the Exchange would have the ability to grant an extension of time for the participant to complete the prescribed continuing education. A participant who is also a registered person must directly request an extension of the prescribed continuing education from the Exchange. The continuing education content for participants would consist of a combination of Regulatory Element content and content selected by FINRA and the CE Council from the Firm Element content catalog. The content would correspond to the registration category for which individuals wish to maintain their qualifications. Participants who are maintaining their qualification status for a principal registration category that includes one or more co-requisite representative registrations must also complete required annual continuing education for the co-requisite registrations in order to maintain their qualification status for the principal registration category. The proposed rule change clarifies that the prescribed continuing education must be completed by December 31 of the calendar year, which is consistent with the timing for the proposed annual Regulatory Element.

[42] *See* proposed Exchange Rule 1903(c). In addition, individuals applying for reregistration must satisfy all other requirements relating to the registration process (*e.g.,* submit a Form U4 (Uniform Application for Securities Industry Registration or Transfer) and undergo a background check).

[43] *See* proposed Exchange Rules 1903(c)(4) *and* (c)(5).

[44] *See* proposed Exchange Rules 1903(c)(1) *and* (c)(6). Further, any content completed by participants would be retroactively nullified upon disclosure of the statutory disqualification. The following example illustrates the application of the proposed rule change to individuals who become subject to a statutory disqualification while participating in the proposed continuing education program. Individual A participates in the proposed continuing education program for four years and completes the prescribed content for each of those years. During year five of his participation, he becomes subject to a statutory disqualification resulting from a foreign regulatory action. In that same year, the Exchange receives a Form U4 submitted by a Member on behalf of Individual A requesting registration with the Exchange. The Form U4 discloses the statutory disqualification event. The Exchange would then retroactively nullify any content that Individual A completed while participating in the proposed continuing education program. Therefore, in this example, in order to become registered with the Exchange, he would be required to requalify by examination. This would be in addition to satisfying the eligibility conditions for association with an Exchange Member firm. *See* Exchange Act Sections 3(a)(39) and 15(b)(4).

[45] *See* proposed Exchange Rule 1903, Interpretation and Policy .01. Such individuals would be required to elect whether to participate by the implementation date of the proposed rule change. If such individuals elect to participate, they would be required to complete their initial annual content by the end of the calendar year in which the proposed rule change is implemented. In addition, if such individuals elect to participate, their initial participation period would be adjusted based on the date that their registration was terminated. The current waiver program for FSAWP participants would not be available to new participants upon implementation of the proposed rule change. *See* proposed Exchange Rule 1900, Interpretation and Policy .09. However, individuals who are FSAWP participants immediately prior to the implementation date of the proposed rule change could elect to continue in that waiver program until the program has been retired. As noted above, FSAWP participants may participate for up to seven years in that waiver program, subject to specified conditions. *See supra* note 9. As discussed above, the proposed rule change provides a five-year participation period for participants in the proposed continuing education program. So as not to disadvantage FSAWP participants, the Exchange has determined to preserve that waiver program for individuals who are participating in the FSAWP immediately prior to the implementation date of the proposed rule change. Because the proposed rule change transitions the Regulatory Element to an annual cycle, FSAWP participants who remain in that waiver program following the implementation of the proposed rule change would be subject to an annual Regulatory Element requirement. *See* proposed changes to Exchange Rule 1903(a)(1). Finally, the proposed rule change preserves the Exchange's ability to extend the time by which FSAWP participants must complete the Regulatory Element for good cause shown. *See* proposed changes to Exchange Rule 1903(a)(2).

[46] *See* proposed Exchange Rule 1903, Interpretation and Policy .02.

[47] *See* The Female Face of Family Caregiving (November 2018), available at *https://www.nationalpartnership.org/our-work/resources/economic-justice/female-face-family-caregiving.pdf.*

[48] The COVID–19 Recession Is the Most Unequal in Modern U.S. History (September 30, 2020),

d. CE Program Implementation

As stated in the FINRA Rule Change, FINRA and the CE Council also plan to enhance the CE Program in other ways, and these additional enhancements do not require any changes to the FINRA rules.[49] As it relates to the rule changes themselves, the changes relating to the Maintaining Qualifications Program (proposed paragraph (c) of Exchange Rule 1903, and Interpretations and Policies .01 and .02) and the Financial Services Affiliate Waiver Program (FSAWP) (Interpretation and Policy .09 to Exchange Rule 1900) will be implemented July 1, 2022. All other changes related to the FINRA Rule Change, including the changes relating to the Regulatory Element, Firm Element and the two-year qualification period, will be implemented January 1, 2023.[50]

Manual Signature

Exchange Rule 1904(c) currently provides that every initial and transfer electronic Form U4 filing and any amendments to the disclosure information on Form U4 must be based on a manually signed Form U4 provided to the Member or applicant for membership by the person on whose behalf the Form U4 is being filed, consistent with FINRA Rule 1010(c). Similarly, Exchange Rule 1904, Interpretation and Policy .03, currently provides that in the event a Member is not able to obtain an associated person's manual signature or written acknowledgement of amended disclosure information on that person's Form U4 prior to filing on such amendment reflecting the information pursuant to proposed Exchange Rule 1903(c)(3), the Member must enter ''Representative Refused to Sign/ Acknowledge'' or ''Representative Not Available'' or a substantially similar entry in the electronic Form U4 field for the associated person's signature. However, FINRA has since amended their Rule 1010(c) to permit firms to choose to rely on electronic signatures to satisfy the signature requirements when filing Form U4.[51] Several other exchanges have also updated their rules to reflect FINRA's updated Rule 1010(c).[52]

The Exchange proposes to amend Exchange Rule 1904(c) and Interpretation and Policy .03 to similarly allow firms to rely on electronic signatures when filing Form U4, consistent with FINRA Rule 1010(c). Specifically, the Exchange proposes to remove the term ''manual'' from ''manual signature'' and the term ''manually'' from ''manually signed.'' The proposed rule change provides Members, and applicants for membership, with an opportunity to better manage operational challenges. Particularly, the COVID–19 pandemic amplified the need to better manage operational challenges like those that arose during the pandemic and that may continue to arise in the future. Additionally, the proposed rule change would not require the use of a particular type of technology to obtain a valid electronic signature from the associated person. The Exchange believes that some firms may be unable to obtain the manual signature of applicants for registration resulting in a significant operational backlog. By permitting these firms to rely on electronic signatures to satisfy the signature requirements of Exchange Rule 1904(c) and Interpretation and Policy .03, the proposed rule change may reduce or eliminate this backlog. For purposes of the proposed rule change, a valid electronic signature would be any electronic mark that clearly identifies the signatory and is otherwise in compliance with the Electronic Signatures in Global and National Commerce Act (''E-Sign Act'') and the guidance issued by the Commission relating to the E-Sign Act.[53]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[54] in general, and furthers the objectives of Section 6(b)(5) of the Act,[55] in particular, in that it is designed to prevent fraudulent and manipulative practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

As noted above, the proposed rule changes seek to align the Exchange Rules with recent changes to FINRA rules.[56] The Exchange believes the proposed rule changes are consistent with the provisions of Section 6(b)(5) of the Act,[57] which requires, among other things, that Exchange Rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest, and Section 6(c)(3) of the Act,[58] which authorizes the Exchange to prescribe standards of training, experience, and competence for persons associated with the Exchange. The Exchange is proposing to adopt such changes substantially in the same form proposed by FINRA with only minor changes necessary to conform to the Exchange's existing rules, such as removal of cross-references to rules that are applicable to FINRA members but not Members of the Exchange.[59] The Exchange believes the proposal is consistent with the Act for the reasons described above.

The Exchange believes the proposed changes to the Regulatory Element will ensure that all Registered Representatives receive timely and relevant training, which will, in turn, enhance compliance and investor protection. The Exchange believes that establishing a path for individuals to maintain their qualification following the termination of a registration will reduce unnecessary impediments to requalification and promote greater diversity and inclusion in the securities industry without diminishing investor protection.

As it relates to the proposed changes to Exchange Rule 1904(c), the Exchange believes the proposed rule change provides firms with the flexibility to

available at *https://www.washingtonpost.com/graphics/2020/business/coronavirus-recession-equality/* and Unemployment's Toll on Older Workers Is Worst in Half a Century (October 21, 2020), available at *https://www.aarp.org/work/working-at-50-plus/info-2020/pandemic-unemployement-older-workers.*

[49] *See supra* note 3. Similar to FINRA, these additional enhances do not require any changes to Exchange Rules.

[50] *See* FINRA Regulatory Notice 21–41 at *https://www.finra.org/rules-guidance/notices/21-41.*

[51] *See supra* note 5.

[52] *See e.g.,* Securities Exchange Act Release Nos. 94400 (March 11, 2022), 87 FR 15286 (March 17, 2022) (SR–NASDAQ–2022–021); 92562 (August 4, 2021), 86 FR 143701 (August 10, 2021) (SR–CBOE–2021–043); *and* 94794 (April 26, 2022), 87 FR 25683 (May 2, 2022) (SR–BOX–2022–016).

[53] *See accord* Securities Exchange Act Release No. 85282 (March 11, 2019), 84 FR 9573 (March 15, 2019) (Order Approving File No. SR–FINRA–2018–040) (discussing valid electronic signatures under existing guidance).

[54] 15 U.S.C. 78f(b).

[55] 15 U.S.C. 78f(b)(5).

[56] *See supra* note 3.

[57] 15 U.S.C. 78f(b)(5).

[58] 15 U.S.C. 78f(c)(3).

[59] Proposed changes to Interpretation and Policy .08 of Exchange Rule 1900 is based on and substantially similar to FINRA Rule 1210.08. The proposed changes to Exchange Rule 1903(a)(1)–(4), proposed changes to Exchange Rule 1903(b), proposed Exchange Rule 1903(c), and proposed Interpretations and Policies .01–.02 to Exchange Rule 1903(c) are based on and substantially similar to FINRA Rules 1240(a)(1)–(4), FINRA Rule 1240(b), FINRA Rule 1240(c) and Supplementary Materials .01 and .02 to FINRA Rule 1240. The Exchange does not currently have a provision analogous to FINRA Rule 3110 and thus has omitted language referring to such provision in its proposed Rules.

rely on electronic signatures to satisfy the signature requirements of Exchange Rule 1904(c). Specifically, the Exchange proposes to amend Exchange Rule 1904(c) and Interpretation and Policy .03, similar to the amendments made by FINRA, to provide the option of filing an initial or a transfer Form U4 based on a manually or an electronically signed copy of the form provided to the Member, or applicant for membership, by the individual on whose behalf the form is being filed. Considering the technological advancements that provide for enhanced authentication and security of electronic signatures, the Exchange believes that it is appropriate to amend Exchange Rule 1904(c) and Interpretation and Policy .03 to provide such flexibility. The proposed rule change also addresses the ongoing public health risks stemming from the outbreak of COVID–19 and the operational challenges that firms continue to face as a result of pandemic repercussions. By permitting these firms to rely on electronic signatures to satisfy the signature requirements of Exchange Rule 1904(c) and Interpretation and Policy .03, the proposed rule change may reduce or eliminate an operational backlog due to the difficulty firms may have faced in obtaining the manual signature of applicants for registration as a result of the impact of the pandemic on daily work environments. The Exchange believes the proposal is consistent with the Act for the reasons described above and for the reasons outlined in the recent filings SR–FINRA–2021–003 and SR–FINRA–2021–015.[60]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. All Members would be subject to the proposed rule change. The proposed rule change relating to the Exchange's CE Program, which is materially identical to the FINRA Rule Change, is designed to result in a more efficient CE Program that addresses relevant regulatory requirements and provides individuals with improved tools and resources to understand and comply with such requirements, enhancing investor protection. Moreover, the proposed rule change would provide new channels for individuals to maintain their qualification status for a terminated registration category and, in so doing, could increase the likelihood that professionals who need to step away from the industry for a period could return, subject to satisfying all other requirements relating to the registration process.

As it relates to the proposed amendments to Exchange Rule 1904(c), the proposed rule change relating to manual signatures is, in all material respects, substantively identical to a recent rule change adopted by FINRA. The Exchange believes the proposed change will reduce a regulatory filing burden for Members by allowing them to rely on Form U4 copies with an electronic signature. All Members will have the option to rely on such forms with an electronic signature (or continue to rely on forms with a manual signature).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days 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[61] and Rule 19b–4(f)(6) thereunder.[62]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), 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 this proposed rule change may become operative immediately upon filing. In addition, Rule 19b–4(f)(6)(iii)[63] requires a self-regulatory organization to give the Commission written notice of its intent to file a proposed rule change under that subsection at least five business days prior to the date of filing, or such shorter time as designated by the Commission. The Exchange has provided such notice.

Waiver of the 30-day operative delay would allow the Exchange to implement proposed changes in a more timely fashion. First, the proposed rule changes regarding manual signatures address operational challenges facing firms due to the ongoing public health risks stemming from the outbreak of COVID–19 and permit firms to rely on electronic signatures to satisfy the signature requirements of Exchange Rule 1904(c) and Interpretation and Policy .03, which may reduce or eliminate an operational backlog, ultimately benefiting the investing public. Moreover, the proposed rule changes do not impose any significant burden on competition because they will apply uniformly to all similarly situated members and associated persons of members. Also, as stated above, the proposed rule changes are substantively the same as changes made by FINRA. Second, waiver of the 30-day operative delay would also allow the Exchange to implement the proposed continuing education changes noted above thereby reducing the possibility of a significant regulatory gap between the FINRA and Exchange Rules. This is consistent with the protection of investors and the public interest by providing more uniform standards across the securities industry and helping to avoid confusion for members of the Exchange that are also FINRA members. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[64]

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:

[60] *See supra* notes 3 and 5.

[61] 15 U.S.C. 78s(b)(3)(A)(iii).

[62] 17 CFR 240.19b–4(f)(6).

[63] 17 CFR 240.19b–4(f)(6)(iii).

[64] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EMERALD–2022–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–EMERALD–2022–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–EMERALD–2022–22 and should be submitted on or before July 27, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[65]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–14290 Filed 7–5–22; 8:45 am]

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[65] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Interest Rates

The Small Business Administration publishes an interest rate called the optional ''peg'' rate (13 CFR 120.214) on a quarterly basis. This rate is a weighted average cost of money to the government for maturities similar to the average SBA direct loan. This rate may be used as a base rate for guaranteed fluctuating interest rate SBA loans. This rate will be 2.75 percent for the July–September quarter of FY 2022.

Pursuant to 13 CFR 120.921(b), the maximum legal interest rate for any third party lender's commercial loan which funds any portion of the cost of a 504 project (see 13 CFR 120.801) shall be 6% over the New York Prime rate or, if that exceeds the maximum interest rate permitted by the constitution or laws of a given State, the maximum interest rate will be the rate permitted by the constitution or laws of the given State.

John Wade,

Chief, Secondary Market Division.

[FR Doc. 2022–14314 Filed 7–5–22; 8:45 am]

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DEPARTMENT OF STATE

[Public Notice: 11777]

30-Day Notice of Proposed Information Collection: Affidavit of Identifying Witness

AGENCY: Department of State.

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 30 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to August 5, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to: *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You must include the DS form number (DS–0071), information collection title, and the OMB control number in any correspondence (if applicable). Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument, and supporting documents to *PPTFormsOfficer@state.gov.* You must include the DS form number (DS–0071) and information collection title.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Affidavit of Identifying Witness.
- *OMB Control Number:* 1405–0088.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Passport Services, Office of Program Management and Operational Support (CA/PPT/S/PMO).
- *Form Number:* DS–0071.
- *Respondents:* Individuals.
- *Estimated Number of Respondents:* 32,260.
- *Estimated Number of Responses:* 32,260.
- *Average Hours Per Response:* 5 min.
- *Total Estimated Time Burden:* 2,688 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper performance of our functions.
- Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Affidavit of Identifying Witness is submitted in conjunction with an application for a U.S. passport. It is used by Passport Agents, Passport Acceptance Agents, and Consular Officers to collect information for the purpose of establishing the identity of the applicant. This affidavit is

completed by the identifying witness when the applicant is unable to establish their identity to the satisfaction of a person authorized to accept passport applications.

Methodology

The Affidavit of Identifying Witness is submitted in conjunction with an application for a U.S. passport. Due to legislative mandates, Form DS–0071 is only available at acceptance facilities, passport agencies, and U.S. embassies and consulates. This form must be completed and signed in the presence of an authorized Passport Agent, Passport Acceptance Agent, or Consular Officer.

Kevin E. Bryant,

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

[FR Doc. 2022–14367 Filed 7–5–22; 8:45 am]

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SURFACE TRANSPORTATION BOARD

[Docket No. AB 1322X]

Wolf Creek Railroad LLC—Abandonment Exemption—in Gibson County, Tenn.

On June 16, 2022, Wolf Creek Railroad LLC (WCR) filed a petition under 49 U.S.C. 10502 for exemption from the prior approval requirements of 49 U.S.C. 10903 to abandon an approximately 10-mile line of railroad (the Line) located within the Milan Army Ammunition Plant (the Plant) in Gibson County, Tenn. There is one station on the Line, and the Line constitutes WCR's entire rail system. The Line traverses U.S. Postal Service Zip Code 38358.

According to WCR, it leased the Line from the U.S. Army Joint Munitions Command (JMC) through JMC's representative, American Ordnance LLC. A portion of the Plant had been repurposed as a business park, and WCR provided common carrier rail service to customers there.[1] On March 31, 2021, the JMC provided notice to WCR that it was terminating the lease as of December 31, 2021, and that WCR was required to cease its rail operations and vacate the Plant. WCR represents that the last customer on the Line was a plastics-transload customer that stopped shipping on the Line in October 2021. Thus, WCR seeks to abandon the Line.

WCR states that the Line and the property that the Line serves are owned by the JMC. Therefore, the Line is located on a federally-owned right-of-way. Any documentation in WCR's possession will be made available promptly to those requesting it.

Citing *A&R Line, Inc.—Abandonment Exemption—in Cass & Pulaski Counties,* AB 855 (Sub-No. 1X) (STB served Aug. 20, 2003), WCR asserts that, because it proposes to abandon its entire railroad system, the imposition of employee protective conditions is not appropriate.

By issuing this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by October 4, 2022.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 120 days after the filing of the petition for exemption, or 10 days after service of a decision granting the petition for exemption, whichever occurs sooner. Persons interested in submitting an OFA must first file a formal expression of intent to file an offer by July 18, 2022, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(1)(i).

Following abandonment, the Line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for interim trail use/rail banking under 49 CFR 1152.29 will be due no later than July 26, 2022.[2]

All pleadings, referring to Docket No. AB 1322X, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on WCR's representative, Eric M. Hocky, Clark Hill, PLC, Two Commerce Square, 2001 Market Street, Suite 2620, Philadelphia, PA 19103. Replies to the petition are due on or before July 26, 2022.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis (OEA) at (202) 245–0294. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by OEA will be served upon all parties of record and upon any other agencies or persons who comment during its preparation. Other interested persons may contact OEA to obtain a copy of the EA (or EIS). EAs in abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA generally will be within 30 days of its service.

Board decisions and notices are available at *www.stb.gov.*

Decided: June 29, 2022.

Mai T. Dinh,

Director, Office of Proceedings.

[FR Doc. 2022–14304 Filed 7–5–22; 8:45 am]

BILLING CODE 4915–01–P

[1] *See Wolf Creek R.R.—Lease & Operation Exemption—Am. Ordnance LLC,* FD 36236 (STB served Nov. 18, 2018).

[2] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments: Trade Strategy to Combat Forced Labor

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice and request for comments.

SUMMARY: The Office of the United States Trade Representative (USTR) is coordinating with all relevant United States federal agencies to develop a focused trade strategy to combat forced labor. The strategy will identify priorities and establish an action plan for utilizing existing and potential new trade tools to combat forced labor in traded goods and services. USTR invites public comments to inform the development of the strategy.

DATES: The deadline for the submission of written comments is August 5, 2022.

ADDRESSES: USTR strongly prefers electronic submissions made through the Federal eRulemaking Portal: *https://www.regulations.gov* (*Regulations.gov*), using Docket Number USTR–2022–0006. Follow the instructions for submitting comments in 'Requirements for Submissions' below. For alternatives to on-line submissions, please contact Jennifer Oetken, Director for Labor Affairs, in advance of the deadline at *Jennifer.L.Oetken@ustr.eop.gov* or (202) 395–2870.

FOR FURTHER INFORMATION CONTACT: Jennifer Oetken, Director for Labor Affairs, at *Jennifer.L.Oetken@ustr.eop.gov* or (202) 395–2870.

SUPPLEMENTARY INFORMATION:

I. Background

On January 25, 2022, U.S. Trade Representative Katherine Tai announced that USTR would develop the first-ever trade strategy to combat forced labor. In developing the strategy, USTR is conducting an interagency review across the U.S. Government through the Trade Policy Staff Committee's (TPSC) Subcommittee on Trade, Forced Labor, and Child Labor of existing trade policies and tools used to combat forced labor, including forced child labor, to determine areas that may need strengthening and gaps that may need to be filled. USTR will use this analysis to establish objectives, priorities, new tools, and key action items to advance development of the strategy. The process is inclusive to maximize input from stakeholders, including labor organizations, civil society, survivors, and the private sector.

II. Public Comment

USTR invites interested parties to submit comments to assist in the development of the forced labor trade strategy. In submitting comments, parties are invited to consider the following questions.

- What actions could the U.S. Government pursue with like-minded trade partners and allies to combat forced labor as an unfair trade practice?
- How can the U.S. Government bolster the forced labor components of trade agreements and trade preference programs to have greater effect?
- What new and innovative trade tools can the U.S. Government develop and utilize to advance efforts to combat forced labor in traded goods and services?
- How can the U.S. Government make the development of trade policy on forced labor a more inclusive process?
- Do you have additional recommendations for monitoring, tracing, or eliminating forced labor in traded goods and services in supply chains?

USTR must receive written comments no later than August 5, 2022. USTR requests that small businesses (generally defined by the Small Business Administration as firms with fewer than 500 employees), or organizations representing small business members, self-identify in their comment, so USTR will be aware of issues of particular interest to small businesses.

III. Requirements for Submissions

You must submit comments by the August 5, 2022 deadline. You must make all submissions in English via *Regulations.gov,* using Docket Number USTR–2022–0006. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the 'type comment' field. USTR will not accept hand-delivered submissions.

To make a submission using *Regulations.gov*, enter Docket Number USTR–2022–0006 in the 'search for' field on the home page and click 'search.' The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice by selecting 'notice' under 'document type' in the 'refine documents results' section on the left side of the screen and click on the link entitled 'comment.' The *Regulations.gov* website offers the option of providing comments by filling in a 'comment' field or by attaching a document using the 'attach files' field. USTR prefers that you provide submissions in an attached document and note 'see attached' in the 'comment' field on the online submission form. At the beginning of the submission, or on the first page (if an attachment) include the following: 'Trade Strategy to Combat Forced Labor.' Include any cover letters, exhibits, annexes, or other attachments to the submission in the same file as the submission itself, and not as separate files.

For any comments submitted electronically that contain business confidential information (BCI), the file name of the business confidential version should begin with the characters 'BCI.' Clearly mark any page containing BCI 'BUSINESS CONFIDENTIAL' on the top of that page. Filers of submissions containing BCI also must submit a public version of their comments. The file name of the public version should begin with the character 'P.' Follow the 'BCI' and 'P' with the name of the person or entity submitting the comments. Filers submitting comments containing no BCI should name their file using the name of the person or entity submitting the comments.

You will receive a tracking number upon completion of the submission procedure at *Regulations.gov*. The tracking number is confirmation that *Regulations.gov* received the submission. Keep the confirmation for your records. USTR is not able to provide technical assistance for *Regulations.gov*. USTR may not consider documents that you do not submit in accordance with these instructions.

If you are unable to provide submissions as requested, Jennifer Oetken, Director for Labor Affairs, in advance of the deadline at *Jennifer.L.Oetken@ustr.eop.gov* or (202) 395–2870. to arrange for an alternative method of transmission.

USTR will place comments in the docket for public inspection, except BCI. General information concerning USTR is available at *www.ustr.gov.*

Joshua Kagan,

Assistant U.S. Trade Representative for Labor Affairs, Office of the United States Trade Representative.

[FR Doc. 2022–14355 Filed 7–5–22; 8:45 am]

BILLING CODE 3290–F2–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–0443]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Procedures for Non-Federal Navigation Facilities

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves aerial navigation aids (NavAids), electrical/electronic facilities, owned and operated by non-Federal sponsors for use by the flying public. ''Non-Federal sponsors'' refers to entities such as state and local governments, businesses, and private citizens. The information to be collected is necessary to ensure that operation and maintenance of these non-Federally owned facilities is in accordance with FAA safety standards. The FAA is not changing its information-collection practices pertaining to non-Federal facilities. It is merely renewing its legal authority to collect that information.

DATES: Written comments should be submitted by August 5, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By email: Non-Federal-Program@faa.gov (Enter docket number into subject line).

FOR FURTHER INFORMATION CONTACT: Natashia Jones by email at:

Natashia.Jones@faa.gov; phone: (817) 222–4038.

SUPPLEMENTARY INFORMATION: The collection involves the compilation of:

- Commissioning data, such as the initial standards and tolerances parameters for the aerial navigation aids (NavAids) and electrical/electronic facilities, owned and operated by non-Federal sponsors;
- Maintenance activities and operational history, such as outages and repairs, for facilities owned and operated by non-Federal sponsors; and
- The facilities' periodically verified parameters for the life of the facility.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0014.

Title: Procedures for Non-Federal Navigation Facilities.

Form Numbers: FAA Form 6000–10; FAA Form 6000–8; FAA Form 6030–1.

Type of Review: Renewal of an information collection.

Background: Title 14 CFR part 171 establishes procedures and requirements for non-Federal sponsors, (''non-Federal sponsors'' refers to entities such as state and local governments, businesses, and private citizens) to purchase, install, operate, and maintain electronic NavAids for use by the flying public, in the National Airspace System (NAS). Part 171 describes procedures for receiving permission to install a facility and requirements to keep it in service. Documenting the initial parameters during commissioning is necessary to have a baseline to reference during future inspections. Another requirement is recording maintenance tasks, removal from service, and any other repairs performed on these facilities in on-site logs to have an accurate history on the performance of the facility. In addition, at each periodic inspection, recording the facilities' current parameters provides performance information for the life of the facility. Records must be kept on site and the FAA must receive copies of the logs.

Respondents: Approximately 2,200 non-Federal facilities/respondents.

Frequency: Information is collected (submitted to FAA Inspectors) on occasion.

Estimated Average Burden per Response: 13.72 hours per year.

- Form 6000–10, 1.72 hours per response
- Form 6000–8, 30 minutes per response
- Form 6030–1, 30 minutes per response

Estimated Total Annual Burden: Approximately 26,429 hours per year.

Issued in Washington, DC, on June 29, 2022.

Shelly Beauchamp,

Manager, Advanced Systems Design Service Team, AJW–121, NAS Modernization Group, Operations Support Directorate, Technical Operations, Air Traffic Organization, Federal Aviation Administration.

[FR Doc. 2022–14326 Filed 7–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0122]

Entry-Level Driver Training: State of Alaska; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that the State of Alaska has applied for an exemption from the Entry-Level Driver Training (ELDT) curriculum that requires the Class A CDL applicant to demonstrate proficiency in proper techniques for initiating vehicle movement, executing left and right turns, changing lanes, navigating curves at speed, entry and exit on the interstate or controlled access highway, and stopping the vehicle in a controlled manner. FMCSA requests public comment on the applicant's request for exemption.

DATES: Comments must be received on or before August 5, 2022.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Number FMCSA–2022–0122 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the Public Participation and Request for Comments section below for further information.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number (FMCSA–2022–0122) for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice DOT/ALL 14 –FDMS, which can be reviewed at *https://www.transportation.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA, at (202) 366–2722 or by email at *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2022–0122), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means.

FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number (''FMCSA–2022–0122'') in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption and the regulatory provision from which the exemption is granted. The notice must specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Applicant's Request

As noted in the Summary above, the State of Alaska has applied for an exemption from the Entry-Level Driver Training (ELDT) curriculum in 49 CFR part 380, Appendix A, Section A3.1, which requires Class A CDL applicants to demonstrate proficiency in proper techniques for initiating vehicle movement, executing left and right turns, changing lanes, navigating curves at speed, entry and exit on the interstate or controlled access highway, and stopping the vehicle in a controlled manner. A copy of the State of Alaska's application for exemption is available for review in the docket for this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on the State of Alaska's application for an exemption. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2022–14446 Filed 7–1–22; 4:15 pm]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Funding Opportunity for the Railroad Crossing Elimination Program

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT)

ACTION: Notice of funding opportunity.

SUMMARY: This notice details the application requirements and procedures to obtain grant funding for eligible projects under the Railroad Crossing Elimination Program for Fiscal Year 2022. This notice solicits applications for the Railroad Crossing Elimination Program funds made available by the Infrastructure Investment and Jobs Act. The opportunity described in this notice is made available under Assistance Listings Number 20.327, ''Railroad Crossing Elimination.''

DATES: Applications for funding under this solicitation are due no later than 5:00 p.m. ET, October 4, 2022. Applications that are incomplete or received after 5:00 p.m. ET, on October 4, 2022 will not be considered for funding. See Section D of this notice for additional information on the application process.

ADDRESSES: Applications must be submitted via *www.Grants.gov.* Only applicants who comply with all submission requirements described in this notice and submit applications through *www.Grants.gov* will be eligible for award. For any supporting application materials that an applicant is unable to submit via *www.Grants.gov* (such as oversized engineering drawings), an applicant may submit an original and two (2) copies to Mr. Douglas Gascon, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–212, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, applicants are advised to use other means of conveyance (such as courier service) to assure timely receipt of materials before the application deadline.

FOR FURTHER INFORMATION CONTACT: For further information related to this notice, please contact Mr. Douglas Gascon, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–212, Washington, DC 20590; email: *douglas.gascon@dot.gov*; phone: 202–493–0239.

SUPPLEMENTARY INFORMATION:

Notice to applicants: FRA recommends that applicants read this notice in its entirety prior to preparing application materials. Definitions of key terms used throughout the NOFO are provided in Section A(2) below. These key terms are capitalized throughout the NOFO. There are several administrative and specific eligibility requirements described herein with which applicants must comply. Additionally, applicants should note that the required Project Narrative component of the application package may not exceed 25 pages in length.

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A. Program Description

1. Overview

Section 22305 of the Infrastructure Investment and Jobs Act (IIJA) (Pub. L. 117–58, November 15, 2021), codified at 49 U.S.C. 22909, authorizes the Railroad Crossing Elimination Program (RCE Program). The purpose of the RCE Program is to fund highway-rail or pathway-rail grade crossing improvement projects that focus on improving the safety and mobility of people and goods. This NOFO is funded through the advanced appropriation in Division J of IIJA. The RCE Program provides a Federal funding opportunity to improve American rail infrastructure to enhance rail safety, improve the health and safety of communities, eliminate highway-rail and pathway-rail grade crossings that are frequently blocked by trains, and reduce the impacts that freight movement and railroad operations may have on underserved communities. Discretionary grant awards, funded through the RCE Program, will support projects that improve safety, economic strength and global competitiveness, equity, and climate and sustainability, consistent with the U.S. Department of Transportation's (DOT) strategic goals.[1]

FRA has a strong interest in promoting grade separations, closing crossings through track relocation, and corridor-wide grade crossing improvements that maximize the safety and efficiency of the U.S. rail network. Highway-rail grade crossing accidents, together with accidents caused by trespassing along the railroad right-of-way, account for 94% of all rail-related deaths and injuries. The safest crossing is no crossing, and grade separating or otherwise eliminating crossings is the most direct way to prevent intrusions into the railroad right-of-way.

The RCE Program will be implemented, as appropriate and consistent with law, in alignment with the priorities in Executive Order 14052, *Implementation of the Infrastructure Investments and Jobs Act* (86 FR 64355), which are to invest efficiently and equitably, promote the competitiveness of the U.S. economy, improve job opportunities by focusing on high labor standards, strengthen infrastructure resilience to all hazards including climate change, and to effectively coordinate with State, local, Tribal, and territorial government partners.

In addition to improving safety, FRA seeks to fund projects under the RCE Program that reduce greenhouse gas emissions and are designed with specific elements to address climate change impacts. Specifically, FRA is looking to award projects that align with the President's greenhouse gas reduction goals, promote energy efficiency, support fiscally responsible land use and efficient transportation design, increase climate resilience, support domestic manufacturing, and reduce pollution.

FRA also seeks to fund projects that address environmental justice, particularly for communities that disproportionally experience climate change-related consequences. Environmental justice, as defined by the Environmental Protection Agency, is the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. As part of the implementation of Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad* (86 FR 7619), FRA seeks to fund projects that, to the extent possible, target at least 40 percent of resources and benefits towards low-income communities, disadvantaged communities, communities underserved by affordable transportation, or overburdened [2] communities. For more information, please consult DOT's disadvantaged communities mapping tool to determine if a proposed project impacts disadvantaged communities: Transportation Disadvantaged Census Tracts (*arcgis.com*) *and at: https://usdot.maps.arcgis.com/apps/dashboards/d6f90dfcc8b44525b04c7ce748a3674a.*

Additionally, FRA seeks to fund projects that proactively address racial equity and barriers to opportunity, including automobile dependence, as a form of barrier, or redress prior inequities and barriers to opportunity. Section E describes racial equity considerations that an applicant can undertake, and FRA will consider during the review of applications.

In addition to prioritizing projects that address climate change, proactively address racial equity, and reduce barriers to opportunity, FRA intends to use the RCE program to support the creation of good-paying jobs with the free and fair choice to join a union and the incorporation of strong labor standards and training and placement programs, especially registered apprenticeships and Local Hire agreements, in project planning stages. Projects that incorporate such planning considerations are expected to support a strong economy and labor market. Section E describes job creation and labor considerations that an applicant can undertake, and that FRA will consider, during the review of applications.

Section E of this NOFO, which outlines the RCE Program grant selection criteria, describes the process for selecting projects that further these goals. Section F.3 describes progress and performance reporting requirements for selected projects, including the relationship between that reporting and the RCE Program's selection criteria.

2. Definitions of Key Terms

Terms defined in this section are capitalized throughout this notice.

a. ''Construction'' means the production of fixed works and structures or substantial alterations to such structures or land and associated costs.

b. ''Commuter Rail Passenger Transportation'' means short-haul rail passenger transportation in metropolitan and suburban areas usually having reduced fare, multiple ride, and commuter tickets and morning and evening peak period operations, consistent with 49 U.S.C. 24102(3).

c. ''Final Design (FD)'' means design activities following Preliminary Engineering, and at a minimum, includes the preparation of final Construction plans consistent with the applicable environmental decision document, detailed specifications, and estimates sufficiently detailed to inform project stakeholders (designers, reviewers, contractors, suppliers, etc.) of the actions required to advance the project from design through completion of Construction.

d. ''Grade Separation or Closure'' means an underpass or overpass to eliminate level crossings between railroad and highway users at an existing highway-rail or pathway-rail grade crossing, or the closing of a highway-rail grade crossing to vehicular or pedestrian traffic.

[1] DOT Strategic Framework FY 2022–2026 (Dec. 2021) at *https://www.transportation.gov/administrations/office-policy/fy2022-2026-strategic-framework.*

[2] Overburdened Community: Minority, low-income, tribal, or indigenous populations or geographic locations in the United States that potentially experience disproportionate environmental harms and risks. This disproportionality can be as a result of greater vulnerability to environmental hazards, lack of opportunity for public participation, or other factors. Increased vulnerability may be attributable to an accumulation of negative or lack of positive environmental, health, economic, or social conditions within these populations or places. The term describes situations where multiple factors, including both environmental and socio-economic stressors, may act cumulatively to affect health and the environment and contribute to persistent environmental health disparities.

e. ''Highway-Rail Grade Crossing'' means a location where a public highway, road, street, or private roadway, including associated sidewalks and pathways, crosses one or more railroad tracks at grade.

f. ''Improvement Project'' means a project related to a highway or pathway-rail crossing including: installation, repair, or improvement of crossings, grade separations, railroad crossing signals, gates, bells, audible warning devices and related technologies; highway traffic signalization, lighting, crossing approach signage, and roadway improvements such as medians or other barriers; pathway improvements such as bollards; railroad crossing panels and surfaces; and other safety engineering improvements, or highway-rail programs to reduce risk.

g. ''National Environmental Policy Act (NEPA)'' is a federal law that requires Federal agencies to analyze and document the environmental impacts of a proposed action in consultation with appropriate Federal, state, and local authorities, and with the public. NEPA classes of action include an Environmental Impact Statement (EIS), Environmental Analysis (EA) or Categorical Exclusion (CE). The NEPA class of action depends on the nature of the proposed action, its complexity, and the potential impacts. For purposes of this NOFO, NEPA also includes all related Federal laws and regulations including the Clean Air Act, Section 4(f) of the Department of Transportation Act, Section 7 of the Endangered Species Act, and Section 106 of the National Historic Preservation Act. Additional information regarding FRA's environmental processes and requirements are located at *https://www.fra.dot.gov/environment*.

h. ''Pathway-Rail Grade Crossing'' means a pathway that crosses one or more railroad tracks at grade and that is: (1) explicitly authorized by a public authority or a railroad; (2) dedicated for the use of non-vehicular traffic, including pedestrians, bicyclists, and others; and (3) not associated with a public highway, road, or street, or a private roadway.

i. ''Preliminary Engineering (PE)'' means engineering design to: (1) define a project, including identification of all environmental impacts, design of all critical project elements at a level sufficient to assure reliable cost estimates and schedules; (2) complete project management and financial plans; and (3) identify procurement requirements and strategies. The PE development process starts with specific project design alternatives that allow for the assessment of a range of rail improvements, specific alignments, and project designs. PE generally occurs concurrently with NEPA and related analyses, and prior to Final Design and Construction.

j. ''Rural Area'' means any area that is not within an area designated as an urbanized area by the most recent Bureau of the Census.

k. ''Track Relocation'' means moving a rail line vertically or laterally to a new location in order to eliminate an existing highway-rail grade crossing. ''Vertical Relocation'' refers to raising above the current ground level or sinking below the current ground level of a rail line. ''Lateral Relocation'' refers to moving a rail line horizontally to a new location.

l. ''Tribal Lands'' means any lands reserved for a Federally-recognized Native American tribe or tribes under treaty or other agreement with the United States, executive order, or federal statute or administrative action as permanent tribal homelands, and where the federal government holds title to the land in trust on behalf of the tribe.

B. Federal Award Information

1. Available Award Amount

The total funding available for awards under this NOFO is $573,264,000.[3] Should additional RCE Program funds become available after the release of this NOFO, FRA may elect to award such additional funds to applications received under this NOFO.

Further, certain funding amounts are set-aside for the following purposes under this NOFO:

(a) Planning Projects—At least three percent of the total grant funds available, or $18,000,000, will be made available for planning projects described in 49 U.S.C. 22909(d)(6). At least 25 percent of these funds, or $4,500,000 will be made available for projects located in Rural Areas or on Tribal Lands.

(b) Rural or Tribal set aside—At least 20 percent of the total grant funds available, or $114,652,800, will be made available for projects located in Rural Areas or on Tribal Lands, as required by 49 U.S.C. 22909(f)(3)(A). At least five percent of these funds, or $5,732,640 will be made available for projects in counties with 20 or fewer residents per square mile, according to the most recent decennial census, provided that sufficient eligible applications have been submitted.

In addition, FRA will make at least $1,500,000 available for grants that carry out Highway-Rail Grade Crossing safety information and education programs.

2. Award Size

FRA will not award grants for less than $1,000,000, except for a planning project, as described in section 49 U.S.C. 22909(d)(6). There are no predetermined maximum dollar thresholds for individual awards, but no more than 20% of the grant funds available ($114,652,800) will be awarded for projects in any single State. FRA anticipates making multiple awards with the available funding. Given the limited amount of funding currently available, FRA may not be able to award grants to all eligible applications even if they meet or exceed the stated evaluation criteria (see Section E, Application Review Information). Projects may require more funding than is available. FRA encourages applicants to propose a project that has operational independence, or a component of such project, that can be completed and implemented with funding under this NOFO as a part of the total project cost together with other, non-Federal sources. (See Section C(3)(c) for more information.)

3. Award Type

FRA will make awards for projects selected under this notice through grant agreements and/or cooperative agreements. Grant agreements are used when FRA does not expect to have substantial Federal involvement in carrying out the funded activity. Cooperative agreements allow for substantial Federal involvement in carrying out the agreed upon investment, including technical assistance, review of interim work products, and increased program oversight. The term ''grant'' is used throughout this document and is intended to reference funding awarded through a grant agreement or a cooperative agreement. The funding provided under this NOFO will be made available to grantees on a reimbursable basis. Applicants must certify that their expenditures are allowable, allocable, reasonable, and necessary to the approved project before seeking reimbursement from FRA. Additionally, the grantee is expected to expend matching funds at the required percentage concurrent with Federal funds throughout the life of the project. See an example of standard terms and conditions for FRA grant awards at: *https://www.fra.dot.gov/eLib/Details/*

[3] Of the $600,000,000 in funding made available in Title J of IIJA, $14,736,000 will be separately made available for Special Transportation Circumstances grants and $12,000,000 will be set aside for award and program oversight conducted by FRA.

L19057. This template is subject to revision.

4. Concurrent Applications

DOT and FRA may be concurrently soliciting applications for transportation infrastructure projects for several financial assistance programs. Applicants may submit applications requesting funding for a particular project to one or more of these programs. In the application for funding under this NOFO, applicants must indicate the other program(s) to which they submitted an application for funding the entire project or certain project components, as well as highlight new or revised information in the application responsive to this NOFO that differs from the previously submitted application(s).

C. Eligibility Information

This section of the notice explains applicant eligibility, cost sharing and matching requirements, project eligibility, and project component operational independence. Applications that do not meet the requirements in this section are ineligible for funding. Instructions for submitting eligibility information to FRA are detailed in Section D of this NOFO.

1. Eligible Applicants

The following entities are eligible applicants for all projects permitted under this notice:

a. A State, including the District of Columbia, Puerto Rico, and other United States territories and possessions;

b. A political subdivision of a State;

c. A federally recognized Indian Tribe.

d. A unit of local government or a group of local governments.

e. A public port authority.

f. A metropolitan planning organization.

g. A group of entities described in any of paragraphs (1) through (6).

Grants under the RCE Program are not subject to the limitation in 49 U.S.C. 22905(f) and may therefore be awarded for commuter rail passenger transportation projects. FRA will transfer such projects to the Federal Transit Administration to administer.

The applicant serves as the primary point of contact for the application, and if selected, as the recipient of the RCE Program grant award. An application may identify entities that are not eligible applicants as project partners.

2. Cost Sharing or Matching

The Federal share of total costs for RCE Program projects funded under this notice shall not exceed 80 percent. The estimated total cost of a project must be based on the best available information, including engineering studies, studies of economic feasibility, and environmental analyses. Additionally, in preparing estimates of total project costs, applicants may use FRA's cost estimate guidance, ''Capital Cost Estimating: Guidance for Project Sponsors,'' which is available at: *https://www.fra.dot.gov/Page/P0926*.

The minimum 20 percent non-Federal share may be comprised of public sector funding (*e.g.,* state, or local) or private sector funding. FRA will not consider any Federal financial assistance [4] or any non-Federal funds already expended (or otherwise encumbered) toward the matching requirement, unless compliant with 2 CFR part 200. In-kind contributions, including the donation of services, materials, and equipment, may be credited as a project cost, in a uniform manner consistent with 2 CFR 200.306. In addition, applicants may count costs incurred for Preliminary Engineering associated with Highway-Rail Grade Crossing and Pathway-Rail Grade Crossing Improvement Projects as part of the total project costs. Such costs are eligible as non-Federal share or for reimbursement, even if they were incurred before project selection for award, consistent with 49 U.S.C. 22909(g).[5] Such costs must have been incurred no earlier than November 15, 2021 and must be otherwise compliant with 2 CFR part 200 and the requirements of this RCE Program.

Before applying, applicants should carefully review the principles for cost sharing or matching in 2 CFR 200.306. See Section D(2)(a)(iii) for required application information on non-Federal match and Section E for further discussion of FRA's consideration of matching funds in the review and selection process. FRA will approve pre-award costs consistent with 2 CFR 200.458, as applicable. See Section D(6). Cost sharing or matching may be used only for eligible expenses under the Program and are subject to the requirements of the Federal award.

[4] See Section D(2)(a)(iii) for supporting information required to demonstrate eligibility of Federal funds for use as match.

[5] FRA interprets the language in 49 U.S.C. 22909(g) to permit FRA to reimburse grantees for Preliminary Engineering costs incurred before the date of project selection, if the costs would be permitted as part of total project costs if incurred after the date of project selection and are consistent with 2 CFR part 200.

3. Other

a. Project Eligibility

The following Highway-Rail or Pathway-Rail Grade Crossing Improvement Projects that focus on improving the safety and mobility of people and goods are eligible for funding under 49 U.S.C. 22909(d), and this NOFO:

(1) Grade separation or closure, including through the use of a bridge, embankment, tunnel, or combination thereof;

(2) Track relocation;

(3) The improvement or installation of protective devices, signals, signs, or other measures the improve safety, provided that such activities are related to a separation or relocation project described in paragraph (1) or (2);

(4) Other means to improve the safety and mobility of people and goods at highway-rail grade crossings (including technological solutions); [6]

(5) A group of related projects described in paragraphs (1) through (4) that would collectively improve the mobility of people and goods; or

(6) The planning, environmental review, and design of an eligible project described in paragraphs (1) through (5).[7]

b. Project Component Operational Independence

If an applicant requests funding for a project that is a component or set of components of a larger project, then the project component(s) must be attainable with the award amount and must comply with all eligibility requirements described in Section C.

In addition, the component(s) must enable independent analysis and decision making, as determined by FRA, under NEPA (*i.e.,* have independent utility, connect logical termini, and do not restrict the consideration of alternatives for other reasonably foreseeable rail projects).

c. Rural or Tribal Lands Project

FRA will consider a project to be in a Rural Area or on Tribal Lands if all or the majority of the project (determined by geographic location(s) where the majority of the project funds will be spent) is located in a Rural Area or on Tribal Lands. However, in the event FRA elects to fund a component of the project, then FRA will reevaluate whether the project is in a Rural Area or on Tribal Lands.

[6] Highway-Rail Grade Crossing Safety Information and Education Programs are eligible under this category.

[7] Projects under this section are eligible independently, or together with construction of a project in paragraph (1) through (5).

D. Application and Submission Information

Required documents for the application are outlined in the following paragraphs. Applicants must complete and submit all components of the application. See *Section D(2)* for the application checklist. FRA welcomes the submission of additional relevant supporting documentation, such as planning, engineering and design documentation, and letters of support from partnering organizations that will not count against the Project Narrative 25-page limit.

1. Address To Request Application Package

Application materials may be accessed at *https://www.Grants.gov*. Applicants must submit all application materials in their entirety through *https://www.Grants.gov* no later than 5:00 p.m. ET, on October 4, 2022. Applicants are strongly encouraged to apply early to ensure that all materials are received before the application deadline. FRA reserves the right to modify this deadline. General information for submitting applications through *Grants.gov* can be found at: *https://www.fra.dot.gov/Page/P0270*. FRA is committed to ensuring that information is available in appropriate alternative formats to meet the requirements of persons who have a disability. If you require an alternative version of files provided, please contact Laura Mahoney at *laura.mahoney@dot.gov;* phone: 202–578–9337.

2. Content and Form of Application Submission

FRA strongly advises applicants to read this section carefully. Applicants must submit all required information and components of the application package to be considered for funding. Applications that are not submitted on time or do not contain all required documentation will not be considered for funding.

Required documents for an application package are outlined in the checklist below.

i. Project Narrative (see D.2.a).
ii. Statement of Work (see D.2.b.i).
iii. Environmental Compliance Documentation (see D.2.b.iii).
iv. SF 424—Application for Federal Assistance.
v. SF 424A—Budget Information for Non-Construction or SF 424C—Budget Information for Construction.
vi. SF 424B—Assurances for Non-Construction or SF 424D—Assurances for Construction.
vii. FRA F 30—Certifications Regarding Debarment, Suspension and Other Responsibility Matters, Drug-Free Workplace Requirements and Lobbying.
viii. FRA F 251—Applicant Financial Capability Questionnaire
ix. SF LLL—Disclosure of Lobbying Activities, if applicable.

a. Project Narrative

This section describes the minimum content required in the Project Narrative of grant applications. The Project Narrative must follow the basic outline below to address the program requirements and assist evaluators in locating relevant information.

I. Cover Page	See D.2.a.i
II. Project Summary	See D.2.a.ii
III. Project Funding	See D.2.a.iii
IV. Applicant Eligibility	See D.2.a.iv
V. Detailed Project Description.	See D.2.a.v
VI. Project Location	See D.2.a.vi
VII. Grade Crossing Information.	See D.2.a.vii
VIII. Evaluation and Selection Criteria.	See D.2.a.viii
IX. Safety Benefit	See D.2.a.ix
X. Project Implementation and Management.	See D.2.a.x
XI. Environmental Readiness.	See D.2.a.xi

The above content must be provided in a narrative statement submitted by the applicant. The Project Narrative may not exceed 25 pages in length (excluding cover pages, table of contents, and supporting documentation). If possible, applicants should submit supporting documents via website links rather than hard copies. If supporting documents are submitted, applicants must clearly identify the relevant portion of the supporting document with the page numbers of the cited information in the Project Narrative. The Project Narrative must adhere to the following outline.

i. *Cover Page:* Include a cover page that lists the following elements in either a table or formatted list:

Project Title	
Applicant	
Federal Funding Requested Under this NOFO	$:
Proposed Non-Federal Match	$: In-Kind:
Does some or all of the proposed Non-Federal Match for the total project cost consist of preliminary engineering costs incurred before project selection?.	If yes, how much?
Other Sources of Federal funding, if applicable	Source: $:
Total Project Cost	$:
Was a Federal Grant Application Previously Submitted for this Project?	Yes/No. If yes, please specify the program, funding year and project title of the previous application.
City(-ies), State(s) Where the Project is Located	
Congressional District(s) Where the Project is Located	
Is this project identified in:	Yes/No. If Yes, please specify in which plans the project is currently identified, and provide the identifying number if applicable.
• The freight investment plan component of a State freight plan, as required under Section 70202(b)(9),. • A State rail plan prepared in accordance with Chapter 227; or. • A State highway-rail grade crossing action plan, as required under section 11401(b) of Passenger Rail Reform and Investment Act of 2015 (title XI of Public Law 114–94).	
Is the Project Located in a Rural Area or on Tribal Land?	
Is the project eligible for a funding set-aside in Section B.1?	If yes, please specify which one [Planning Projects, Safety Information and Education Program, Rural or Tribal Set-Aside].

If the Project is located in a Rural Area or Tribal Land, is the Project Located in a county with 20 or fewer residents per square mile, according to the most recent decennial census.	
U.S. DOT Crossing Number(s) [8] (if applicable)	
Is the Project located on real property owned by someone other than the applicant? ..	If yes, list real property owners and the nature of the property interest.

ii. *Project Summary:* Provide a brief 4–6 sentence summary of the proposed project and what the project will entail. Include challenges the proposed project aims to address and summarize the intended outcomes and anticipated benefits that will result from the proposed project.

iii. *Project Funding:* Indicate in table format the amount of Federal funding requested, the proposed non-Federal match, and total project cost. Identify the source(s) of matching and other funds, and clearly and distinctly reflect these funds as part of the total project cost in the application budget. Specifically, identify the financial support, if any, from impacted rail carriers. Include funding commitment letters outlining funding agreements, as attachments or in an appendix. If Federal funding is proposed as match, demonstrate the applicant's determination of eligibility for such use, and the legal basis for that determination. Also, note if the requested Federal funding under this NOFO or other programs must be obligated or spent by a certain date due to dependencies or relationships with other Federal or non-Federal funding sources, related projects, law, or other factors. If applicable, provide the type and estimated value of any proposed in-kind contributions, as well as substantiate how the contributions meet the requirements in 2 CFR 200.306. Finally, specify whether Federal funding for the project has previously been sought, and identify the Federal program and fiscal year of the funding request(s), as well as highlight new or revised information in the RCE Program application that differs from the application(s) to other financial assistance programs. If costs incurred for Preliminary Engineering activities, consistent with Section C.2 are proposed as match, describe the activities including the date(s) costs were incurred.

EXAMPLE PROJECT FUNDING TABLE

Task No.	Task name/project component	Cost	Percentage of total cost
1			
2			
Total Project Cost			
Federal Funds Received from Previous Grant			
Federal Funding Request Under this NOFO			
Non-Federal Funding/Match	Cash: ..... In-Kind: ..... Preliminary Engineering costs, consistent with Section C.2:.		
Portion of Non-Federal Funding from the Private Sector			
Please list amounts per source			
Portion of Total Project Costs Spent in a Rural Area or on Tribal Lands			
Pending Federal Funding Requests			

iv. *Applicant Eligibility:* Explain how the applicant meets the applicant eligibility criteria outlined in *Section C* of this notice including where appropriate citations to applicable enabling legislation for the applicant.

v. *Detailed Project Description:* Include a detailed project description that expands upon the brief project summary. This detailed description should provide, at a minimum: additional background on the challenges the project aims to address; the expected outcomes; the expected users and beneficiaries of the project, including all railroad operators; the specific components and elements of the project; and any other information the applicant deems necessary to justify the proposed project. For all projects, applicants must provide information about proposed performance measures, as described in *Section F(3)(c)* and required in 2 CFR 200.301. . Applicants should specify whether the project will result in the elimination of one or more grade crossings through grade separation or otherwise.

vi. *Highway-Rail Grade Crossing Safety Information and Education Programs:*—For these projects, specify how the program will help prevent and reduce pedestrian, motor vehicle and other accidents, incidents, injuries and facilities, and how the program will help improve awareness along railroad rights-of-way and at highway-rail grade crossings.

vii. *Project Location:* Include geospatial data for the project, as well as a map of the project's location. Geospatial data can be expressed in terms of decimal degrees for latitude and longitude of at least five decimal places of precision or start and end

[8] *https://railroads.dot.gov/safety-data/crossing-and-inventory-data/crossing-inventory-lookup.*

mileposts designating railroad code and subdivision name. On the map, include the Congressional districts in which the project will take place.

viii. *Grade Crossing Information:* Cite specific DOT National Grade Crossing Inventory information, including the railroad that owns the infrastructure (or the crossing owner, if different from the railroad), the primary railroad operator, the DOT crossing inventory number, and the roadway at the crossing. Applicants can search for data to meet this requirement at the following link: *http://safetydata.fra.dot.gov/OfficeofSafety/default.aspx.*

ix. *Evaluation and Selection Criteria:* Include a thorough discussion of how the proposed project meets all of the evaluation and selection criteria, as outlined in *Section E* of this notice. If an application does not sufficiently address the evaluation criteria and the selection criteria, it is unlikely to be a competitive application.

x. *Safety Benefit:* Applicants are strongly encouraged to submit safety justifications for the project that rely on standardized, objective safety metrics and data, if available, including data from sources such as: GradeDec.Net; National Risk Index; 49 CFR part 234; safety metrics found in Appendix D of 49 CFR part 222; the FRA crossing incident dashboard (FRA Safety Data & Reporting | FRA (*dot.gov*)); or other relevant safety data or metrics.

xi. *DOT Strategic Goals:* To the extent feasible, and consistent with the selection criteria described in Section F.2, applicants should describe efforts to consider climate change and sustainability impacts, as well as efforts to improve equity and reduce barriers to opportunity in project planning. In addition, applicants should describe how planning activities and project delivery actions advance good-paying, quality jobs and workforce programs and hiring policies that promote workforce inclusion.

xii. *Project Implementation and Management:* Describe proposed project implementation and project management arrangements, including between the applicant and project partners, if any. Include descriptions of the expected arrangements for project contracting, contract oversight and control, change-order management, risk management, and conformance to Federal requirements for project progress reporting (see *https://www.fra.dot.gov/Page/P0274*). Describe past experience in managing and overseeing similar projects.

xiii. *Environmental Readiness:* If the NEPA process is complete, an applicant should indicate the date of completion, and provide a website link or other reference to the documents demonstrating compliance with NEPA, which might include a final Categorical Exclusion, Finding of No Significant Impact, or Record of Decision. If the NEPA process is not yet underway, the application should state this. If the NEPA process is underway, but not complete, the application should detail the type of NEPA review underway, where the project is in the process, and indicate the anticipated date of completion of all NEPA-related milestones. If the last agency action with respect to NEPA documents occurred more than three years before the application date, the applicant should describe why the project has been delayed and why NEPA documents have not been updated and include a proposed approach for verifying and, if necessary, updating this material in accordance with applicable NEPA requirements. Additional information regarding FRA's environmental processes and requirements are located at *https://www.fra.dot.gov/environment.*

b. Additional Application Elements

Applicants must submit:

i. A Statement of Work (SOW) addressing the scope, schedule, budget, and performance measures for the proposed project if it were selected for award. The SOW must contain sufficient detail so FRA, and the applicant, can understand the expected outcomes of the proposed work to be performed and can monitor progress toward completing project tasks and deliverables during a prospective grant's period of performance. Applicants must submit an SOW, schedule, budget, and performance measures to be considered for award. These four required documents are labeled Example General Grants—Attachments 2–5 and are located at *https://www.fra.dot.gov/Page/P0325.* Applications that do not include all four of the grant package templates will be considered incomplete and will not be reviewed. When preparing the budget, the total cost of a project must be based on the best available information as indicated in cited references that include engineering studies, economic feasibility studies, environmental analyses, and information on the expected use of equipment or facilities.

ii. Environmental compliance documentation, as applicable, if a website link is not cited in the Project Narrative.

iii. SF 424—Application for Federal Assistance.

iv. SF 424A—Budget Information for Non-Construction or SF 424C—Budget Information for Construction.

v. SF 424B—Assurances for Non-Construction or SF 424D—Assurances for Construction.

vi. FRAF 30—Certifications Regarding Debarment, Suspension and Other Responsibility Matters, Drug-Free Workplace Requirements and Lobbying, located at *https://railroads.dot.gov/elibrary/fra-f-30-certifications-regarding-debarment-suspension-and-other-responsibility-matters.*

vii. FRA F 251—Applicant Financial Capability Questionnaire, located at *https://railroads.dot.gov/elibrary/fra-f-251.*

viii. SF LLL—Disclosure of Lobbying Activities, if applicable.

Standard OMB Forms needed for the electronic application process are at *www.Grants.gov.*

c. Post-Selection Requirements

See Section F(2) of this notice for post-selection requirements.

3. Unique Entity Identifier and System for Award Management (SAM)

To apply for funding through *Grants.gov*, applicants must be properly registered in SAM before submitting an application; provide a valid unique entity identifier in its application; and continue to maintain an active SAM registration as described in detail below. Complete instructions on how to register and submit an application can be found at *www.Grants.gov.* Registering with *Grants.gov* is a one-time process; however, it can take up to several weeks for first-time registrants to receive confirmation and a user password. FRA recommends that applicants start the registration process as early as possible to prevent delays that may preclude submitting an application package by the application deadline. Applications will not be accepted after the due date. Delayed registration is not an acceptable justification for an application extension.

FRA may not make a grant award to an applicant until the applicant has complied with all applicable SAM requirements. If an applicant has not fully complied with these requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Late applications that are the result of a failure to register or comply with *Grants.gov* applicant requirements in a timely manner will not be considered. If

an applicant has not fully complied with the requirements by the submission deadline, the application will not be considered. To submit an application through *Grants.gov*, applicants must:

a. Register With the SAM at *www.SAM.gov*

All applicants for Federal financial assistance must maintain current registrations in the SAM database. An applicant must be registered in SAM to successfully register in *Grants.gov*. The SAM database is the repository for standard information about Federal financial assistance applicants, recipients, and subrecipients. Organizations that have previously submitted applications via *Grants.gov* are already registered with SAM, as it is a requirement for *Grants.gov* registration. Please note, however, that applicants must update or renew their SAM registration at least once per year to maintain an active status. Therefore, it is critical to check registration status well in advance of the application deadline. If an applicant is selected for an award, the applicant must maintain an active SAM registration with current information throughout the period of the award, including information on a recipient's immediate and highest-level owner and subsidiaries, as well as on all predecessors that have been awarded a federal contract or grant within the last three years, if applicable. Information about SAM registration procedures is available at *www.sam.gov.*

b. Obtain a Unique Entity Identifier

On April 4, 2022, the federal government stopped using DUNS numbers. The DUNS Number was replaced by a new, non-proprietary identifier that is provided by the System for Award Management (*SAM.gov*). This new identifier is called the Unique Entity Identifier (UEI), or the Entity ID. To find or request a Unique Entity Identifier, please visit *www.sam.gov.*

c. Create a *Grants.gov* Username and Password

Applicants must complete an Authorized Organization Representative (AOR) profile on *www.Grants.gov* and create a username and password. Applicants must use the organization's UEI to complete this step. Additional information about the registration process is available at: *https://www.grants.gov/web/grants/applicants/organization-registration.html.*

d. Acquire Authorization for Your AOR From the E-Business Point of Contact (E-Biz POC)

The E-Biz POC at the applicant's organization must respond to the registration email from *Grants.gov* and login at *www.Grants.gov* to authorize the applicant as the AOR. Please note there can be more than one AOR for an organization.

e. Submit an Application Addressing All Requirements Outlined in This NOFO

If an applicant has trouble at any point during this process, please call the *Grants.gov* Customer Center Hotline at 1–800–518–4726, 24 hours a day, 7 days a week (closed on Federal holidays). For information and instructions on each of these processes, please see instructions at: *http://www.grants.gov/web/grants/applicants/apply-for-grants.html.*

4. Submission Dates and Times

Applicants must submit complete applications to *www.Grants.gov* no later than 5:00 p.m. ET, October 4, 2022. Applicants will receive a system-generated acknowledgement of receipt. FRA reviews *www.Grants.gov* information on dates/times of applications submitted to determine timeliness of submissions. Late applications will be neither reviewed nor considered. Delayed registration is not an acceptable reason for late submission. To apply for funding under this announcement, all applicants are expected to be registered as an organization with *Grants.gov*. Applicants are strongly encouraged to apply early to ensure all materials are received before this deadline.

To ensure a fair competition of limited discretionary funds, the following conditions are not valid reasons to permit late submissions: (1) failure to complete the *Grants.gov* registration process before the deadline; (2) failure to follow *Grants.gov* instructions on how to register and apply as posted on its website; (3) failure to follow all the instructions in this NOFO; and (4) technical issues experienced with the applicant's computer or information technology environment.

5. Intergovernmental Review

Intergovernmental Review is required for this program. Applicants must contact their State Single Point of Contact to comply with their State's process under Executive Order 12372.

6. Funding Restrictions

Consistent with 2 CFR 200.458, as applicable, FRA will only approve pre-award costs if such costs are incurred pursuant to the negotiation and in anticipation of the grant agreement and if such costs are necessary for efficient and timely performance of the scope of work. Under 2 CFR 200.458, grant recipients must seek written approval from FRA for pre-award activities to be eligible for reimbursement under the grant. Activities initiated prior to the execution of a grant or without FRA's written approval may be ineligible for reimbursement or matching contribution. Cost sharing or matching may be used only for authorized Federal award purposes.

7. Other Submission Requirements

For any supporting application materials that an applicant cannot submit via *Grants.gov*, such as oversized engineering drawings, an applicant may submit an original and two (2) copies to Douglas Gascon, Federal Railroad Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, FRA advises applicants to use other means of conveyance (such as courier service) to assure timely receipt of materials before the application deadline. Additionally, if documents can be obtained online, explaining to FRA how to access files on a referenced website may also be sufficient.

Note: Please use generally accepted formats such as .pdf, .doc, .docx, .xls, .xlsx and .ppt, when uploading attachments. While applicants may embed picture files, such as .jpg, .gif, and .bmp in document files, applicants should not submit attachments in these formats. Additionally, the following formats will not be accepted: .com, .bat, .exe, .vbs, .cfg, .dat, .db, .dbf, .dll, .ini, .log, .ora, .sys, and .zip.

E. Application Review Information

1. Criteria

a. Eligibility, Completeness, and Applicant Risk Review

FRA will first screen each application for applicant and project eligibility (eligibility requirements are outlined in Section C of this notice), completeness (application documentation and submission requirements are outlined in Section D of this notice), and the 20 percent minimum non-Federal match.

FRA will then consider applicant risk, including the applicant's past performance in developing and delivering similar projects.

b. Evaluation Criteria

FRA will evaluate all eligible and complete applications using the evaluation criteria outlined in this section to determine project benefits and technical merit.

i. Project Benefits

FRA will evaluate application information for the extent to which the proposed project —

(A) Improves safety at Highway-Rail or Pathway Rail Grade Crossings;

(B) Proposes to grade separate, eliminate, or close one or more Highway-Rail or Pathway-Rail Grade Crossings;

(C) Improves the mobility of both people and goods;

(D) Reduces emissions, protects the environment, and provides community benefit (including noise reduction);

(E) Improves access to emergency services;

(F) Improves access to communities;

(G) Provides economic benefit; and

(H) Uses contracting incentives to employ local labor, to the extent permissible under Federal law.

ii. Technical Merit

FRA will evaluate application information for the degree to which —

(A) The tasks and subtasks outlined in the statement of work (SOW) are appropriate to achieve the expected outcomes of the proposed project;

(B) The application demonstrates strong project readiness and ability to meet RCE Program requirements;

(C) The technical qualifications and experience of key personnel the applicant proposes to lead and perform the technical efforts, including the qualifications of the primary and supporting organizations, demonstrates the ability to fully and successful execute the proposed project within the proposed time frame and budget;

(D) The project is identified in the freight investment plan component of a state freight plan, a state rail plan, a state highway-rail grade crossing action plan, a state freight plan, or other equivalent document;

(E) The project will use innovative technologies, innovative design and construction techniques, or construction materials that reduce greenhouse gas emissions;

(F) The project will use financial support from impacted rail carriers; and

(G) The project will improve the mobility of multiple modes of transportation, including ingress and egress from freight facilities, or users of nonvehicular modes of transportation such as pedestrians, bicycles, and public transportation.

c. Selection Criteria

After the eligibility and completeness review and the evaluation criteria outlined in this section, FRA will then consider the extent to which the projects address the following program preferences and DOT Strategic Goals:

(A) Safety

FRA will assess the project's ability to foster a safe transportation system for the movement of goods and people, consistent with the Department's strategic goal to reduce transportation-related fatalities and serious injuries across the transportation system. Such considerations will include, but are not limited to, the extent to which the project improves safety at highway-rail grade crossings, reduces incidences of rail-related trespassing, and upgrades infrastructure to achieve a higher level of safety.[9]

(B) Equitable Economic Strength and Improving Core Assets

FRA will assess the project's ability to contribute to economic progress stemming from infrastructure investment and associated job creation in the industry. Such considerations will include, but are not limited to, the extent to which the project results in long-term job creation by supporting good-paying jobs directly related to the project with free and fair choice to join a union, such as through the use of project labor agreements, registered apprenticeships, and local hiring provisions, or other targeted preferential hiring requirements, or other similar standards or protections; invests in vital infrastructure assets and provides opportunities for families to achieve economic security through rail industry employment.

(C) Equity and Barriers to Opportunity

FRA will assess the project's ability to address equity and barriers to opportunity, to the extent possible within the program and consistent with law Such considerations will include, but are not limited to, the extent to which the project improves or expands transportation options, mitigates the safety risks and detrimental quality of life effects that rail lines can have on communities, and expands workforce development and training opportunities to foster a more diverse rail industry. This will also include community engagement efforts already taken or planned, the extent to which engagement efforts are designed to reach impacted communities, whether engagement is accessible for persons with disabilities or limited English proficient persons within the impacted communities, and how community feedback is taken into account in decision-making.

(D) Climate Change and Sustainability

In support of E.O. 14008, ''Tackling the Climate Crisis at Home and Abroad,'' FRA will assess the project's ability to reduce the harmful effects of climate change and anticipate necessary improvements to prepare for extreme weather events. Such considerations will include, but are not limited to, the extent to which the project reduces emissions, promotes energy efficiency, increases resiliency, and recycles or redevelops existing infrastructure.

(E) Transformation of Our Nation's Transportation Infrastructure

FRA will assess the project's ability to expand and improve the nation's rail network, which needs to balance new infrastructure for increased capacity with proper maintenance of aging assets. Such considerations will include, but are not limited to, the extent to which the project adds capacity to congested corridors, and ensures assets will be improved to a state of good repair.

(F) Eliminating Crossings and Making Corridor-Wide Improvements

FRA will assess whether the project results in the elimination of one or more grade crossings through grade separations, closing crossings through track relocation, and corridor-wide grade crossing improvements.

(G) Geographic Diversity

In determining the allocation of program funds, FRA may also consider geographic diversity, diversity in the size of the systems receiving funding, and the applicant's receipt of other competitive awards. FRA will allocate program funds consistent with 49 U.S.C. 22909(f)(3).

2. Review and Selection Process

FRA will conduct a four-part application review process, as follows:

a. Screen applications for applicant and project eligibility, completeness, the minimum match and applicant risk including past performance in developing and delivering similar projects;

[9] To best evaluate the safety benefit of a particular proposal, FRA encourages applicants to submit justifications that rely on standardized, objective safety metrics and data, if available, including: Grade Dec.Net; National Risk Index; 49 CFR part 234; Safety metrics found in Appendix D of 49 CFR part 222; FRA crossing incident dashboard (FRA Safety Data & Reporting | FRA (*dot.gov*)); and Other relevant safety data or metrics.

b. Evaluate remaining applications (completed by technical panels applying the evaluation criteria);

c. Review and apply selection criteria and recommend initial selection of projects for the FRA Administrator's review (completed by a Senior Review Team, which includes senior leadership from the Office of the Secretary and FRA); and

d. Select recommended awards for the Secretary's or his designee review and approval (completed by the FRA Administrator).

3. Reporting Matters Related to Integrity and Performance

Before making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold of $250,000 (see 2 CFR 200.88 Simplified Acquisition Threshold), FRA will review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). See 41 U.S.C. 2313.

An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.

FRA will consider any comments by the applicant, in addition to the other information, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR 200.205.

F. Federal Award Administration Information

1. Federal Award Notice

FRA will announce applications selected for funding in a press release and on FRA's website after the application review period. This announcement is FRA's notification to successful and unsuccessful applicants alike. FRA will contact applicants with successful applications after announcement with information and instructions about the award process. This notification is not an authorization to begin proposed project activities. FRA requires satisfaction of applicable requirements by the applicant and a formal agreement signed by both the grantee and the FRA, including an approved scope, schedule, and budget, before obligating the grant. See an example of standard terms and conditions for FRA grant awards at *https://railroads.fra.dot.gov/elibrary/award-administration-and-grant-conditions.* This template is subject to revision.

2. Administrative and National Policy Requirements

In connection with any program or activity conducted with or benefiting from funds awarded under this notice, recipients of funds must comply with all applicable requirements of Federal law, including, without limitation: the Constitution of the United States; the relevant authorization and appropriations, the conditions of performance, nondiscrimination requirements, and other assurances made applicable to the award of funds in accordance with regulations of DOT; and applicable Federal financial assistance and contracting principles promulgated by the Office of Management and Budget (OMB). In complying with these requirements, grantees, in particular, must ensure that no concession agreements are denied or other contracting decisions made on the basis of speech or other activities protected by the First Amendment. If FRA determines that a recipient has failed to comply with applicable Federal requirements, FRA may terminate the award of funds and disallow previously incurred costs, requiring the recipient to reimburse any expended award funds. See an example of standard terms and conditions for FRA grant awards at *https://railroads.dot.gov/elibrary/award-administration-and-grant-conditions.* This template is subject to revision.

Examples of administrative and national policy requirements include: 2 CFR part 200; procurement standards at 2 CFR part 200 subpart D—Procurement Standards; 2 CFR 1207.317 and 2 CFR 200.401; compliance with Federal civil rights laws and regulations; disadvantaged business enterprises requirements; debarment and suspension requirements; drug-free workplace requirements; FRA's and OMB's Assurances and Certifications; Americans with Disabilities Act; safety requirements; NEPA; environmental justice requirements; compliance with 49 U.S.C. 24905(c)(2) for the duration of NEC Projects; and 2 CFR 200.315, governing rights to intangible property. Unless otherwise stated in statutory or legislative authority, or appropriations language, all financial assistance awards follow the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards at 2 CFR part 200 and 2 CFR part 1201.

Assistance under this NOFO is subject to the grant conditions in 49 U.S.C. 22905, including protective arrangements that are equivalent to the protective arrangements established under section 504 of the Railroad Revitalization and Regulatory Reform Act of 1976 (45 U.S.C. 836) with respect to employees affected by actions taken in connection with the project to be financed in whole or in part by grants subject to 49 U.S.C. 22905,[10] the provision deeming operators rail carriers and employers for certain purposes, and grantee agreements with railroad right-of-way owners for projects using railroad rights-of-way (see D.2.b.xi). In addition, recipients shall obtain necessary approvals, required under 49 U.S.C. 22909(e)(2)(A), if applicable, from any impacted rail carriers or real property owners before proceeding with the construction of a project funded by a grant under this NOFO. For planning projects, the applicant may submit instead an acknowledgment that it agrees to work collaboratively with impacted rail carriers and right-of-way owners. This condition applies notwithstanding 49 U.S.C. 22909(j)(2) and 49 U.S.C 22905(e)(1).

Grants under the RCE Program are not subject to the limitation in 49 U.S.C. 22905(f) and may therefore be awarded for commuter rail passenger transportation projects. FRA will transfer such projects to the Federal Transit Administration to administer, consistent with 49 U.S.C. 22909(j).

Projects that have not sufficiently considered climate change and sustainability in their planning, as determined by FRA, will be required to do so before receiving funds for construction, consistent with Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad* (86 FR 7619). In the grant agreement, recipients will be expected to describe activities they have taken, or will take prior to obligation of construction funds that addresses climate change and environmental justice (EJ). Activities that address climate change include, but are not limited to, demonstrating: the project will result in significant greenhouse gas emissions reductions; the project supports emissions reductions goals in a Local/Regional/State plan; and the project primarily focuses on funding for state of good repair and clean transportation options, including public transportation,

[10] FRA has posted guidance at *https://railroads.dot.gov/elibrary/frequently-asked-questions-about-rail-improvement-grant-conditions-under-49-usc-ss-22905c1* to assist grantees implementing the protective arrangements.

walking, biking, micro-mobility. Activities that address EJ include, but are not limited to: basing project design on the results of a proven EJ screening tool (developed by another Federal agency such as the EPA, a state agency, etc.); conducting enhanced, targeted outreach to EJ communities; considering EJ in alternatives analysis and final project design; and supporting a modal shift in freight or passenger movement to reduce emissions or reduce induced travel demand.

Projects must consider and address equity and barriers to opportunity in their planning, as determined by FRA, and as a condition of receiving construction funds, consistent with Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* (86 FR 7009). The grant agreement should include the recipient's description of activities they have taken, or will take prior to obligation of construction funds that addresses equity and barriers to opportunity. These activities may include, but are not limited to: completing an equity impact analysis for the project; adopting an equity and inclusion program/plan; conducting meaningful public engagement to ensure underserved communities are provided an opportunity to be involved in the planning process; including investments that either redress past barriers to opportunity or that proactively create new connections and opportunities for underserved communities; hiring from local communities; improving access to or providing economic growth opportunities for underserved, overburdened, or rural communities; or addressing historic or current inequitable air pollution or other environmental burdens and impacts.

Each applicant selected for grant funding should ensure planning activities and project delivery actions advance good-paying, quality jobs and workforce programs and hiring policies that promote workforce inclusion, consistent with Executive Order 14025, *Worker Organizing and Empowerment* (86 FR 22829), and Executive Order 14052, *Implementation of the Infrastructure Investment and Jobs Act* (86 FR 64335). Specifically, the project must support: (a) strong labor standards and the choice to join a union,[11] including project labor agreements and distribution of workplace rights notices; (b) support of high-quality workforce development programs, including registered apprenticeship, labor-management training programs, and supportive services to help train, place, and retain people in good-paying jobs and apprenticeship; and (c) comprehensive planning and policies to promote hiring and inclusion for all groups of workers, including through the use of local and economic hiring preferences, linkage agreements with workforce programs that serve these underrepresented groups, and proactive plans to prevent harassment.[12]

Consistent with E.O. 11246, *Equal Employment Opportunity* (30 FR 12319, and as amended), all federally-assisted contractors are required to make good faith efforts to meet the goals of 6.9% of construction project hours being performed by women, in addition to goals that vary based on geography for construction work hours and for work being performed by people of color. The U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) has a Mega Construction Project Program through which it engages with project sponsors as early as the design phase to help promote compliance with non-discrimination and affirmative action obligations. Through the program, OFCCP offers contractors and subcontractors extensive compliance assistance, conducts compliance evaluations, and helps to build partnerships between the project sponsor, prime contractor, subcontractors, and relevant stakeholders. OFCCP will identify projects that receive an award under this notice and are required to participate in OFCCP's Mega Construction Project Program from a wide range of federally assisted projects over which OFCCP has jurisdiction and that have a project cost above $35 million. DOT will require project sponsors with costs above $35 million that receive awards under this funding opportunity to partner with OFCCP, if selected by OFCCP, as a condition of their DOT award. Under that partnership, OFCCP will ask these project sponsors to make clear to prime contractors in the pre-bid phase that project sponsor's award terms will require their participation in the Mega Construction Project Program. Additional information on how OFCCP makes their selections for participation in the Mega Construction Project Program is outlined under ''Scheduling'' on the Department of Labor website: *https://www.dol.gov/agencies/ofccp/faqs/construction-compliance.*''

[11] Federal funds may not be used to support or oppose union organizing, whether directly or as an offset for other funds.

[12] IIJA div. B § 25019 provides authority for funds made available under title 49 and title 23 to use geographical and economic hiring preferences, including local hire, for construction jobs, subject to any applicable State and local laws, policies, and procedures.

Critical Infrastructure Security and Resilience

It is the policy of the United States to strengthen the security and resilience of its critical infrastructure against both physical and cyber threats. Each applicant selected for Federal funding under this notice must demonstrate, prior to the signing of the grant agreement, efforts to consider and address physical and cybersecurity risks relevant to the transportation mode and type and scale of the project. Projects that have not appropriately considered and addressed physical and cyber security and resilience in their planning, design, and project oversight, as determined by the Department and the Department of Homeland Security, will be required to do so before receiving funds for construction consistent with Presidential Policy Directive 21—Critical Infrastructure Security and Resilience and the National Security Presidential Memorandum on Improving Cybersecurity for Critical Infrastructure Control Systems.

Domestic Preference Requirements

Assistance under this NOFO is subject to the Buy America requirements in 49 U.S.C. 22905(a) and the Build America, Buy America Act, Public Law 117–58, 70901–52. In addition, as expressed in Executive Order 14005, *Ensuring the Future Is Made in All of America by All of America's Workers* (86 FR 7475), it is the policy of the executive branch to maximize, consistent with law, the use of goods, products, and materials produced in, and services offered in, the United States. FRA expects all applicants to comply with that requirement without needing a waiver. However, to obtain a waiver, a recipient must be prepared to demonstrate how they will maximize the use of domestic goods, products, and materials in constructing their project.

Civil Rights and Title VI

Recipients of Federal transportation funding will be required to comply fully with Title VI of the Civil Rights Act of 1964 and implementing regulations (49 CFR 21), the Americans with Disabilities Act of 1990 (ADA), Section 504 of the Rehabilitation Act of 1973, and all other civil rights requirements. The Department's and FRA's Office of Civil Rights may provide resources and technical assistance to recipients to ensure full and sustainable compliance with Federal civil rights requirements.

Performance and Program Evaluation

Recipients and subrecipients are also encouraged to incorporate program evaluation, including associated data collection activities from the outset of their program design and implementation, to meaningfully document and measure their progress towards meeting an agency priority goal(s). Title I of the Foundations for Evidence-Based Policymaking Act of 2018 (Evidence Act), Public Law 115–435 (2019) urges Federal awarding agencies and Federal assistance recipients and subrecipients to use program evaluation as a critical tool to learn, to improve equitable delivery, and to elevate program service and delivery across the program lifecycle. Evaluation means ''an assessment using systematic data collection and analysis of one or more programs, policies, and organizations intended to assess their effectiveness and efficiency.'' 5 U.S.C. 311. Credible program evaluation activities are implemented with relevance and utility, rigor, independence and objectivity, transparency, and ethics (OMB Circular A–11, Part 6 Section 290).

For grant recipients receiving an award, evaluation costs are allowable costs (either as direct or indirect), unless prohibited by statute or regulation, and such costs may include the personnel and equipment needed for data infrastructure and expertise in data analysis, performance, and evaluation. (2 CFR part 200).

3. Reporting

a. Progress Reporting on Grant Activity

Each applicant selected for a grant will be required to comply with all standard FRA reporting requirements, including quarterly progress reports, quarterly Federal financial reports, and interim and final performance reports, as well as all applicable auditing, monitoring and close out requirements. Reports may be submitted electronically. Pursuant to 2 CFR 170.210, non-Federal entities applying under this NOFO must have the necessary processes and systems in place to comply with the reporting requirements should they receive Federal funding.

b. Additional Reporting

Applicants selected for funding are required to comply with all reporting requirements in the standard terms and conditions for FRA grant awards including 2 CFR 180.335 and 2 CFR 180.350.

If the Federal share of any Federal award under this NOFO may include more than $500,000 over the period of performance, applicants are informed of the post award reporting requirements reflected in—Award Term and Condition for Recipient Integrity and Performance Matters.

c. Performance Reporting

Each applicant selected for funding must collect information and report on the project's performance using measures mutually agreed upon by FRA and the grantee to assess progress in achieving strategic goals and objectives.

H. Federal Awarding Agency Contacts

For further information related to this notice, please contact Douglas Gascon, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–212, Washington, DC 20590; *douglas.gascon@dot.gov*; 202–493–0239.

I. Other Information

All information submitted as part of or in support of any application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If the application includes information the applicant considers to be a trade secret or confidential commercial or financial information, the applicant should do the following: (1) Note on the front cover that the submission ''Contains Confidential Business Information (CBI)''; (2) mark each affected page ''CBI''; and (3) highlight or otherwise denote the CBI portions.

The DOT regulations implementing the Freedom of Information Act (FOIA) are found at 49 CFR part 7 Subpart C—Availability of Reasonably Described Records under the Freedom of Information Act and sets forth rules for FRA to make requested materials, information and records publicly available under FOIA. Unless prohibited by law and to the extent permitted under the FOIA, contents of application and proposals submitted by successful applicants may be released in response to FOIA requests.

In addition, following the completion of the selection process and announcement of awards consistent with 49 U.S.C 22909(i), FRA will post online a list of all eligible applicants submitting an application, a list of all proposed projects and applicants that FRA determines are ineligible, and a list of the grant recipients that were selected to receive grant funding under the RCE Program on an annual basis. Except for information withheld under the previous paragraph, FRA may also make application narratives publicly available or share application information within DOT or with other Federal agencies if FRA determines that sharing is relevant to the respective program's objectives.

Issued in Washington, DC.

Amitabha Bose,

Administrator.

[FR Doc. 2022–14344 Filed 7–5–22; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0052]

Advisory Committee on Underride Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Solicitation of nominations for appointment to the advisory committee on Underride Protection (ACUP).

SUMMARY: NHTSA is soliciting applications for appointment to the U.S. Department of Transportation's (DOT) ACUP. The purpose of ACUP is to provide advice and recommendations to the Secretary of Transportation on safety regulations to reduce underride crashes and fatalities relating to underride crashes.

DATES: Applications for membership must be received by NHTSA on or before 5 p.m. EST, August 5, 2022.

ADDRESSES: If you wish to apply for membership, your application should be submitted to:

- *Email: ACUP@dot.gov.*
- *Mail: Use only overnight mail and send to:* U.S. Department of Transportation, National Highway Traffic Safety Administration, Office of Rulemaking, Attn: ACUP, 1200 New Jersey Avenue SE, NRM–130, Washington, DC 20590.

The ACUP charter can be found in the docket to this notice.

FOR FURTHER INFORMATION CONTACT: James Myers, Chief, Special Vehicles and Systems Division, Office of Rulemaking, National Highway Traffic Safety Administration, U.S. Department of Transportation, *James.Myers@dot.gov* or 202–493–0031. Any committee related questions should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

Background

ACUP is established pursuant to Section 23011(d) of the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act,

Public Law 117–58, which requires the creation of an advisory committee on underride protection, and in accordance with the Federal Advisory Committee Act, 5 U.S.C. app. 2. ACUP provides information, advice, and recommendations to the Secretary of Transportation on safety regulations to reduce underride crashes and fatalities relating to underride crashes.

Description of Duties

The Committee shall act solely in an advisory capacity. Duties include the following:

a. Gather information as necessary to discuss issues presented by the Designated Federal Officer (DFO).

b. Deliberate on issues relevant to safety regulations related to underride crashes and fatalities from underride crashes.

c. Provide written consensus advice to the Secretary on underride protection to reduce underride crashes and fatalities relating to underride crashes.

d. Submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives a biennial report that—

i. describes the advice and recommendations made to the Secretary; and

ii. includes an assessment of progress made by the Secretary in advancing safety regulations relating to underride crashes.

Membership

In accordance with BIL, ACUP will comprise not more than 20 members who are qualified to serve on the Committee because of their expertise, training, or experience. The Committee shall include two representatives from each of the following categories:

- Truck and trailer manufacturers.
- Motor carriers, including independent owner-operators.
- Law enforcement.
- Motor vehicle engineers.
- Motor vehicle crash investigators.
- Truck safety organizations.
- The insurance industry.
- Emergency medical service providers.
- Families of underride crash victims.
- Labor organizations.

To ensure the recommendations of the Committee have considered the needs of diverse groups served by the Department, the membership of the Committee shall, to the extent practicable, include persons with lived experience and knowledge of the needs of underrepresented groups with regard to race, ethnicity, religion, disability, sexual orientation, gender identity, and other factors.

The Secretary of Transportation shall appoint each member for the duration of the charter, which is 2 years, unless otherwise renewed in accordance with FACA. The Secretary may reappoint a member or terminate any member's tenure at his discretion. The Secretary may extend appointments and may appoint replacements for members who have resigned outside a stated term, as necessary. If a member's status as a representative of an identified category materially changes after appointment, the member's representative status will be terminated, unless certain requirements are met. These requirements include the following: (1) continued active involvement in the identified category, (2) the concurrence by the NHTSA Administrator with the representative's continued participation, (3) the member's continued participation is consistent with applicable statutory authorities and Presidential directives, and the (4) the member's continued participation is deemed essential for the fulfillment of the committee's mission.

ACUP members will not receive pay or other compensation from NHTSA for their ACUP service, but are entitled to reimbursement of their travel expenses, including per diem. The ACUP shall meet at least once a year.

Qualifications

Members will be selected for their expertise, training, or experience and their ability to represent one of the identified categories.

Materials To Submit

Qualified individuals interested in serving on the ACUP are invited to apply for appointment by submitting a resume or curriculum vitae along with letters of recommendation to one of the locations listed in the **ADDRESSES** section by the deadline listed in the **DATES** section. Please include your full legal name and date of birth in your application. Each applicant must identify the category that he or she seeks to represent. Nominations are open to all individuals without regard to race, color, religion, sex, national origin, age, mental or physical disability, marital status, or sexual orientation. Evaluations will be based on the materials submitted.

Authority: Issued under authority in 49 CFR 1.95 and 501.8.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2022–14329 Filed 7–5–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Requesting Comments on 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 proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning final regulations in Treasury Decision (TD) 8458 relating to real estate mortgage investment conduits.

DATES: Written comments should be received on or before September 6, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include OMB Control No. 1545–1276 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Jon Callahan, (737) 800–7639, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *jon.r.callahan@irs.gov.*

SUPPLEMENTARY INFORMATION: The IRS is currently seeking comments concerning the following information collection tools, reporting, and record-keeping requirements:

Title: Real Estate Mortgage Investment Conduits.

OMB Number: 1545–1276.

Regulation Project: TD 8458.

Abstract: Internal Revenue Code (IRC) section 860G provides definitions and special rules pertaining to real estate mortgage investment conduits (REMIC). IRC section 860E outlines the treatment of income in excess of daily accruals on residual interests and imposes an excise tax on the transfer of a residual interest in a REMIC to a disqualified organization. Treasury Regulations section 1.860E–2(a)(5) requires the REMIC to furnish, on request of the party responsible for the tax and to the Internal Revenue Service (IRS), information sufficient to compute the present value of the anticipated excess

inclusions. Treasury Regulations sections 1.860E–2(a)(7) and 1.860E–2(b)(2) provide that the tax will not be imposed on the party otherwise liable for the tax if the transferee or record holder with interest in a pass-thru entity furnishes an affidavit stating that they are not a disqualified organization.

Current Actions: There is no change to the existing collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 1,600.

Estimated Time per Respondent: 20 minutes.

Estimated Total Annual Burden Hours: 525.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 30, 2022.

Jon R. Callahan,

Tax Analyst.

[FR Doc. 2022–14354 Filed 7–5–22; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 87 Wednesday,
No. 128 July 6, 2022

Part II

Department of Health and Human Services

Food and Drug Administration

42 CFR Parts 485 and 489

Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 485 and 489

[CMS–3419–P]

RIN 0938–AU92

Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish conditions of participation that Rural Emergency Hospitals (REH) must meet to participate in the Medicare and Medicaid programs. These requirements are intended to ensure that a high quality of care is furnished by REHs. This proposed rule also includes changes to the requirements Critical Access Hospital would have to meet to participate in the Medicare and Medicaid programs. Proposed payment policies and enrollment policies for REHs will be developed under separate rulemaking.

DATES: To be assured consideration, comments must be received at one of the addresses provided below by August 29, 2022.

ADDRESSES: In commenting, please refer to file code CMS–3419–P.

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 *https://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–3419–P, P.O. Box 8016, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3419–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Kianna Banks, (410) 786–3498.
Capt. Scott Cooper, U.S. Public Health Service (USPHS), (410) 786–9465.
Kristin Shifflett, (410) 786–4133.
Lela Strong, (410) 786–3213.

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: *https://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

A. Introduction

Americans who live in rural areas of the nation make up about 20 percent of the United States (U.S.) population, and they often experience shorter life expectancy, higher all-cause mortality, higher rates of poverty, fewer local doctors, and greater distances to travel to see health care providers, compared to their urban and suburban counterparts.[1] In addition, one in five rural residents identifies as Black, Hispanic, American Indian/Alaska Native (AI/AN), Asian American/Pacific Islander (AA/PI), or a combination of ethnic backgrounds. Compared to the non-Hispanic White rural population, these rural minority groups often and regularly experience several disadvantageous social determinants of health.[2]

The health care inequities that many rural Americans face raise serious concerns that the trend for poor health care access and worse outcomes overall in rural areas will continue unless the potential causes of such health care inequities are addressed.

There have been growing concerns over the closures of rural hospitals and critical access hospitals (CAHs). Between 2010 and February 2022, 138 rural hospitals stopped providing inpatient services, 44 of which were Critical Access Hospitals. There were 75 complete hospital closures where all services ended and 63 hospital conversions where inpatient services ended but some type of health care service continued.[3] Rural hospitals report they continue to face the threat of closure because they lack sufficient patient volume to offer traditional hospital inpatient acute care services required for Medicare payment; however, the demand still exists for emergency and outpatient services in areas served by these hospitals. Rural hospitals are essential to providing health care to their communities and the closure of these hospitals limits access to care for the communities they once served and reduces employment opportunities, further impacting local economies. Barriers such as workforce shortages, can impact health care access in rural communities and can lead to unmet health needs, delays in receiving appropriate care, inability to get preventive services, financial burdens, and preventable hospitalizations.[4]

The Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), was signed into law on December 27, 2020. In this legislation, Congress established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). These providers will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals that were CAHs or rural hospitals with not more than 50 beds, participating in Medicare, as of the date of enactment of the CAA, may submit an application to convert to and enroll in Medicare as an REH. An REH will receive Medicare payment for REH services furnished on or after January 1, 2023.

REHs are expected to help address the barriers in access to health care, particularly emergency services and other outpatient services that result

[1] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[2] Health Resources & Services Administration (2021). Rural Hospital Programs. *https://www.hrsa.gov/rural-health/rural-hospitals/.*

[3] UNC: Cecil G. Sheps Center for Health Services Research. (2022). Rural Hospital Closures. *https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.*

[4] Healthy People 2020 (n.d.) Access to Health Services. *https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services.*

from rural hospital closures, and by doing so, may help address observed inequities in health care in rural areas.

On January 20 and 21, 2021, President Biden issued three Executive orders related to issues of health equity: Executive Order 13985 ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government;'' [5] Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation;'' [6] and Executive Order 13995 ''Ensuring an Equitable Pandemic Response and Recovery.'' [7]

Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' requires the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality by recognizing and working to redress inequities in its policies and programs that serve as barriers to equal opportunity. In accordance with this Executive order, persons who live in rural areas are identified as belonging to underserved communities that have been adversely affected by inequality.

Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation,'' requires the Federal Government to prevent and combat discrimination, including when accessing health care, on the basis of gender identity or sexual orientation, and to fully enforce Title VII of the Civil Rights Act. This Executive order also requires the Federal Government to fully enforce other laws that prohibit discrimination on the basis of gender identity or sexual orientation, all of which impact all persons, including those in rural communities.

In accordance with Executive Order 13995, ''Ensuring an Equitable Pandemic Response and Recovery,'' the Federal Government must identify and eliminate health and social inequities resulting in disproportionately higher rates of exposure, illness, and death related to COVID–19 and take swift action to prevent and remedy differences in COVID–19 care and outcomes within communities of color and other underserved populations. The Executive order highlights the observed inequities in rural and Tribal communities, territories, and other geographically isolated communities. We believe the services furnished by REHs, could be one means of addressing some of the issues raised in these orders, particularly, barriers to access health care in rural communities.

Consistent with these Executive orders, in implementing the new REH provider type, we are committed to advancing equity for all, including racial and ethnic minorities, members of the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) community, people with limited English proficiency, people with disabilities, rural populations, and people otherwise adversely affected by persistent poverty or inequality.

We are proposing at this time to establish conditions of participation (CoPs) for REHs as a new Medicare provider type, consistent with the provisions of section 125 of the CAA. In developing the proposed CoPs for REHs, we have considered the role that we believe REHs can play in helping to advance equity and ensure access to available services and quality health care in rural communities. Proposed payment and enrollment policies for REHs will be developed in separate rulemaking.

B. Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type

Section 125 of Division CC of the CAA was signed into law on December 27, 2020 and establishes REHs as a new Medicare provider type that will receive Medicare payment for services furnished on or after January 1, 2023. Section 125 of the CAA added section 1861(kkk) to the Social Security Act (the Act), which sets forth the requirements for REHs. Section 1861(kkk)(2) of the Act defines an REH as a facility that is enrolled in the Medicare program as an REH; does not provide any acute care inpatient services (other than post-REH, that is after discharge from an REH, or post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements of a staffed emergency department; meets staff training and certification requirements established by the Secretary of the Department of Health and Human Services (the Secretary); and meets certain CoPs applicable to hospital emergency departments and CAHs with respect to emergency services.

Additionally, section 125(a)(1) of the CAA added section 1861(kkk)(1) of the Act, which requires that REHs provide emergency department services and observation care, and, at the election of the REH, other medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking. The REH must also have a staffed emergency department 24 hours a day, 7 days a week, have a physician, nurse practitioner, clinical nurse specialist, or physician assistant available to furnish rural emergency hospital services in the facility 24 hours a day, and meet applicable staffing requirements similar to those for CAHs.[8]

In order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of enactment of the CAA, 2021 (December 27, 2020), was a CAH or a rural hospital with not more than 50 beds. For the purpose of REH designation, the statute defines rural as a county (or equivalent unit of local government) considered rural (as defined in section 1886(d)(2)(D) of the Act), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. To be treated as being located in a rural area for the purpose of REH eligibility, we are proposing as part of this proposed rule that a hospital located in a metropolitan county must have had an active reclassification from urban to rural status as specified in 42 CFR 412.103 as of December 27, 2020. In addition, the REH must meet certain other requirements under section 1861(kkk) of the Act, including, but not limited to the following:

- An annual per patient average of 24 hours or less in the REH;
- Staff training and certification requirements established by the Secretary;
- Emergency services CoPs applicable to CAHs;

[5] 86 FR 7009 (Jan. 25, 2021). The White House. (2021). Briefing Room: Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-andsupport-for-underserved-communities-through-thefederal-government/.*

[6] 86 FR 7023 (Jan. 25, 2021). The White House. (2021). Briefing Room: Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-preventing-and-combatingdiscrimination-on-basis-of-gender-identity-orsexual-orientation/.*

[7] 86 FR 7193 (Jan. 26, 2021). The White House. (2021). Briefing Room: Executive Order on Ensuring an Equitable Pandemic Response and Recovery. *https://www.whitehouse.gov/briefing-room/presidentialactions/2021/01/21/executive-order-ensuring-anequitable-pandemic-response-and-recovery/.*

[8] Congress.gov. (2020). H.R.133—Consolidated Appropriations Act, 2021. *https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf.*

- Hospital emergency department CoPs determined applicable by the Secretary;
- The applicable SNF requirements (if the REH includes a distinct part SNF);
- A transfer agreement with a level I or level II trauma center; and
- Any other requirements the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in an REH.

Starting on January 1, 2023, an REH that provides rural emergency hospital services (as defined in section 1861(kkk)(1) of the Act) will receive a Medicare payment for those services pursuant to section 1834(x)(1) of the Act, as added by section 125 of the CAA, that is equal to the amount of payment that would otherwise apply under the Medicare Hospital Outpatient Prospective Payment System (OPPS) for covered outpatient department services increased by 5 percent. The beneficiary co-payments for these services will be calculated the same way as under the OPPS for the service, excluding the 5 percent payment increase. In addition, section 1834(x)(2) of the Act provides an additional monthly facility payment to an REH. The details of the payment policies for REHs will be developed in separate notice and comment rulemaking.

To participate in the Medicare program and receive payment for services furnished to Medicare beneficiaries, providers of services such as hospitals, home-health agencies, hospices, SNFs, and now REHs must enter into a provider agreement with Centers for Medicare & Medicaid Services (CMS), in accordance with section 1866 of the Act. Medicaid providers (every person or institution providing services under the state plan), likewise, must enter into agreements with state Medicaid agencies to be eligible for participation in that program as described in section 1902(a)(27) of the Act. By entering into a provider agreement, a facility agrees that it will comply with the applicable requirements of the Medicare and Medicaid statutes and the regulations that the Secretary issues under the respective statute.

Section 1861(kkk)(7) of the Act requires the Secretary to establish quality measurement reporting requirements for REHs, which may include claims-based outcome measures and/or patient experience surveys. An REH is required to submit quality measure data to the Secretary with respect to each year beginning in 2023 (or each year beginning on or after the date that is one year after one or more measures are first specified), and the Secretary is required to establish procedures to make the data available to the public on the CMS website. Quality measure specifications and quality reporting requirements for REHs will be developed in future rulemaking.

The Quality Improvement Organization requirements of the Act shall apply to REHs in the same manner that they apply to hospitals and CAHs, in accordance with section 1866(a) of the Act (as amended by section 125(b)(1) of the CAA). In addition, the requirements established at section 1864 of the Act for hospitals and CAHs to be surveyed for compliance with the CoPs shall apply to REHs in the same manner as other hospitals and CAHs, in accordance with section 125(d)(2) of the CAA.

Under section 1864 of the Act, CMS uses state surveyors to determine whether a provider or supplier subject to certification qualifies for an agreement to participate in Medicare. Additionally, under section 1865 of the Act, some providers or suppliers subject to certification have the option to instead elect to be accredited by private accrediting organizations (AOs) whose Medicare accreditation programs have been approved by CMS as having standards and survey procedures that meet or exceed all applicable Medicare requirements and be deemed to meet Federal requirements. The survey process for Medicare- and Medicaid-participating providers and suppliers provides an opportunity for these providers and suppliers to demonstrate compliance with all of the applicable CoPs, conditions for coverage (CfCs), conditions for certification, or requirements. The methods used by CMS to determine compliance with the regulations include surveys conducted by a state survey agency, surveys conducted by AOs that have deeming authority for Medicare providers and suppliers, and self-attestation. CMS would require REHs participating in Medicare to demonstrate and maintain compliance with the provisions included in the final rule.

C. Summary of Comments by Interested Parties in Response to REH Request for Information

In preparation for developing these proposed standards and to gain a clear understanding of the challenges faced by facilities providing health care services in rural communities, we published a Request for Information (RFI) on REHs in the proposed rule, ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals'' (86 FR 42018) on August 4, 2021. CMS sought public input on a broad range of issues to inform our policymaking in establishing this new provider type. The RFI solicited public input on the concerns of rural providers, including in the areas of health and safety standards, health equity, payment policies, quality measures and quality reporting, and additional considerations and unintended consequences that should be considered during the development of standards for REHs. As previously noted in section I.B of this proposed rule, the details of the payment policy and quality measures and quality reporting requirements for REHs will be developed via future rulemaking.

Commenters on the RFI generally noted that CMS should remain flexible in the development of standards for REHs and take into consideration the challenges associated with the provisi0on of health care services in rural communities. Specific themes from the comments received centered on suggested CoPs including requirements for staffing, transfers, and supervision, services that should be offered by REHs, and the health equity implications for REHs. Several commenters stated that the CoPs currently in place for CAHs would be sufficient for REHs and that the CoPs for REHs should not be more rigorous than those for CAHs. Commenters also recommended that REHs should provide maternal health, behavioral/mental health services, and telehealth services to further support the communities that they will serve. With regard to health equity, several interested parties commented that REHs could have significant value for underserved, rural populations by maintaining local access to care, reducing travel times for care, and serving as leaders for community health improvement efforts including efforts to address the social determinants of health. We note that CMS is committed to reducing inequities in rural communities and we are considering the best approach to address health equity in the standards for all Medicare-and Medicaid-participating providers and suppliers, including REHs.

The REH RFI public comments are available for review at *https://www.regulations.gov/document/CMS-2021-0124-0002/comment.* We have reviewed all comments from interested parties and have taken them into consideration while drafting this

proposed rule. We appreciate the interested parties' input and responses to our outreach efforts thus far.

During the development of the policies to implement this new provider type, we reviewed the public comments received on the REH RFI, and held public listening sessions with national organizations representing interested parties as well as tribal communities. We also gave presentations at CMS' hospital, rural health, and SNF open door forums and sought public feedback. We carefully reviewed the hospital and CAH requirements to determine which requirements would be appropriate (as is or based on modification) for REHs.

II. Provisions of the Proposed Regulation

A. Rural Emergency Hospital Conditions for Participation (Proposed Part 485, Subpart E)

We propose to add a new subpart E in 42 CFR part 485, to incorporate the REH CoPs. Proposed subpart E which would include all the health and safety standards for REHs. Overall, the proposed requirements are modeled closely after the CoPs for CAHs. In some instances, we have also proposed requirements that are similar to the CoPs for hospitals and CfCs for Ambulatory Surgical Centers (ASCs). In each of the sections below, we specify the existing requirements for CAHs, hospitals, or ASCs that we used to guide the proposed requirements.

1. Basis and Scope (Proposed § 485.500)

We propose to set forth the basis and scope of part 485, subpart E, at § 485.500. As previously noted, proposed part 485, subpart E, would implement section 1861(kkk) of the Act, which establishes the requirements that an REH must meet in order to participate in the Medicare program. Section 1833(a) of the Act serves as the basis for the establishment of payment of benefits covered under Medicare for REHs.

2. Definitions (Proposed § 485.502)

At § 485.502, we propose to define certain terms that would be used throughout the REH CoPs. We propose to define the term ''Rural Emergency Hospital or REH'' in accordance with the definition set forth in section 1861(kkk) of the Act. In accordance with the Act, we propose to define Rural Emergency Hospital or REH as an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. The REH must not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-REH or post-hospital extended care services.

We received several comments on the REH RFI indicating that the average length of stay should be increased in certain instances, such as when the REH is providing services to a patient who is need of inpatient psychiatric or inpatient rehabilitation services. The commenters stated that placement of these patients in an inpatient facility could be difficult with some patients potentially remaining in the REH for observation services for weeks. Commenters noted further that these patients may produce an average length of stay that exceeds the proposed 24-hour annual per patient average length of stay. Other commenters requested that CMS be flexible in recognizing bed capacity issues for those patients awaiting placement in an inpatient facility and practice enforcement discretion related to the proposed length of stay requirement.

However, in accordance with section 1861(kkk)(1)(A) of the Act, services furnished by the REH must not exceed an annual per patient average of 24 hours in the REH. We would expect an REH to transfer patients whom the REH determines require a higher level of care as soon as possible. We do understand that there may be occasional circumstances in which a facility is not immediately available to provide a higher level of care, resulting in patients receiving services at the REH for more than 24 hours. However, we believe that this will occur at a frequency that will not seriously affect the REH's average length of stay. As a result, we do not anticipate that the REH would be at risk for exceeding the statutory annual per patient average length of stay of 24 hours or less.

3. Basic Requirements (Proposed § 485.504)

At § 485.504 we propose to set forth the basic requirements for REHs in accordance with section 1861(kkk) of the Act. Participating REHs would be limited to those facilities that meet the definition in proposed § 485.502 and have in effect a provider agreement as defined at 42 CFR 489.3. We would add REHs to the list of providers required to obtain a provider agreement at § 489.2(b) in the ''Conforming Amendments'' section of this proposed rule.

4. Designation and Certification of REHs (Proposed § 485.506)

At § 485.506 we propose to set forth the criteria for CMS certification of an REH in accordance with section 1861(kkk) of the Act. We propose to establish that CMS would certify a facility as an REH if the facility was, as of the date of enactment of the CAA, a CAH, or a hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) considered rural (as defined in section 1886(d)(2)(D) of the Act), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. In addition, to be treated as being located in a rural area for the purpose of REH eligibility, we are proposing as part of this proposed rule that a hospital located in a metropolitan county must have had an active reclassification from urban to rural status as specified in section 42 CFR 412.103 as of December 27, 2020.

5. Compliance With Federal, State, and Local Laws and Regulations (Proposed § 485.508)

Consistent with the requirements for all Medicare- and Medicaid-participating providers and suppliers, we propose to require REHs to comply with Federal, state, and local laws and regulations.

At § 485.508(a) we propose to require the REH to be in compliance with applicable Federal laws, state, and local laws and regulations. In accordance with section 1861(kkk)(5) of the Act, we also propose to require at § 485.508(b) that the REH is located in a state that provides for the licensing of such hospitals under state or applicable local law. In addition, under § 485.508(b)(1) and (2), we propose that the REH be licensed in the state as an REH or be approved as meeting standards for licensing by the agency in the state or locality responsible for licensing hospitals. We note that in many instances, states and localities, have more stringent laws and regulations than the Federal requirements. In cases in which state law or regulations are more stringent, the REH would need to comply with the more stringent state or local requirements to meet the proposed requirements at § 485.508(a).

At § 485.508(c), we propose to require that the REH ensure that personnel are licensed or meet other applicable standards required by state or local laws to provide services within the applicable scope of practice. Some commenters on the REH RFI recommended that CMS encourage

licensure portability among health care practitioners. Commenters indicated that allowing practitioners to practice in multiple states would greatly support both in-person and virtual care models in rural areas where the closest health care provider may be across the state line. This proposed standard does not prohibit a practitioner that is licensed in a different state than where the REH is located from providing care at the REH; state laws govern whether this is permissible.

6. Condition of Participation: Governing Body and Organizational Structure of the REH (Proposed § 485.510)

To ensure appropriate oversight of the REH, we propose at § 485.510 to require the REH to have an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. This aligns with the CAH CoP for organizational structure at § 485.627(a). In addition to oversight, we expect the responsibilities of the governing body or responsible individual to include ensuring that the REH is effectively executing its policies and decision-making about the REH's vision, mission, and strategies. If an REH does not have an organized governing body, we propose to require that the person or persons legally responsible for the conduct of the REH carry out the functions specified in this part that pertain to the governing body.

Consistent with the hospital governing body CoPs at § 482.12, we propose at § 485.510(a)(1) to require the governing body, in accordance with state law, to determine which categories of practitioners are eligible candidates for appointment to the medical staff. Additionally, consistent with the interpretive guidelines for CAHs in Appendix W of the State Operations Manual for the standard for *Governing Body or Responsible Individual* at § 485.627(a), we propose to require that the governing body of the REH appoint members of the medical staff after considering the recommendations of the existing members of the medical staff. The role of the medical staff is the promotion of patient safety and the quality of care. This proposal would give maximum flexibility to an REH in determining and granting staff privileges and organizing its medical staff, and it would allow the REH to grant specific privileges related to patient care to various other types of licensed practitioners as it needed, in addition to the privileges it would choose to grant to doctors of medicine or osteopathy. For example, an REH could choose to grant medical staff privileges to nurse practitioners and physician assistants if this is allowable under state law. We also propose to require that the REH's governing body must ensure that its medical staff is accountable to the governing body for the quality of patient care provided by the REH; organizes itself under bylaws; and ensures that the criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

Many rural populations suffer from limited access to care due to a shortage of health care professionals, especially physicians. Often times, clinicians other than physicians provide important care services to rural communities with physicians providing oversight. This may occur in many different ways, including via the use of mobile health, video and audio technologies, digital photography and remote patient monitoring. With the development of technology that facilitates ''telemedicine,'' a physician could utilize a variety of methods to provide health care services, including being on-site at a facility or at a distant site furnishing services remotely to a patient located at an originating site.

Commenters on the REH RFI noted that REHs should be able to be an originating site (that is, the location where a Medicare patient receives medical services from a physician or other clinician through a telecommunications system) for the provision of telehealth services. As noted in the CY 2022 Medicare Physician Fee Schedule final rule (86 FR 65057), section 125(c) of the CAA amended section 1834(m)(4)(C)(ii) of the Act to add REHs to the list of permissible telehealth originating sites. In accordance with section 1834(m)(4)(C)(ii)(XI) of the Act, as added by section 125(c) of the CAA, we finalized a revision to § 410.78(b)(3) of our regulations to add REH, as defined in section 1861(kkk)(2) of the Act, as a permissible originating site for telehealth services furnished on or after January 1, 2023.

For the purposes of this rule, similar to our interpretation in the policy set out in our final rule, ''Medicare and Medicaid Programs; Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging'' (76 FR 25550 through 25556), we see telemedicine as encompassing the overall delivery of health care to the patient through the practice of patient assessment, diagnosis, treatment, consultation, transfer and interpretation of medical data, and patient education all via a telemedicine link (for example, audio, video, and data telecommunications as may be utilized by distant-site physicians and practitioners). Therefore, in order to make clear that the credentialing and privileging provisions proposed for REHs are not limited to the narrower subset of services and sites eligible for Medicare telehealth payment, we chose to use the term, ''telemedicine,'' throughout this rule instead of ''telehealth.'' As noted previously, payment policies for REHs, including for services furnished via telehealth/telemedicine, will be addressed in separate notice and comment rulemaking.

In recognition of the important role that telemedicine can play in the provision of care in rural communities, we believe it is necessary to establish a more efficient process for REHs to credential and privilege clinicians who provide telemedicine services for the REH's patients. We are proposing requirements similar to the telemedicine credentialing and privileging process requirements established for hospitals and CAHs that would allow for an optional and more streamlined credentialing and privileging process that REHs may use for practitioners providing telemedicine services for their patients. We believe that like small hospitals and CAHs seeking to provide enhanced access to care through the use of telemedicine services for their patients, REHs might lack the resources to fully carry out the traditional credentialing and privileging process for all of the physicians and practitioners that may be available to provide telemedicine services. In addition to the costs and administrative staff needed for this process, REHs would also most likely not have in-house medical staff with the clinical expertise to adequately evaluate and privilege the wide range of specialty physicians that larger hospitals can provide their patients through the use of telemedicine services. Therefore, at § 485.510(a)(8) we are proposing that REH's governing body ensure that when telemedicine services are furnished to the REH's patients through an agreement with a Medicare-participating hospital (the ''distant-site''—the site at which the physician or practitioner is located at the time the service is provided via a communications system, as defined at section 1834(m)(4)(A) of the Act), the agreement must specify that it is the responsibility of the governing body of the distant-site hospital providing the telemedicine services to meet the requirements in § 485.510(a)(1) through (7) with regard to its physicians and practitioners who are providing telemedicine services. These provisions

cover the distant-site hospital's governing body responsibilities for its medical staff that all Medicare-participating hospitals must currently meet and that REHs would be required to meet when this rule is finalized. The proposed requirements at § 485.510(a)(8) would allow the governing body of the REH whose patients are receiving the telemedicine services to grant privileges based on the recommendations of its medical staff, who would rely on information provided by the distant-site hospital, as a more efficient means of privileging the individual distant-site physicians and practitioners. This provision would be accompanied by the proposed requirement in the ''Medical staff'' CoP at § 485.510(a), which would provide the basis on which the REH's governing body, through its agreement as noted above, can choose to have its medical staff rely upon information furnished by the distant-site hospital when making recommendations on privileges for the individual physicians and practitioners providing such services. This option would not prohibit an REH's medical staff from continuing to perform its own periodic appraisals of telemedicine members of its staff, nor would it bar them from continuing to use the proposed traditional credentialing and privileging process proposed at § 485.512(a)(2). The intent of this proposed requirement is to relieve burden for REHs by providing for a less duplicative and more efficient privileging scheme with regard to physicians and practitioners providing telemedicine services. However, in an effort to ensure accountability to the process, we are proposing within this same provision (§ 485.512(a)(3)) that the REH, in order to choose this less burdensome option for privileging, must ensure that (1) the distant-site hospital providing the telemedicine services is a Medicare-participating hospital; (2) the individual distant-site physician or practitioner is privileged at the distant-site hospital providing telemedicine services, and that this distant-site hospital provides a current list of the physician's or practitioner's privileges; (3) the individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH, whose patients are receiving the telemedicine services, is located; and (4) with respect to a distant-site physician or practitioner granted privileges by the REH, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital this information for use in its periodic appraisal of the individual distant-site physician or practitioner. We are also proposing, at a minimum, the information sent for use in the periodic appraisal would have to include all adverse events that may result from telemedicine services provided by the distant-site physician or practitioner to the REH's patients and all complaints the REH has received about the distant-site physician or practitioner. We are also proposing at § 485.512(c)(5) to require that REH's medical staff bylaws include criteria for determining privileges and a procedure for applying the criteria to individuals requesting privileges. We are proposing to add language to stipulate that in cases where distant-site physicians and practitioners are requesting privileges to furnish telemedicine services through an agreement with an REH, the criteria for determining those privileges and the procedure for applying the criteria would be subject to the proposed requirements at §§ 485.510(a)(8) and (9) and 485.512(a)(3) and (4).

Similar to the revisions we made in the ''Changes Affecting Hospital and Critical Access Hospital Conditions of Participation'' final rule (76 FR 25556), we have also concluded that it is important that the medical staff of a distant-site telemedicine entity, which may not be a Medicare-participating hospital, be included in an optional and streamlined credentialing and privileging process for those REHs electing to enter into agreements for telemedicine services with such entities. However, similar to the situation we faced for hospitals and CAHs in the May 2011 final rule (that is, the inclusion of distant-site telemedicine entities into this streamlined process without CMS having any regulatory or oversight authority over these entities), we realized that the proposed requirements for REHs would need to hold distant-site telemedicine entities accountable to the originating-site REH for meeting CMS practitioner credentialing and privileging standards. And like the current requirements for hospitals and CAHs using telemedicine services, REHs would need to provide, upon request when surveyed, the most current telemedicine services agreement showing that the distant-site entities providing the services are required to comply with the CMS standards (even though CMS has no direct authority over those entities) in order for the REH to make use of the more streamlined process when credentialing and privileging practitioners from these distant-site telemedicine entities.

Similar to our regulations proposed for REHs using the telemedicine services of distant-site Medicare-participating hospitals, the written agreement between the REH and the distant-site telemedicine entity would be the foundation for ensuring accountability on both sides. However, due to the differences already discussed between Medicare-participating distant-site hospitals providing telemedicine services and distant-site practitioners under section 1834(m) of the Act providing similar services, there must also be differences in the way the regulations are written.

Therefore, we are also proposing requirements that would apply to the credentialing and privileging process and the agreements between REHs and distant-site telemedicine entities (§§ 485.510(a)(9) and 485.512(a)(4)). These provisions would require the governing body of the REH (or responsible individual), through its written agreement with the distant-site telemedicine entity, to ensure that the distant-site telemedicine entity, acting as a contractor of services, furnishes its services in a manner that enables the REH to comply with all applicable CoPs and standards. For the contracted services, the applicable CoPs and standards would include, but are not limited to, the credentialing and privileging requirements for distant-site physicians and practitioners furnishing telemedicine services.

7. Condition of Participation: Provision of Services (Proposed § 485.514)

Several commenters on the REH RFI indicated that CMS should remain flexible in the development of the standards for REHs and that the standards should closely mirror the CAH requirements, where appropriate. Consistent with the CAH CoPs at § 485.635(a)(1), we propose at § 485.514(a) to require that the REH's health care services must be furnished in accordance with appropriate written policies that are consistent with applicable state law and at § 485.514(b) that the REH must have policies that are developed with the advice of members of the REH's professional health care staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff. This requirement aligns with the CAH CoPs at § 485.635(a)(2).

At § 485.514(c) we propose requirements for the written policies to include a description of the services the REH furnishes (including those furnished through agreement or arrangement), policies and procedures

for emergency medical services, guidelines for the medical management of health problems, and policies and procedures that address the post-acute care needs of all patients receiving services furnished by an REH. Because the statute prohibits REHs from the provision of inpatient services (with the exception of patients receiving SNF services in a distinct part SNF), post-acute care for an REH patient is any care the REH patient receives once they are discharged from the REH. Lastly, at § 485.514(d), we propose to require the policies to be reviewed at least biennially by the group of professional personnel required at § 485.514(b) and updated as necessary by the REH. These requirements align with the CAH CoPs at § 485.635(a)(3).

8. Condition of Participation: Emergency Services (Proposed § 485.516)

In accordance with section 1861(kkk)(2)(D)(iv) of the Act, as added by section 125(a)(1)(B) of the CAA, REHs must comply with the CAH emergency services requirements at § 485.618 as well as the hospital emergency services requirements, which are located at § 482.55, as determined to be applicable. We note that at § 482.12(f) if emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate. Conversely, CAHs are required by the CoPs to provide emergency services, resulting in different emergency services requirements for each of these provider types. However, one similarity in the hospital and CAH emergency services requirements is that CAHs and hospitals (should they choose to provide emergency services) are required to have emergency services that meet the needs of their respective patients presenting at the individual facility. We believe that it is important that the REH emergency services also meet the needs of its patients. As such, at § 485.516 we propose to require that the REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

Additionally, because the primary function of an REH is to provide emergency services, similar to the requirements for hospitals, we propose at § 485.516(a) that the REH must have emergency services that are organized under the direction of a qualified member of the medical staff and are integrated with other departments of the REH. We anticipate that there will be instances in which a patient is receiving outpatient services other than emergency services and may unexpectedly require care in the emergency department. In this instance, having emergency services that are integrated with the other departments of the REH will facilitate care coordination and promote patient-centered care.

At § 485.516(b), we propose that there be adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility. To comply with this requirement, we would expect the REH to conduct an analysis based on the anticipated staffing needs and once the REH begins to provide services, the analysis would include actual staffing needs. Lastly, at § 485.516(c), we propose to require the REH to provide emergency services that meet the CAH requirements specified at § 485.618(a) through (e), as required by section 1861(kkk)(2)(D)(iv)(I) of the Act. We are seeking comment on the proposed staffing requirements for the provision of emergency services in an REH to gain insight on the appropriateness of not requiring a practitioner to be on-site at the REH at all times.

9. Condition of Participation: Laboratory Services (Proposed § 485.518)

We believe that like hospitals, REHs should provide laboratory services that are determined to be appropriate and necessary based on the level of services provided at the REH. This portion of the provision aligns with the hospital CoP at § 482.27. Efficient laboratory support is a crucial to providing quality emergency services, especially given the continued rise in emergency department visits. Efficient laboratory support positively impacts emergency services by contributing to the assessments used to determine diagnosis and treatment and whether a patient should be discharged home or transferred to a higher level of care. Emergency departments generally provide laboratory services by utilizing point of care testing, a laboratory technician based in the emergency department, or an emergency department stat (''Statim'', Latin for ''immediately'') laboratory either directly or through a contractual agreement with a laboratory. Overall, the ability to provide quality laboratory services in the emergency department decreases the overall length of stay for patients, therefore we are proposing at § 485.518 that REHs, similar to CAHs (§ 485.635(b)(2)), must provide basic laboratory services that are essential to the immediate diagnosis and treatment of the patient. The CAH requirements cite specific laboratory services that should be provided by the CAH, such as chemical examination of urine, hemoglobin or hematocrit, blood glucose, examination of stool specimens for occult blood, pregnancy tests, and primary culturing for transmittal to a certified laboratory. However, we believe that given the REH's nature of primarily providing emergency services, it is appropriate that REHs provide laboratory services that are consistent with nationally recognized standards of care for emergency services. In addition to the laboratory services identified in the CAH CoPs, we encourage the REH to provide laboratory services that include a complete blood count, basic metabolic panel (also known as a ''chem 7''), magnesium, phosphorus, liver function tests, amylase, lipase, cardiopulmonary tests (troponin, brain natriuretic peptide, and d-dimer), lactate, coagulation studies (prothrombin time, partial thromboplastin time, and international normalized ratio), arterial blood gas, venous blood gas, quantitative human chorionic gonadotropin, and urine toxicology. In accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA), at § 485.518(a), we are proposing to require that the REH must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with the CLIA requirements at 42 CFR part 493. Furthermore, at § 485.518(b) we are also proposing that REHs must have emergency laboratory services available that would be essential to the immediate diagnosis of the patient, 24 hours a day. This proposal is appropriate given the provision that REHs must provide emergency services 24 hours a day. In addition, this proposal is consistent with comments received on the REH RFI noting that laboratory services should be required for REHs.

10. Condition of Participation: Radiologic Services (Proposed § 485.520)

Radiologic services play an integral role in the provision of emergency services. Commenters on the REH RFI noted that radiologic services, also referred to as imaging services, should be provided at REHs. A study in the American Journal of Roentgenology noted that, ''The use of imaging in the emergency department (ED) has increased over time, and by 2010 nearly half of all ED visits in the U.S. included at least one imaging test.'' [9] These

[9] Ali S. Raja, Ivan K. Ip, Aaron D. Sodickson, Ron M. Walls, Steven E. Seltzer, Joshua M. Kosowsky, and Ramin Khorasani (2014). *American Journal of*

imaging tests include computed tomography (CT), also known as a computerized axial tomography (CAT) scan, magnetic resonance imaging (MRI), and ultrasound. These tests can be used to diagnose bone fractures, infections, arthritis, injuries from trauma, tumors and cancers. They can also be used to monitor and evaluate the growth and development of a fetus, and offer a way to examine many of the body's internal organs such as the liver, gallbladder, kidneys, and bladder.

We expect that REHs will need to provide radiologic services given their focus on emergency services and given the number of emergency department patients who receive imaging services. Therefore, we propose that the REH radiologic requirements mirror the hospital radiologic requirements found at § 482.26, which is consistent with the current CAH standard at § 485.635(b)(3) and interpretative guidelines for CAHs in Appendix W of the State Operations Manual (SOM).

The CAH standard for radiology services found at § 485.635(b)(3) requires and that these services are furnished by personnel qualified under state law and do not expose patients or staff to radiation hazards. In addition, we note that the interpretative guidelines for § 485.635(b)(3) in Appendix W of the SOM provides guidance for designating qualified radiologic personnel, developing policies and procedures that ensure safety from radiation hazards, inspecting and maintaining radiologic equipment, and maintaining CAH radiology records.

We are proposing to align the REH requirements with the hospital requirements for radiologic services and propose additional standards related to safety, personnel responsibilities, and record keeping. We believe that facilities that may transition to an REH would presently be performing these activities to support the delivery of radiology services. We also believe that these proposed requirements are in accordance with the interpretative guidelines that CAHs currently follow for the provision radiological services. We do not expect these proposed requirements to create additional burden for REHs over those applicable to CAHs.

As such, at § 485.520, we propose to require that the REH must provide diagnostic radiologic services. We propose to require that all radiologic services furnished by the REH must be provided by qualified personnel in accordance with state law and do not expose REH patients or personnel to radiation hazards at § 485.520(a). Like hospitals, we are also proposing to require that the REH must have radiologic services that meet the needs of their patients. For example, we expect an REH that is located in a mining community to offer x-ray services due to the effects of mining on one's lungs or an REH being able to furnish ultrasounds to evaluate the growth and health of a fetus.

At § 485.520(b), we are proposing basic factors relating to safety hazard standards for patients and personnel by specifying that the REH must institute proper safety precautions, perform periodic inspections of equipment, periodically check radiation workers for exposure, and only provide radiologic services based on the order of practitioners with clinical privileges or authorization by the medical staff and governing body. We propose the personnel standard at § 485.520(c) to require that a qualified radiologist, or other personnel qualified under state law either full-time, part-time, or on a consulting basis interpret radiologic tests that require specialized knowledge. This requirement can be fulfilled through arrangements with off-site providers via telehealth. Like hospitals, we propose that the radiologist in an REH must sign reports only of their interpretations. We propose to allow the medical staff and the individual responsible for radiological services to designate who is qualified to use radiological equipment. Lastly, at § 485.520(d), we also propose to require that records of departmental activities be maintained and that radiological reports and films be preserved for 5 years, consistent with the proposed requirements for the maintenance and retention of the REH medical records.

11. Condition of Participation: Pharmaceutical Services (Proposed § 485.522)

Pharmaceutical services are another integral part of the provision of health care services in an emergency department. The Journal of Medical Toxicology cited in a 2018 article that, ''Clinical pharmacists are integral to the care and safety of patients in the hospital, particularly in specialty and high-risk settings. Emergency departments (EDs) represent care environments that carry unique risks.'' [10] The article continues to note, ''Adult and pediatric patients present with undifferentiated medical, neurological, traumatic, psychiatric, and surgical complaints 24 [hours] a day, 7 days a week. Patients are generally unfamiliar to the emergency care providers, may be unable to communicate relevant medical information, and may require time-sensitive interventions. When present, ED crowding is associated with increased risk for medication errors.'' [10] Given these identified risks, we believe that the REH should have standards for pharmaceutical services.

While the current CAH requirements do not have a separate CoP for pharmaceutical services, there are standards throughout the CAH CoPs for the oversight, storage, and administration of drugs and biologicals. Regulations at § 485.623(b)(3) requires the CAH to store drugs and biologicals properly, and § 485.635(a)(3)(iv) requires the CAH to develop rules for the storage, handling, dispensation, and administration of drugs and biologicals including a drug storage area administered in accordance with accepted principles. In addition, there are standards throughout the CAH CoPs regarding provisions for infection prevention and control and antibiotic stewardship programs that reference pharmacy leadership and pharmacy services. Therefore, we believe that providers that may transition to an REH would currently be performing the proposed REH requirements to support the delivery of pharmaceutical services; we do not expect these proposed requirements to create additional burden for REHs.

We are proposing to require that the REH's pharmaceutical services meet the needs of the patients at proposed § 485.522. According to the American Society of Health-System Pharmacists Guidelines on Emergency Medicine Pharmacy Services, some factors that an ED is expected to consider when determining how the pharmaceutical services can best meet the needs of the patients include the type and setting of the ED (for example, academic, community, urban, or rural), the size of the ED, the number of annual visits, the patient population served, and any specialty services available.[11] At § 485.522(a), we propose to require the REH to have a pharmacy or drug storage

Roentgenology, (203)2, 355–360. *https://doi.org/10.2214/AJR.13.11892.*

[10] Farmer, B.M., Hayes, B.D., Rao, R., Farrell, N., & Nelson, L. (2018). The Role of Clinical Pharmacists in the Emergency Department. *Journal of medical toxicology: official journal of the American College of Medical Toxicology, 14*(1), 114–116. *https://doi.org/10.1007/s13181-017-0634-4.*

[11] American Society of Health-System Pharmacists (2021). ASHP guidelines on emergency medicine pharmacist services. *Am J Health-Syst Pharm,* 78(3):261–275. *https://doi.org/10.1093/ajhp/zxaa378.*

area that is administered in accordance with accepted professional principles and in accordance with state and Federal laws. Additionally, we propose to require at § 485.522(a)(1) that a registered pharmacist or other qualified individual in accordance with state scope of practice laws direct the pharmaceutical services or, when appropriate, have a drug storage area that is supervised by an individual who is competent to do so. Rural communities are often challenged by the lack of pharmacists willing to move to rural areas and for this reason, we recognize that there may be REHs that can provide pharmaceutical services only by having a drug storage area that is under the supervision of a qualified individual. In these instances, the facility must establish qualifications for the individual with oversight of the drug storage area for competency purposes and ensure that someone is fulfilling the role who meets those requirements. This is consistent with the interpretive guidelines for the CAH CoPs contained in Appendix W of the SOM for § 485.635(a)(3). We are proposing that this individual be available for a sufficient time to provide such oversight based on the scope and complexity of the services offered at the REH. This individual would not be required to be a full-time pharmacist. We believe sufficient time provides the REH with the flexibility to determine how frequently the pharmacist or other qualified individual is available.

Furthermore, the CAH interpretive guidelines for § 485.635(a)(3) states that the compounding, packaging, and dispensing of drugs be consistent with accepted professional principles. In accordance with the Food and Drug Administration, accepted professional principles for compounding, packaging, and dispensing of drugs include having a licensed pharmacist, or in some cases a physician, perform these activities (or having them performed under the supervision of a licensed pharmacist, when appropriate). As such, we propose at § 485.522(b) that all compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or other qualified individual in accordance with state scope of practice laws and be performed consistent with state and Federal laws. In addition, we propose that all drugs and biologicals must be kept in secure areas, and locked when appropriate. All drugs listed in Schedules II, III, IV, and V as outlined in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91–513, as amended), must be locked within a secure area and only authorized personnel may have access to locked areas. We propose that outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use and drugs and biologicals can only be removed from the pharmacy or storage area by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and state law. These proposed requirements are also consistent with the CAH interpretive guidelines for § 485.635(a)(3).

Lastly, at § 485.522(c) we propose to set forth the standards for the administration of drugs. We note that the existing CAH CoP at § 485.635(a)(3)(iv) requires that the CAH have written policies that include the rules for the storage, handling, dispensation, and administration of drugs and biologicals. The CAH CoPs continue to require that these rules provide that there is a drug storage area that is administrated in accordance with accepted professional principles. Similarly, we propose to require that drugs be prepared and administered in an REH according to established policies and acceptable standards of practice and consistent with the CAH requirement at § 485.635(a)(3)(v), we propose to require that any adverse reactions be reported to the physician responsible for the patient and documented in the record. While the CAH CoPs require that the CAH have procedures for reporting adverse drug reactions and errors in the administration of drugs, we recognize that a nationally recognized standard of practice is to report adverse drug reactions to the physician responsible for the care of the patient. We propose at § 485.522(c)(2) and (3) respectively, that the REH must administer blood transfusions, blood products and intravenous medications in accordance with state law and approved medical staff policies and procedures, and that orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or other authorized prescriber. We also propose at § 485.522(c)(4) to require that the REH have a procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

12. Condition of Participation: Additional Outpatient Medical and Health Services (Proposed § 485.524)

In addition to the provision of emergency services and observation care, section 1861(kkk)(1)(A)(ii) of the Act allows REHs to provide additional outpatient medical and health services as specified by the Secretary through rulemaking. We received comments on the REH RFI recommending that CMS allow REHs to provide additional outpatient services that include radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. We are proposing at § 485.524 that REHs be allowed to provide additional medical and health outpatient services that include, but are not limited, to those identified by commenters. We note that the REH may provide additional outpatient medical and health care services beyond those specified; however, we expect that the REH would be able to demonstrate that the service is needed based on an assessment of its community as required by proposed § 485.524(a). The decision should be based on a health needs assessment that is achieved by taking a systematic approach to ensuring that the services furnished by an REH are appropriate and meet the needs of the community.

Commenters on the REH RFI highlighted that providing rehabilitation services to rural communities requires overcoming the challenges of the landscape, limited referral options, and a shortage of therapists.

In addition, one of the health care needs in many rural communities is improving access to maternal health care services. As noted in CMS' Issue Brief *Improving Access to Maternal Health Care in Rural Communities:*[12]

> A lack of access to high quality maternal health services in rural communities is the result of many factors including hospital and obstetric department closures, workforce shortages, and access to care challenges arising from the social determinants of health which have contributed to disparities in maternal health care for rural women and their babies. These access challenges can result in a number of negative maternal health outcomes including premature birth, low-birth weight, maternal mortality, severe maternal morbidity, and increased risk of postpartum depression. These health disparities affect American Indian and Alaska Native and women of color disproportionately. Since one in five Americans live in a rural community, including approximately 18 million women of reproductive age, it is critical that federal, regional, state, local agencies and communities work together to improve access to high quality maternal health services in rural communities.

[12] Centers for Medicare and Medicaid Services (2019). Improving Access to Maternal Health Care in Rural Communities—Issue Brief. *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf.*

The issue brief, which was published in 2019, highlights the role hospitals closures have played in the access issues to maternal health services in rural communities, noting that between 2004 and 2014, 179 rural counties lost or closed their hospitals obstetric services, contributing to the fact that fewer than 50 percent of rural women have access to perinatal services within a 30-mile radius.[12]

Additionally, the Biden-Harris Administration has made it their highest priority to improve access to maternal health care services. The Administration published a fact sheet on April 13, 2022, announcing actions to be taken to address the maternal health crisis in the United States (*Fact Sheet: Biden-Harris Administration Announces Additional Actions in Response to Vice President Harris's Call to Action on Maternal Health, https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/13/fact-sheet-biden-harris-administration-announces-additional-actions-in-response-to-vice-president-harriss-call-to-action-on-maternal-health/*). These actions include:

- Calling on states to expand their postpartum Medicaid and Children's Health Insurance Program coverage;
- Proposing the ''Birthing-Friendly'' hospital designation to drive improvements in maternal health outcomes and maternal health equity;
- Engaging the health care industry to improve health outcomes;
- Strengthening Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Programs;
- New funding for the State Maternal Health Innovation and Implementation (State MHI) Program;
- Publication of a new Maternal Health Best Practice Guide for providers to incorporate telehealth for prenatal and postpartum care, and monitoring within high-risk pregnancy;
- Investing in doulas;
- Restoring access to Title X family planning services nationwide to fill service gaps caused by the withdrawal of Title X providers from the program; and
- Including in the proposed FY 2023 budget a proposed $470 million to be used to reduce maternal mortality and morbidity rates; expand maternal health initiatives in rural communities; implement implicit bias training for healthcare providers; create pregnancy medical home demonstration projects; and address the highest rates of perinatal health disparities, including by supporting the perinatal health workforce.

Given the highlighted challenges faced by those living in rural communities of accessing maternal health services and consistent with the Administration's priorities in improving access to these services, we believe it would be beneficial that REHs provide maternal health services that include prenatal care, low-risk labor and delivery and postnatal care. We are seeking input on the issue of whether REHs should be permitted to provide low-risk labor and delivery, and whether or not we should require that the REH also provide outpatient surgical services in the event surgical labor and delivery intervention is necessary. REHs should base their determination on what is considered a ''low-risk'' delivery on nationally recognized standards and guidelines. If a laboring patient presents to the REH for labor and delivery services and subsequently requires emergency surgical intervention, the REH would be responsible for providing the emergency and stabilizing treatment prior to transfer, including any emergency surgical procedures including but not limited to c-sections. Once the patient is stabilized, they may be transferred to an appropriate level of care for mother and baby given that the average length of inpatient stay for an uncomplicated c-section is 2.7 days.[13] In such cases, we would encourage the REH to provide the patient's follow-up and postpartum care so long as the patient's needs are within the scope of practice of the practitioners providing services at the REH. We would expect that the REH would leverage clinicians other than only physicians so that a variety of trained professionals or support persons could help to address barriers to access to care and the maternal health workforce shortage in rural areas by utilizing nurse practitioners, nurse midwives, and doulas as allowed by state law.

The provision of behavioral health services is also a challenge in rural communities. According to the Rural Health Information Hub, ''. . . approximately 7.7 million nonmetropolitan adults reported having any mental illness (AMI) in 2020, accounting for 20.5% of nonmetropolitan adults. In addition, 1.8 million, or 4.8%, of adults in nonmetropolitan areas reported having serious thoughts of suicide during the year.'' [14] The Rural Health Information Hub also presents specific challenges in this area, including the following: [15]

- *Accessibility*—Rural residents often travel long distances to receive services, are less likely to be insured for mental health services, and providers are less likely to recognize a mental illness.
- *Availability*—Chronic shortages of mental health professionals exist and mental health providers are more likely to practice in urban centers.
- *Affordability*—Some rural residents may not be able to afford the cost of health insurance or the cost of out-of-pocket care if they lack health insurance.
- *Acceptability*—Rural residents may be more susceptible to the stigma of needing or receiving mental health care in small communities where everyone knows each other and fewer choices of trained professionals can lead to a lack of faith in confidentiality, as well as a reliance on the informal care of family members, close friends, and religious leaders.

Several commenters on the REH RFI indicated that REHs should provide behavioral health services that include substance use disorder treatment. According to the Centers for Disease Control and Prevention, ''Rates of drug overdose deaths are rising in rural areas, surpassing rates in urban areas.'' [15] Additionally, treatment for alcohol and illicit drug use was generally the same or higher in nonmetropolitan counties compared to metropolitan counties, according to data from the 2018 National Survey on Drug Use and Health (Substance Abuse and Mental Health Services Administration, *https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2018R2/NSDUHDetTabsSect5pe2018.htm#tab5-9a*). The survey highlighted substance use disorders related to alcohol, methamphetamines, and opioids, particularly noting that rural counties exhibited a higher rate of opioid overdoses than urban counties and that opioid misuse is high in states with large rural populations. There are several factors that contribute to substance use disorder in rural communities, including high rates of poverty and unemployment, increased availability of prescription opioids, and barriers to treatment. These barriers include the level of complexity related to treatment of substance use disorders, which includes individual and group counseling, inpatient and outpatient treatment, case management, and

[13] Federspiel, J.J., Suresh, S.C., Darwin, K.C., & Szymanski, L.M. (2020). Hospitalization Duration Following Uncomplicated Cesarean Delivery: Predictors, Facility Variation, and Outcomes. AJP reports, 10(2), e187–e197. *https://doi.org/10.1055/s-0040-1709681*.

[14] Rural Health Information Hub (2021). Rural Mental Health. *https://www.ruralhealthinfo.org/topics/mental-health*.

[15] Center for Disease Control and Prevention (2017). Rural Health—Drug Overdose. *https://www.cdc.gov/ruralhealth/drug-overdose/*.

medication, as well as additional services and programs. Difficulties associated with navigating these treatment modalities may, and often does lead to delays in treatment. This adds to existing access to care issues in rural communities where there are shortages of providers, ultimately resulting in delays in treatment. This further illustrates the need for behavioral health services in rural areas, given the access to care issues which are more prevalent in rural areas when compared to non-rural areas. Additionally, given the data provided related to substance use in rural communities, we would expect that some REHs may be interested in being opioid treatment providers. We note that providing these services is not prohibited by the statute at 1866(kkk) so long as the treatment remains an outpatient service, given that the statute does prohibit REHs from providing inpatient services (except those services provided in a distinct part SNF of the REH).

If the REH chooses to provide additional outpatient medical and health services, we propose at § 485.524(a)(1) to require that the provision of the additional service be based on nationally recognized guidelines and standards of practice, aligning the proposed requirement with the hospital CoPs for outpatient services at § 482.54. Given that the REH does not provide inpatient services, patients requiring a higher level of care would be required to be transferred to an acute care hospital or CAH. As a result of this, and based on comments received on the REH RFI, we further propose to require that the REH have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate. Some of the REH RFI comments also indicated that REHs should be required to have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH. Hospital admissions and transfers account for roughly 20 percent of all patient dispositions from the emergency department across the U.S.[16] As a result, we can expect that REHs will transfer at least 20 percent of their patients so we agree with commenters and are therefore proposing to require that REHs have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH.

Ensuring effective communication between providers of health care services and patients and their family is a critical element in the provision of care and the discharge or transfer of patients. We are proposing to require that the REH have effective communication systems in place between the REH and patients (or responsible individuals) and their family, ensuring that the REH is responsive to their needs and preferences. We believe this would assist with effective care coordination as well as improved patient outcomes.

At § 485.524(b), we propose personnel requirements for REHs who choose to provide additional outpatient medical and health services. These requirements ensure that the additional services provided by the REH are overseen by at least one responsible individual, have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, and are provided by a physician or other clinician with experience and training in the specialty service area.

At § 485.524(c) we propose to specify standards that REHs must have for ordering outpatient medical and health services that are consistent with the hospital requirements at 42 CFR 482.54(c). Specifically, we propose to require outpatient medical and health services to only be ordered by a practitioner who: (1) is responsible for the care of the patient; (2) is licensed in the state where they provide care to the patient; (3) is acting within their scope of practice under state law; and (4) is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. We also propose that these requirements would apply to those practitioners who are appointed to the REH's medical staff and who have been granted privileges to order the applicable outpatient services; and those practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the REH for ordering the applicable outpatient services and for referring patients for such services.

Lastly, the importance of allowing REHs to provide outpatient surgical services was especially noted by commenters in response to the REH RFI. A 2011 rural policy brief by the Rural Policy Research Institute (RUPRI) Center for Rural Health Policy Analysis states that, ''Like residents of any community, rural residents have surgical needs that range from the predictable (*e.g.,* cataract procedures) to the emergent (*e.g.,* appendectomy). Innovations in surgery over the past several decades have made possible the provision of many surgical procedures on an outpatient basis, reducing inpatient admissions.'' [17] The policy brief found that across four states (Colorado, North Carolina, Vermont, and Wisconsin) in 2011, surgeries were performed across 107 CAHs with an average of 522 outpatient procedures performed per year. This is 75 to 80 percent of the total surgical procedure volume in the state for that year and demonstrates that there will be a need for outpatient surgical services in communities in which CAHs convert to an REH. Therefore, we propose at § 485.524(d) to set forth standards for an REH performing outpatient surgical services that are consistent with the CAH requirements for surgical services at § 485.639. These include proposed standards for ensuring that the services are conducted in a safe manner by qualified practitioners with specific protocols for administering anesthesia.

Given that in accordance with the statutory provision at section1861(kkk)(1)(A) of the Act services furnished by the REH must not exceed an annual per patient average of 24 hours in the REH, we expect REHs, like ASCs, to provide surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.

13. Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs (Proposed § 485.526)

The Department of Health and Human Services (HHS) is particularly concerned about health care associated infections (HAIs), as they are a significant cause of morbidity and mortality in the U.S. In 2015, there were an estimated 687,000 cases of HAIs in U.S hospitals with 72,000 inpatients with HAIs that died during that same time period.[18] Additionally, HHS is concerned about the growing threat to patient safety posed by organisms that are resistant to antibiotics, referred to as ''multi-drug resistant organisms (MDROs).'' Options for treating patients

[16] American College of Emergency Physicians—ACEP Now (2019). Latest Data Reveal the ED's Role as Hospital Admission Gatekeeper. *https://www.acepnow.com/article/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/.*

[17] Rural Policy Research Initiative Rural Health Center for Rural Health Policy Analysis—Rural Policy Brief (2011). Surgical Services in Critical Access Hospitals, 2011. *https://rupri.public-health.uiowa.edu/publications/policybriefs/2015/Surgical%20Services%20in%20CAHs.pdf.*

[18] Centers for Disease Control and Prevention (2020). Data Portal. *https://www.cdc.gov/hai/data/portal/index.html.*

with MDRO infections are very limited, resulting in increased mortality, as well as increased hospital lengths of stay and costs. In response, HHS launched an Action Plan in April 2009 with updates in 2013 and 2018 toward the prevention and elimination of HAIs. (HHS. ''HHS Action Plan to Prevent Healthcare-Associated Infections.'' Accessed 5 March 2014 *https://www.hhs.gov/ash/initiatives/hai/actionplan/index.html*.) The HHS Action Plan identifies policy changes, some addressed here in this proposed rule, in an effort to provide better, more efficient care.

We are proposing a CoP for infection prevention and control and antibiotic stewardship programs for REHs at § 482.526 in an effort to mirror similar infection prevention and control requirements for hospitals and CAHs (at §§ 482.42 and 485.640, respectively) that reflect state-of-the-art practices and terminology. We are also proposing a standard that would require an REH to develop and maintain an antibiotic stewardship program as an effective means to improve REH antibiotic-prescribing practices and curb patient risk for possibly deadly *Clostridium difficile infections* (CDIs), as well as other future, and potentially life-threatening, antibiotic-resistant infections. We would promote better alignment of an REH's infection control and antibiotic stewardship efforts with nationally recognized guidelines and emphasize the role and accountability of an REH's governing body in program implementation and oversight. We believe that these requirements, together, would promote a more patient-centered culture of safety focused on infection prevention and control as well as appropriate antibiotic use (consistent with the requirements for hospitals and CAHs), while allowing REHs the flexibility to align their programs with the guidelines best suited to them.

Therefore, similar to the requirements that we finalized with regard to infection prevention and control and antibiotic stewardship programs for hospitals and CAHs in the September 30, 2019 final rule ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732), we are proposing in this rule that each REH has facility-wide infection prevention and control and antibiotic stewardship programs that are coordinated with the REH quality assessment and performance improvement (QAPI) program, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. Further, we are proposing in this rule at § 485.526(a)(1) that the REH ensure that an individual (or individuals), who are qualified through education, training, experience, or certified in infection, prevention and control, are appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program at the REH and that the appointment is based on the recommendations of medical staff and nursing leadership.

At § 485.526(a)(2) we propose that the infection prevention and control program, as documented in its policies and procedures, employ methods for preventing and controlling the transmission of infections within the REH and between the REH and other health care settings. The program, as documented in its policies and procedures, would have to employ methods for preventing and controlling the transmission of infection within the REH setting (for example, among patients, personnel, and visitors) as well as between the REH (including outpatient services) and other institutions and health care settings. At § 485.526(a)(3) we are proposing that the infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also address any infection control issues identified by public health authorities. We are proposing at § 485.526(a)(4) that the infection prevention and control program reflect the scope and complexity of the services provided by the REH.

At § 485.526(b)(1) we propose to set standards for the organization and policies of the antibiotic stewardship program. Specifically, we propose to require that the REH's governing body ensure that an individual, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship is appointed as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff and pharmacy leadership. The proposed requirements at § 485.526(b)(2)(i) through (iii) would ensure that certain goals for an antibiotic stewardship program are met. These include demonstrating coordination among all components of the REH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, and nursing and pharmacy services; documenting the evidence-based use of antibiotics in all departments and services of the REH; and documenting improvements, including sustained improvements, in proper antibiotic use. We believe that these three components are essential for an effective program.

The provisions at § 485.526(b)(3) and (4) would require the REH to ensure that the antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use, and that the REH's stewardship program reflects the scope and complexity of services offered. We believe these proposed requirements are necessary to promote a facility-wide culture of quality improvement.

We would require that the governing body or responsible individual ensure that the infection prevention and control issues identified by the infection prevention and control professionals be addressed in collaboration with REH leadership. Therefore, at § 485.526(c)(1)(i) and (ii), we propose certain requirements that the governing body or responsible individual must adhere to including—

- Ensuring systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities to demonstrate the implementation, success, and sustainability of such activities; and
- Ensuring all HAIs and other infectious diseases identified by the infection prevention and control program and antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with REH QAPI leadership.

At § 485.526(c)(2)(i) through (vi), we propose that the responsibilities of the infection prevention and control professionals would include the development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines. The infection preventionist(s)/infection control professional(s) would be responsible for all documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

Additionally, the infection preventionist(s)/infection control professional(s) would be responsible for the following—

- Communication and collaboration with the REH's QAPI program on infection prevention and control issues;
- Competency-based training and education of REH personnel and staff including professional health care staff and, as applicable, personnel providing services in the REH under agreement or arrangement, on the practical applications of infection prevention and control guidelines, policies and procedures;
- Prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by REH personnel; and
- Communication and collaboration with the antibiotic stewardship program.

At § 485.526(c)(3), we propose requirements for the leader(s) of the antibiotic stewardship program that are similar, but not identical, to the proposed responsibilities for the REH's designated infection preventionist(s)/infection control professional(s) at proposed § 485.526(c)(2). We believe that an REH's antibiotic stewardship program is the most effective means for ensuring appropriate antibiotic use. We also believe that such a program would require a leader who is responsible and accountable for its success. Therefore, we propose that the leader of the antibiotic stewardship program would be responsible for the development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics. We do not expect that each new leader would develop a new antibiotic stewardship program, unless it is determined that a new program is necessary. We also propose that the leader of the antibiotic stewardship program would be responsible for all documentation, written or electronic, of antibiotic stewardship program activities. The leader would also be responsible for communicating and collaborating with medical and nursing staff, pharmacy leadership, and the REH's infection prevention and control and QAPI programs, on antibiotic use issues.

We also propose that the leader would be responsible for the competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

Similar to a standard in the hospital CoPs, we propose a standard at § 485.526(d) for REHs that would allow for the governing body of an REH that is part of a system consisting of multiple, separately certified hospitals, CAHs, and/or REHs using a single system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, to elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities, including any REHs, after determining that such a decision is in accordance with all applicable state and local laws. We are proposing a similar standard for CAHs at § 485.640(g), which is discussed in section B.3 of this proposed rule. The system's single governing body would be responsible for ensuring that each of its separately certified REHs met the requirements of this section. We note that each separately certified REH subject to the system's single governing body would need to demonstrate that the unified and integrated infection prevention and control and antibiotic stewardship programs:

- Were established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH;
- Established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration; and
- Had mechanisms in place to ensure that issues localized to particular REHs were duly considered and addressed.

The REH would also need to demonstrate that it had designated a qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship at the REH to be responsible for:

- Communicating with the system's unified infection prevention and control and antibiotic stewardship programs;
- Implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs; and
- Providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

Finally, in response to the COVID–19 pandemic, on September 2, 2020, CMS published an interim final rule with comment period to track the incidence and impact of COVID–19 to assist public health officials in detecting outbreaks and saving lives (85 FR 54820). CMS then published a final rule with comment containing reporting requirements for hospitals and CAHs to report acute respiratory illness during the public health emergency (PHE) for COVID–19 (85 FR 86304) on December 4, 2020. Lastly, on November 5, 2021, CMS published an interim final rule with comment establishing COVID–19 vaccination requirements for most Medicare- and Medicaid-certified providers and suppliers (86 FR 61623). Consistent with the recent changes we made to the hospital and CAH infection control CoPs related to COVID–19 (87 FR 28108) and the declared PHE, we are proposing the following three standards in this proposed rule for REHs:

- Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential, which would require an REH to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS–CoV–2/COVID–19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency, directly related to such specific pathogens and infectious diseases.
- COVID–19 reporting, which would require an REH to electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary, including the REH's current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the REH and the current usage rate for those therapeutics beginning at the conclusion of the COVID–19 PHE, and continuing until April 30, 2024, unless the Secretary specifies an earlier end date.
- COVID–19 Vaccination of REH staff, which would require the REH to develop and implement policies and procedures to ensure that all staff, with the exception of those with valid exemptions, are fully vaccinated for COVID–19 until November 4, 2024, unless the Secretary specifies an earlier end date for the requirements of this paragraph. Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 establishes a general 3-year timeline for publishing a Medicare final regulation after a

proposed regulation or an interim final regulation has been published. The referenced November 4, 2024 date aligns with the statutory 3-year ''Section 902'' deadline for the IFC that implemented the COVID–19 staff vaccination requirements for the provider and supplier types covered under that rule.

14. Condition of Participation: Staffing and Staff Responsibilities (Proposed § 485.528)

Sections 1861(kkk)(1)(B)(i) and (ii) of the Act require that the emergency department of the REH be staffed 24 hours a day, 7 days a week. We propose to implement this requirement at § 485.528(a). The statute does not speak to the type of staff at the REH that is required to fulfill this role. As such, we believe that REHs should have the flexibility to determine how to staff the emergency department at the REH 24 hours, 7 days a week. We expect that the individual(s) staffing the emergency department is competent to receive patients and activate the appropriate medical resources for the treatment of the patient. This includes, but is not limited to notifying a practitioner of the patient's arrival in the emergency department. Such staff may include a nurse, nursing assistant, clinical technician, or an emergency medical technician, (EMT).

Furthermore, in accordance with section 1861(kkk)(1)(B)(iii) of the Act, we propose for REHs to meet the applicable CAH requirements at § 485.631 for staffing and staff responsibilities. We believe that many of the CAH staffing requirements are appropriate for application to REHs and as a result, at § 485.528(b) through (e), we set for the proposed standards for staffing, responsibilities of the doctor of medicine or osteopathy, physician assistant, nurse practitioner, and clinical nurse specialist responsibilities similar to CAHs. For instance, the CAH CoPs require at § 485.631(a)(5) that a registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients. Since REHs are required to furnish emergency services and observation care, we are proposing a similar requirement as CAHs to require that a registered nurse, clinical nurse specialist, or licensed practical nurse be on duty whenever the REH has one or more patients receiving emergency services or observation care.

We also propose to require standards for the periodic review of clinical privileges and performance that are also identical to the CAH standards at § 485.631, with the exception of the CAH standard at § 485.631(b)(1)(iv), which requires that the CAH periodically review and sign the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants. We are not proposing this standard for REHs given that the REH would provide outpatient services exclusively.

We do not believe that it is necessary to apply the CAH requirement that a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates (§ 485.631(a)(4)) to REHs. Instead, we are proposing to require that the REH standards align with the CAH emergency services requirements at § 485.618. The CAH provision at § 485.618(d) requires that there be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within specified timeframes. This allows for the alignment of the REH proposed provisions with the CAH emergency services standards, as required by the statute.

In response to the REH RFI, commenters indicated that CMS should require board-certified emergency physicians to serve as medical directors of the REH. While we agree that having a board-certified emergency physician serving as the medical director of the REH would benefit patients by ensuring that the REH is overseen by a highly qualified physician with a high level of expertise in emergency medicine, we believe that requiring this of REHs would be unduly burdensome due to the challenges faced by rural communities in obtaining and retaining medical professionals to provide health care services. While we are not proposing to require that REHs have a board-certified emergency physician serve as the medical director, we would encourage REHs to have such a physician serve in the capacity of medical director if possible.

15. Condition of Participation: Nursing Services (Proposed § 485.530)

The CoPs for hospitals and CAHs include a provision for nursing services. However, given that each of these providers offers acute care inpatient services, we do not believe that all of the nursing services requirements for hospitals and CAHs would be appropriate for REHs, which is an outpatient-only provider. In evaluating the appropriateness of nursing services requirements for REHs, we also took into consideration the CfCs for ambulatory surgery centers at 42 CFR part 416 since they only offer outpatient services.

Consistent with the hospital requirements, we propose to require that REHs have an organized nursing service that is available to provide 24-hour nursing services at § 485.530 for the provision of patient care. We believe that the REH should have a sufficient number of nurses available to provide services, based on the number of patients receiving services in the REH and the level of care required to be provided to those patients.

Similar to the standard hospitals at § 482.23(a), we propose at § 485.530(a) to require that patient care responsibilities must be delineated for all nursing service personnel and that nursing services must be provided in accordance with recognized standards of practice. Also consistent with the hospital standards for nursing services, we propose to require at § 485.530(b) that the REH have a director of nursing who is a licensed registered nurse and who is responsible for the operation of the nursing services.

16. Condition of Participation: Discharge Planning (Proposed § 485.532)

Hospitals and CAHs have very similar discharge planning requirements at §§ 482.43 and 485.642, respectively. These requirements were revised in the final rule entitled ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51836). Many commenters on the REH RFI noted the importance of having in-depth discharge planning requirements for REHs, highlighting the need for REH patients to have safe, well-coordinated discharge processes due to the availability of fewer health care resources in rural environments. As a result, we propose to closely align the proposed discharge planning requirements for REHs with the requirements for hospitals and CAHs. Specifically, we are proposing at § 485.532 to require that the patient's discharge plan address the patient's goals of care and treatment preferences. During the discharge planning process, we would expect that the appropriate medical staff would discuss the patient's post-acute care goals and treatment preferences with the patient, the patient's family or their caregiver/

support persons (or both) and subsequently document these goals and preferences in the medical record. We would expect these documented goals and treatment preferences to be taken into account throughout the entire discharge planning process. We note that as a provider of emergency services, the REH may receive patients from nursing homes who require emergency care. Having a robust discharge planning process in place is imperative for this patient population. There may be instances in which a patient comes to the REH from a nursing home and the nursing home expresses an intent not to accept the patient or delays the patient's return back to the nursing home after the completion of emergency care by the REH. Under these circumstances, we would encourage the REH to contact their State's long-term care ombudsman or State Survey Agency. We also encourage the REH to inform patients who arrive from or are discharged to a long-term care facility about how to contact the Ombudsman and State Survey Agency, as there may be quality of care or quality of life concerns to be reported. The Administration of Community Living's Long-Term Care Ombudsman Programs, ''. . . work to resolve problems related to the health, safety, welfare, and rights of individuals who live in LTC facilities, such as nursing homes, board and care and assisted living facilities, and other residential care communities. Ombudsman programs promote policies and consumer protections to improve long-term services and supports at the facility, local, state, and national levels.'' [19]

At § 485.532(a) introductory text and (a)(1), we propose to require that REHs implement a discharge planning process to begin identifying, early in the provision of services, the anticipated post-discharge goals, preferences, and needs of the patient and begin to develop an appropriate discharge plan for patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning. Timely identification of the patient's goals, preferences, and needs and development of the discharge plan would reduce delays in the overall discharge process. Patient referrals to or consultation with community care organizations will be a key step, for some, in assuring successful patient outcomes. Therefore, we believe that discharge planning for patients is a process that involves the consideration of the patient's unique circumstances, treatment preferences, and goals of care, and is not solely a documentation process.

In addition, in order to encourage patient engagement and understanding of their discharge plan or instructions, we recommend that providers follow the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (*https://www.thinkculturalhealth.hhs.gov/clas/standards*), which provide guidance on providing instructions in a culturally and linguistically appropriate manner. We remind providers of their obligations to take reasonable steps to provide meaningful access to individuals with limited English proficiency in accordance with Title VI of the Civil Rights Act of 1964 and section 1557 of the Patient Protection and Affordable Care Act (the Affordable Care Act). In addition, providers are reminded to take appropriate steps to ensure effective communication with individuals with disabilities, including the provision of auxiliary aids and services, in accordance with section 504 of the Rehabilitation Act, the Americans with Disabilities Act, and section 1557 of the Affordable Care Act (see, *https://www.hhs.gov/civil-rights* and *https://www.ada.gov* for more information on these requirements). Discharge planning would be of little value to patients who cannot understand or appropriately follow the discharge plans discussed in this proposed rule. Without appropriate language assistance or auxiliary aids and services, discharge planners would not be able to fully involve the patient and caregiver/support person in the development of the discharge plan. Furthermore, the discharge planner would not be fully aware of the patient's goals for discharge.

Additionally, effective discharge planning would assist REHs in complying with the U.S. Supreme Court's holding in *Olmstead* v. *L.C.* (527 U.S. 581 (1999)), which found that the unjustified segregation of people with disabilities is a form of unlawful discrimination under the ADA. We note that effective discharge planning may assist REHs in ensuring that individuals being discharged who would otherwise be entitled to institutional services, have access to community-based services when—(1) such placement is appropriate; (2) the affected person does not oppose such treatment; and (3) the placement can be reasonably accommodated. As noted by comments received in response to the REH RFI, discharge planning should focus on returning the patient to a home or community-based setting to the fullest extent possible with necessary supports and service. These proposed discharge planning standards are aimed at achieving this goal.

At § 485.532(a)(2), we propose to require an REH to perform a discharge planning evaluation that must include an evaluation of a patient's likely need for appropriate services following care that has been furnished by an REH, including, but not limited to, hospice care services, post-REH extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

At § 485.532(a)(3) we propose to require that the patient's discharge needs evaluation and discharge plan must be documented and completed on a timely basis, based on the patient's goals, preferences, strengths, and needs, so that appropriate arrangements for post-REH care are made before discharge. This requirement would prevent the patient's discharge or transfer from being unduly delayed. We expect that in response to this requirement, REHs would establish more specific time frames for completing the evaluation and discharge plans based on the needs of their patients and their own operations. All relevant patient information would be incorporated into the discharge plan to facilitate its implementation and the discharge plan must be included in the patient's medical record. The results of the evaluation must also be discussed with the patient or patient's representative. Furthermore, we believe that REHs will use their evaluation of the discharge planning process, with solicitation of feedback from other providers and suppliers in the community, as well as from patients and caregivers, to revise their timeframes, as needed. We encourage REHs to make use of available health information technology, such as electronic health records, as well as entities that can facilitate exchange, such as health information exchanges, to enhance the efficiency and effectiveness of their discharge process.

At § 485.532(a)(4), we propose to require the REH to arrange for the development and initial implementation of a discharge plan for those patients so identified as well as for other patients upon the request of the patient's physician. We propose at § 485.532(a)(5) to require that a registered nurse, social worker, or other personnel qualified in

[19] Administration of Community Living (2021). Long-Term Care Ombudsman Program. *https://acl.gov/programs/Protecting-Rights-and-Preventing-Abuse/Long-term-Care-Ombudsman-Program.*

accordance with the REH's discharge planning policy coordinate the discharge needs evaluation and the development of the discharge plan.

At § 485.532(a)(6) we propose to require that the REH's discharge planning process must ensure an ongoing patient evaluation throughout the patient's REH stay or visit to identify any changes in the patient's condition that would require modifications to the discharge plan. The evaluation to determine a patients continued stays at the REH (or in other words, their readiness for discharge or transfer), is a current standard of medical practice.

We propose to require at § 485.532(a)(7) that the hospital assess its discharge planning process on a regular basis and include, as part of the assessment, an ongoing review of a representative sample of discharge plans. We expect that this would include patients who were emergency department revisits, or presented to the emergency department within 30 days of a previous visit, to ensure that the REH is responsive to the discharge needs of patients.

In addition to standards for evaluating the discharge needs of patients and the development of discharge plans, the hospital and CAH discharge planning provisions also require that the hospital and CAH assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), SNF, inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH) data on quality measures and data on resource use measures. Furthermore, the CoPs require the hospital and CAH to ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences. We believe these requirements are applicable to REHs given that we expect some patients of the REH to be discharged to a post-acute care provider. As result, we propose at § 485.532(a)(8) to require REHs to share data on quality measures and resource use measures of local post-acute care providers with patients to assist them in selecting a post-acute care provider.

We propose at § 485.532(b) to require that the REH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

The Agency for Healthcare Research and Quality released an environmental scan report on Improving the Emergency Department Discharge Process, that evaluated the state of the emergency department discharge process and ways in which it can be improved.[20] The report found that a high-quality emergency department discharge incorporates the following:

- Informs and educates patients on their diagnosis, prognosis, treatment plan, and expected course of illness. This includes informing patients of the details of their visit (treatments, tests, procedures).
- Supports patients in receiving post-emergency department discharge care. This might include medications, home care of injuries, use of medical devices/equipment, further diagnostic testing, and further health care provider evaluation.
- Coordinates emergency department care within the context of the health care system (other health care providers, social services, etc.).

We believe discharge planning requirements proposed for REHs address the goals identified in the report.

17. Condition of Participation: Patient's Rights (Proposed § 485.534)

It is imperative for patients to have the ability to exercise certain rights and protections while seeking and receiving necessary care and services at an REH. As previously mentioned, the appropriate provision of behavioral health is very important in the treatment and safety of patients and staff. Behavioral health is a challenge in rural areas, due to the accessibility, affordability, acceptability and availability of these services. We anticipate beneficiaries may rely on REH's to access behavioral health care services, therefore we believe it is important to have policies and procedures in place for REHs and CAHs (discussed later in this rule) in the event of a mental health crisis and the need for the use of restraints and seclusions. We propose to establish a CoP for patient's rights at § 485.534 that would set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. Furthermore, we propose to establish the patient's rights CoP for REHs closely to the patient's rights CoP for hospitals at § 482.13. This would include proposed requirements for the REH to inform patients of and exercise their rights, address privacy and safety, adhere to the confidentiality of patient records, responsibilities for the use of restraint and seclusion, and adherence to patient visitation rights. We propose to add these same patient's rights CoPs for CAHs, as well. Some of these requirements are currently in the SOM for CAHs while some are not explicitly required. We believe that these patient rights provisions are important for hospitals, CAHs, and REHs. However, we note that some of the provisions proposed in this section for REHs and, also for CAHs as discussed later, are less prescriptive than those for hospitals because we are proposing to allow for these providers to develop policies and procedures based on the scope of services they provide and patient populations that they serve. For example, we believe that REHs, like CAHs, will have a lower volume of patients than hospitals and the use of restraints and seclusion would not be as frequent as other providers. REHs would not be providing inpatient services and if a patient presents at the REH in crisis or needing a level of care so acute that restraints or seclusions may become necessary, we would expect the REH to arrange for the transfer of the patient to a higher level of care. We are specifically soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Notice of Rights

At § 485.534(a), we propose that an REH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. This includes a proposal to require the REH to establish a process for the oversight and prompt resolution of patient grievances and for informing each patient whom to contact to file a grievance.

[20] Johns Hopkins University, Armstrong Institute for Patient Safety and Quality (2014). Improving the emergency department discharge process: environmental scan report. (Prepared by Johns Hopkins University, Baltimore, MD, under Contract No. HHSA 2902010000271.). Agency for Healthcare Research and Quality; Publication No. 14(15)–0067–E. *https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/systems/hospital/edenvironmentalscan/edenvironmentalscan.pdf.*

Exercise of Rights

At § 485.534(b), we propose to specify those rights a patient has regarding their medical care, which includes the right to make informed decisions regarding their care, to be fully informed about such care, and the right to request or refuse treatment. We note that this right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. In addition, we propose to specify that the patient also has the right to formulate advance directives and to have REH staff and practitioners who provide care in the REH comply with these directives.

Privacy, Safety, and Confidentiality of Patient Records

At § 485.534(c), we propose to specify that the patient has the right to personal privacy, receive care in a safe setting, and be free from all forms of abuse or harassment. At § 485.534(d), we propose to specify that the patient has the right to the confidentiality of their medical records and the right to access their medical records. When requested, we propose that the REH must provide the patient with their records in a form and format requested by the requestor and within a reasonable timeframe, as not to frustrate the legitimate efforts of individuals to gain access to their own medical records.

Use of Restraints and Seclusion

At § 485.534(e), we propose those patient's rights relating to the use of restraints and seclusion. We are proposing requirements that are less burdensome than those existing restraint and seclusion requirements for hospitals because given the level of services provided by REHs and the anticipated patient volume, we expect the likelihood of their need to utilize restraints and seclusion to be relatively low. In addition, in the event that there are patients requiring restraint and seclusion we would expect them to be transferred to a higher level of care. We note that we have similar expectations for CAHs and are proposing similar requirements for CAHs in this rule. Specifically, we propose to specify that all patients have the right to be free from physical or mental abuse, from corporal punishment, and from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. We propose that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time. We propose to define restraint as any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). We propose to define seclusion as the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

At § 485.534(e)(2), we propose to require that the restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm, and at § 485.534(e)(3) that the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, staff member, or others from harm. At § 485.534(e)(4), we propose that the REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. These requirements allow for the REH to use restraints and seclusion in the event that it is necessary and as a last resort to respond to immediate safety concerns, but lessens the burden and allows for more flexibility than the existing hospital CoPs. We believe that allowing the REH the flexibility to develop their own policies and procedures for restraints and seclusion based on the scope of services they provide is necessary given their patient volumes, populations, and access to resources. We propose to require that the policies and procedures that are developed be consistent with current standards of practice. As noted, we are soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Staff Training Requirements for the Use of Restraints or Seclusion

The following staff training requirements are not as prescriptive as the existing hospital requirements, and we are proposing these same requirements for CAHs in this rule. At § 485.534(f) we propose to establish staff training requirements for the use of restraints and seclusion. Specifically, we propose that the patient has the right to safe implementation of restraint or seclusion by trained staff. We propose at § 485.534(f)(1) that the REH must provide competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion. To ensure that the use of restraint and seclusion for patients receiving services in an REH is respectful of, and responsive to, individual patient preferences, needs and values, we propose to require that the training be patient-centered. Additionally, to ensure that staff are educated and trained on using the least restrictive intervention necessary for the safety of the patients and REH staff, we propose at § 485.534(f)(2) to require that the REH staff train their staff in alternatives to the use of restraint and seclusion. For example, staff should have trauma-informed knowledge competencies and be aware of effective de-escalation techniques that can be used to avoid the use of restraint and seclusion and the trauma that may be associated with their use. Trained peer workers (people who share similar experiences of being diagnosed with mental health conditions, substance use disorders, or both) and community health workers (CHWs) may also serve a useful role in assisting patients and other staff. This could include helping to monitor use of restraint and seclusion, deescalating interactions with patients and contributing to a positive and supportive environment for patients, family members, and REH staff. REHs are encouraged to consider the use of peer workers and CHWs in their staffing plans. For further information, please see the 2007 guidance on use of peers in the Medicaid program (*https://www.medicaid.gov/federal-policy-guidance/downloads/SMD081507A.pdf*) and resources from the Substance Abuse and Mental Health Services Administration (*https://www.samhsa.gov/brss-tacs/recovery-*

support-tools/peers). In addition, facilities are encouraged to consider any nutritional needs while a patient is restrained, such as a need to provide food and water.

Death Reporting Requirements

The following requirements are similar to the hospital requirements at § 482.13. At § 485.534(g), we propose to establish requirements that REHs must follow when reporting deaths associated with the use of seclusion or restraint. Specifically, we propose to require that the REH must report to CMS, by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day the following information—(1) Each death that occurs while a patient is in restraint or seclusion; (2) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; (3) Each death known to the REH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. We note that ''reasonable to assume'' in this context would include, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

For instances when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the REH staff must record in an internal log or other system, the following information—(1) Any death that occurs while a patient is in such restraints; (2) Any death that occurs within 24 hours after a patient has been removed from such restraints. Furthermore, we propose that staff must also document in the patient's medical record the date and time the death was reported to CMS or recorded in the internal log or other system. Also, for instances when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s),we propose to require that entries into the internal log or other system must be documented no later than seven days after the date of death of the patient, include the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es), and to be made available in either written or electronic form to CMS immediately upon request.

Patient Visitation Rights

At § 485.534(h), we propose to establish requirements related to a patient's visitation rights. These requirements are consistent with the current hospital and CAH regulations. Specifically, we propose to require that an REH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH must inform patients (or support persons, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights. Each patient should be informed (or support persons, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend. The patient also has the right to withdraw or deny such consent at any time, not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability, and ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

18. Condition of Participation: Quality Assessment and Performance Improvement Program (QAPI program) (Proposed § 485.536)

Patient safety and quality improvement remains a challenge in our nation's hospitals. In 2001, the Institute of Medicine (IOM) released a pivotal report, ''Crossing the Quality Chasm'' in which it stated that ''the American healthcare delivery system is in need of fundamental change'' and recognized that ''quality problems are everywhere affecting many patients.'' [21] In a 2004 educational publication co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the American Health Lawyers Association (AHLA), Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors, the authors discuss the IOM report and state that the oversight of quality and patient safety is becoming clearly recognized as a core fiduciary responsibility of health care organizations.[22] They further note that promoting quality of care and preserving patient safety are at the core of the health care industry and the reputation of each health care organization and suggest that ''contemporary health care quality, patient safety and cost efficiency initiatives provide an opportunity for health care organizations to make a positive difference to society while promoting their missions and enhancing their financial success.'' In their 2013 expert panel report, the Association of American Medical Colleges describes the work of the competent health professional as not only delivering health care, but also working to improve it, including identifying problems in care delivery and working with others to enhance performance.[23]

While progress has been made towards the goal of increased patient safety since the publication of the 2001 IOM report, including a reduction in hospital-acquired conditions (HACs) and hospital fall-related injuries and improvements in patient handoffs, the mitigation of medical errors and adverse events and protection of patient safety remain serious concerns.[24] [25] [26] According to 2018 data from the Centers for Disease Control (CDC), approximately 1 in 31 hospital patients develops an HAI, such as a surgical site infections or catheter-related bloodstream infections (CRBIs) and the effects can be painful, costly, and even deadly.[27]

[21] Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington (DC): National Academies Press (US); 2001. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK222274/* doi: 10.17226/10027.

[22] United States Department of Health and Human Services, Office of Inspector General & American Health Lawyers Association. (2004). Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors. *https://oig.hhs.gov/documents/compliance-guidance/813/CorporateResponsibilityFinal_9-4-07.pdf.*

[23] Association of American Medical Colleges. (2014). Teaching for Quality: Integrating Quality Improvement and Patient Safety across the Continuum of Medical Education. *https://www.aamc.org/media/26316/download?attachment.*

[24] Agency for Healthcare and Research Quality. (2020, July) AHRQ National Scorecard on Hospital-Acquired Conditions: Final Results for 2014 through 2017. *https://www.ahrq.gov/hai/pfp/index.html.*

[25] Dupree, E., Fritz-Campiz, A., Musheno, D. (2014). A New Approach to Preventing Falls with Injuries. *Journal of Nursing Care Quality, 29*(2), p. 99–102.

[26] Starmer, A.J. et al. (2014). Changes in Medical Errors after Implementation of a Handoff Program. *New England Journal of Medicine, 371,* p. 1803–1812. DOI: 10.1056/NEJMsa1405556.

[27] Centers for Disease Control and Prevention. (2018, October 5). Healthcare-Associated Infections

Continued

An effective QAPI program that is engaged in continuous improvement efforts is essential to a provider's ability to deliver high quality and safe care to its patients, while reducing the incidence of medical errors and adverse events. Therefore, we believe the QAPI programs for REHs should conform to the current health care industry standards that require providers to proactively design quality improvement into each program at the outset, monitor data (indicators, measures and reports of staff/residents/families), determine root causes of problems, develop and implement plans that affect system improvement, and monitor the success of this systematic approach to improving quality.

At § 485.536, we propose to require that every REH develop, implement, and maintain an effective, ongoing, REH-wide, data-driven QAPI program. This requirement would ensure that the REH systematically reviews its operating systems and processes of care to identify and implement opportunities to deliver effective care to its patients focusing on improving health outcomes and preventing and reducing medical errors.

In the development of the proposed requirements for the REH QAPI program, we reviewed the CAH QAPI requirements at § 485.641, which we note are also closely aligned with the hospital QAPI requirements at § 482.21. We also took into account the comments on the REH RFI and input from other interested parties who requested that CMS consider the clinical and administrative limitations that rural providers experience and, where appropriate, we have proposed requirements that minimize burden while maintaining the ability of the REH to proactively maximize quality improvement activities and programs.

The proposed QAPI program contains the following five parts: (a) Program and scope; (b) Program data collection and analysis; (c) Program activities; (d) Executive responsibilities; and (e) Unified and integrated QAPI program for an REH in a multi-hospital system.

Similar to the program scope standard for hospitals at § 482.21(a)(1) and (2), at § 485.536(a)(1), we propose to require the REH to have an ongoing QAPI program that reflects improvement in quality indicators related to health outcomes and reductions in medical errors. In proposed paragraph § 485.536(a)(2) we would require REHs to measure, analyze, and track these quality indicators. At § 485.536(b), we propose to mirror the program data collection and analysis standard for CAHs at § 485.641(b) and require that the REH's QAPI program incorporate quality indicator data including patient care data, quality measures data, and other relevant data in order to attain quality improvement.

Similar to the program activities standard for hospitals at § 482.21(c), at § 485.536(c)(1), we propose to require the REH to set priorities for its performance improvement activities and that these activities are focused on high-risk, high-volume, or problem-prone areas. We also propose to require the REH to consider the incidence, prevalence, and severity of problems in those identified areas and that the set priority areas affect health outcomes, patient safety, and quality of care. At § 485.536(c)(2) and (3), we propose to require the REH's performance improvement activities to track medical errors and adverse events, analyze their cause, and implement preventive actions. We would expect the REH to conduct analyses at regular intervals to track performance and ensure that improvements are sustained.

We propose at § 485.536(d), similar to the standard for executive responsibilities for hospitals at § 482.21(e) that the responsibilities for the REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials include ensuring that the QAPI program is implemented and maintained, properly evaluated, and appropriately resourced.

Lastly, consistent with the standard included at § 482.21(f) in the hospital CoPs for QAPI programs, we are proposing at § 485.536(e) to allow REHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program if in accordance with all applicable state and local laws. Specifically, we propose to specify that the system's governing body would be responsible and accountable for ensuring that each of its separately certified REHs met the proposed QAPI program requirements. We expect this allowance, if finalized, would be beneficial to REHs that may lack time, resources or staff to implement an REH-specific QAPI program. The REH would be able to benefit from the resources and expertise of a multi-hospital system in implementing their QAPI program, as well as potentially reducing the time and labor investments required to enact and maintain the program.

We are interested in input from the public regarding possible unintended consequences that could occur as a result of allowing REHs to participate in a unified and integrated QAPI program. We are interested in feedback regarding how the integrated health system's governing body will ensure that they consider the REH's unique circumstances and any significant differences in patient populations and services offered at the REH. We also seek comments regarding how the integrated health system's governing body would ensure that an REH participating in a unified and integrated QAPI program provided the appropriate level of care to patients being treated in the REH, including being appropriately transferred to another facility when necessary.

19. Condition of Participation: Agreements (Proposed § 485.538)

Section 1861(kkk)(2)(C) of the Act, as added by the CAA, requires an REH to have in effect a transfer agreement with a level I or level II trauma center. In accordance with section 1861(kkk)(2)(C) of the Act, at § 485.538 we propose to require that REHs must have in effect an agreement with at least one Medicare-certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. We would require that the level I or level II trauma center meets certain licensure requirements including being licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the state. It is also acceptable for the level I or II trauma center to be located in a state other than the state where the REH is located. In addition, we propose to require that the level I or level II trauma center must also be licensed or designated by the state or local government authority as level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

We received several comments to the REH RFI regarding transfer agreements between REHs and hospitals that are not designated as a level I or II trauma center. Specifically, commenters stated that due to distance, or the possibility that level I or level II trauma centers may not have available beds, many rural CAHs currently transfer patients to level III or level IV trauma centers based on the patient's specific needs. Commenters requested that CMS allow these facilities to retain these

(HAIs). HAI Data. *https://www.cdc.gov/hai/data/index.html.*

agreements, should they convert to REHs. We would expect REHs to comply with the CoP detailed at § 485.538 and to have a transfer agreement in place with a level I or II trauma center. However, we do not believe that the statute precludes an REH from also having a transfer agreement with a hospital that is not designated as a level I or II trauma center. An REH may have pre-existing relationships with hospitals that are not designated as level I or level II trauma centers. In these instances, the proposed requirement would not preclude them from maintaining those relationships and leveraging resources and capacity that may be available to deliver care that is beyond the scope of care delivered at the REH.

We note that section 125(b)(2) of the CAA also amended subparagraphs (I) and (N) of section 1866(a)(1) of the Act, to apply the Emergency Medical Treatment and Labor Act (EMTALA) requirements under section 1867 of the Act, to REHs. One commenter on the REH RFI recommended EMTALA waivers for REHs to divert patients to other hospitals if they require a higher level of care than the REH is able to provide. However, the statutory requirements for REHs do not allow an EMTALA waiver.

20. Condition of Participation: Medical Records (Proposed § 485.540)

The maintenance of a medical records system is a longstanding requirement in both the hospital and CAH CoPs. In the development of proposed requirements for medical records for REHs, we reviewed the CoPs for medical records for CAHs established at § 485.638, including the requirements finalized in the May 2020 final rule, ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access'' (85 FR 25510 through 25585), focused on electronic patient event notifications of a patient's admission, discharge, and/or transfer to another health care facility or to another community provider. We also considered the comments from the REH RFI that encouraged CMS to closely align the CoPs for REHs with currently established requirements for CAHs. After reviewing the CoPs for medical records for CAHs at § 485.638, we believe that the requirements established for medical records for CAHs are also appropriate for REHs. We also would expect that many facilities that may elect to convert to an REH would presently have these systems in place, which may minimize administrative burden. Therefore, at § 485.540(a), we propose to require that the REH must maintain a medical records system in accordance with written policies and procedures, that the records must be legible, complete, accurately documented, readily accessible, and systematically organized and that a designated member of the professional staff is responsible for maintaining the records. We also propose to require that for each patient receiving health care services, the REH maintains a record that includes, as applicable, identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient. We propose that the record requirements include reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings and all orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics or progress notes describing the patient's response to treatment. Lastly, we propose that the record include dated signatures of the doctor of medicine or osteopathy or other health care professional.

At § 485.540(b) and (c), we propose to require the REH to maintain the confidentiality of record information and to ensure records are retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

Lastly, at § 485.540(d), we propose a standard for electronic notifications if the REH utilizes an electronic medical records system or other electronic administrative system that conforms with the content exchange standard at 45 CFR 170.205(d)(2). This requirement is intended to limit the applicability of this CoP to those REHs which currently possess an EHR or other electronic administrative system with the technical capacity to generate information for electronic patient event notifications. As discussed in the CMS Interoperability and Patient Access final rule (85 FR 25585), electronic patient event notifications can be an effective tool for improving care coordination across settings, especially for patients at discharge. We propose to require the REH to demonstrate that the system's notification capacity is fully operational and sends notifications with at least specified patient information, as appropriate, and facilitates the exchange of health information when the patient is registered, discharged, or transferred from the REH's emergency department. Finally, we propose to require that the REH make a reasonable effort to ensure that the system sends the notifications to certain recipients including, the patient's applicable post-acute care and primary care services providers.

21. Condition of Participation: Emergency Preparedness (Proposed § 485.542)

Over the past several years, the U.S. has been challenged by several natural and man-made disasters. As a result of the September 11, 2001 terrorist attacks, the subsequent anthrax attacks, the catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, tornadoes and floods in the spring of 2011, the 2009 H1N1 influenza pandemic, and Hurricane Sandy in 2012 and most recently, the COVID–19 pandemic, readiness for public health emergencies has been put on the national agenda. On September 16, 2016, we published a final rule, ''Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers'' (81 FR 63860), to establish emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to plan adequately for both natural and man-made disasters, and coordinate with Federal, state, tribal, regional, and local emergency preparedness systems. Disasters can disrupt the health care environment and change the demand for health care services. This makes it essential that health care providers and suppliers ensure that emergency management is integrated into their daily functions and values.

Thus, we are proposing emergency preparedness requirements to establish a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness for REHs that aligns with the existing emergency preparedness standards for Medicare and Medicaid participating providers and suppliers. These proposed requirements mirror the existing CAH emergency preparedness requirements. The emergency preparedness requirements for all Medicare-participating providers and suppliers are consistent, with some differences based on the provider type (such as inpatient versus outpatient).

Consistent with the standards for all Medicare and Medicaid participating providers and suppliers, we propose to require REHs to comply with all

applicable Federal, state, and local emergency preparedness requirements. In addition, we propose to require that the REH establish and maintain an emergency preparedness program that addresses four core elements that we believe are central to an effective emergency preparedness system. The four elements are: (1) risk assessment and planning; (2) policies and procedures; (3) communication; and (4) training and testing.

At § 485.542(a), we propose to require that REHs develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. Specifically, we propose to require that the REHs emergency plan must—(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, (2) Include strategies for addressing emergency events identified by the risk assessment, (3) Address the patient population, including, but not limited to, the type of services the REH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans, and (4) Include a process for cooperation and collaboration with local, tribal, regional, state, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

At § 485.542(b), we propose to require REHs to develop and implement policies and procedures, that are based on the emergency plan, risk assessment, and communication plan, and must be reviewed and updated at least every 2 years. Specifically, we propose to require that the policies and procedures must address the following:

- Provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, including, but not limited to food, water, medical and pharmaceutical supplies, other sources of energy to maintain temperatures, emergency lighting, fire detection and sewage and waste disposal;
- A system to track the location of on-duty staff and sheltered patients in the REH's care during an emergency, and if staff are being relocated the REH must document the specific name and location of the receiving facility or other location;
- Safe evacuation from the REH, to include consideration of care and treatment needs of the evacuees, staff responsibilities and transportation and identification of the evacuation location(s);
- A means to shelter in place for any patients, staff and volunteers that remain at the REH;
- A system of medical documentation that preserves patient information, protects confidentiality of all patient information and secures and maintains the availability of the records;
- The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of state and federally designated health care professionals to address surge needs during an emergency; and
- The role of the REH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

We believe that small and rural REHs would be able to develop an appropriate emergency preparedness plan and develop policies and procedures in accordance with our proposed requirements with the assistance of resources in their state and local community guidance.

At § 485.542(c), we propose to require REHs to develop and maintain an emergency preparedness communication plan that complies with both Federal and state law and must be reviewed and updated at least every 2 years. The communication plan must include the following:

- Names and contact information for staff, entities providing services under agreement, patients' physicians and volunteers;
- Contact information for Federal, state, tribal, regional, and local emergency preparedness staff and other sources of assistance;
- Primary and alternate means for communicating with the REH's staff and Federal, state, tribal, regional, and local emergency management agencies;
- A method for sharing information and medical documentation for patients under the REH's care, as necessary, with other health care providers to maintain the continuity of care;
- A means, in the event of an evacuation, to release patient information;
- A means of providing information about the general condition and location of patients under the facility's care; and
- A means of providing information about the REH's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

We would expect patient care to be well-coordinated within the REH, across healthcare providers, and with state and local public health departments and emergency management agencies and systems to protect patient health and safety in the event of a disaster. The following link is to FEMA's comprehensive preparedness guide to develop and maintain emergency operations plans: *https://www.fema.gov/sites/default/files/2020-05/CPG_101_V2_30NOV2010_FINAL_508.pdf.* During an emergency, it is critical that REHs, have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the facilities and to ensure that these functions are carried out in a safe and effective manner.

At § 485.542(d), we propose to require the REH to develop and maintain an emergency preparedness training and testing program that is based on the emergency plan, policies and procedures and communication plan, and reviewed and updated at least every 2 years. We propose to require at § 485.542(d)(1) that the training program include initial training in the emergency preparedness policies and procedures for new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles. We also propose to require the facility to provide emergency preparedness training at least every 2 years, maintain documentation of all emergency preparedness training, demonstrate staff knowledge of emergency procedures, and if the emergency preparedness policies and procedures are significantly updated, conduct training on the updated policies and procedures. The Homeland Security Exercise and Evaluation Program (HSEEP), developed by FEMA, includes a section on the establishment of a Training and Exercise Planning Workshop (TEPW). The TEPW section provides guidance to organizations in conducting an annual TEPW and developing a Multi-year Training and Exercise Plan (TEP) in line with the HSEEP (*https://www.fema.gov/sites/default/files/2020-04/Homeland-Security-Exercise-and-Evaluation-Program-Doctrine-2020-Revision-2-2-25.pdf*).

We propose at § 485.542(d)(2) to require that the REH conduct exercises to test the emergency plan at least annually. Specifically, we propose to require that the REH conduct two testing exercises, a full-scale or functional exercise and an additional exercise of its choice, every 2 years. First, the REH must participate in a full-scale exercise that is community-based. When a community-based exercise is not accessible, we propose that the REH

must conduct a facility-based functional exercise or if the REH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the REH is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event. Second, the REH must conduct an additional exercise, opposite the year the full-scale or functional exercise is conducted, that may include, but is not limited to a second full-scale exercise that is community-based, or an individual, facility-based functional exercise, a mock disaster drill, or a tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. Lastly, we propose to require that the REH must analyze its response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the REH's emergency plan, as needed.

We propose at § 485.625(e)(1)(i) that REHs must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the NFPA®. In addition to the emergency power system inspection and testing requirements found in NFPA® 99 and NFPA® 110 and NFPA® 101, we proposed that REHs test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the REH anticipates it will require during an emergency.

Finally, at § 485.542(f), we propose to specify that if an REH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the REH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, we propose that the unified and integrated emergency preparedness program must demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program and be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

In addition, we propose that each separately certified REH in the system must be capable of actively using the unified and integrated emergency preparedness program and is in compliance. We also propose that the unified and integrated emergency preparedness program must include a unified and integrated emergency plan that is based on a documented community-based risk assessment, utilizing an all-hazards approach and a documented individual facility-based risk assessment for each separately certified REH within the health system, utilizing an all-hazards approach. Lastly, we propose that the unified and integrated emergency preparedness program must have integrated policies and procedures, a coordinated communication plan, and training and testing programs.

22. Condition of Participation: Physical Environment (Proposed § 485.544)

The LSC is a compilation of fire safety requirements for new and existing buildings, and is updated and published every 3 years by the National Fire Protection Association (NFPA), a private, nonprofit organization dedicated to reducing loss of life due to fire. The Medicare and Medicaid regulations have historically incorporated these requirements by reference, along with Secretarial waiver authority. The statutory basis for incorporating NFPA's LSC into the regulations we apply to Medicare and, as applicable, Medicaid providers and suppliers is the Secretary's facility-specific authority to stipulate health and safety regulations for each type of Medicare and (if applicable) Medicaid-participating facility. For REHs, that statutory authority is set out at new section 1861(kkk)(2)(D)(v) of the Act. The following provisions we have proposed are similar to the Hospital, CAH, and ASC LSC and Health Care Facilities Code requirements.

The 2012 Edition of the Life Safety Code

As stated previously, the LSC is a compilation of fire safety requirements for new and existing buildings, and is updated and published every 3 years by the NFPA. The NFPA 101®2012 edition of the LSC (including the technical interim amendments (TIAs)) provides minimum requirements, with due regard to function, for the design, operation and maintenance of buildings and structures for safety to life from fire. Its provisions also aid life safety in similar emergencies. The NFPA 99® 2012 edition of the Health Care Facilities Code (including the TIAs) provides minimum requirements for health care facilities for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and appliances, including other hazards associated with the primary hazards.

We review each new edition of the NFPA 101 and NFPA 99 every 3 years to see if there are any significant provisions that we need to adopt, but there is no requirement to use the most recent version. We will continue to review these documents every 3 years to see if there are relevant or updated provisions that we need to adopt. The 2012 edition of the LSC includes provisions that we believe are vital to the health and safety of all patients and staff. Our intention is to ensure that patients and staff continue to experience the highest degree of fire safety possible. All Medicare and Medicaid participating providers and suppliers are currently subject to the requirements of the 2012 edition of the LSC and the 2012 edition of the Health Care Facilities Code as adopted by CMS.

Therefore, in this rule we propose to incorporate by reference the NFPA 101® 2012 edition of the LSC, issued August 11, 2011, and all Technical Interim Amendments issued (TIA) April 16, 2014; and the NFPA 99®2012 edition of the Health Care Facilities Code, issued August 11, 2011, and all TIA issued prior to April 16, 2014. (1) NFPA 101, LSC, 2012 edition, issued August 11, 2011; (i) TIA 12–1 to NFPA 101, issued August 11, 2011. (ii) TIA 12–2 to NFPA 101, issued October 30, 2012. (iii) TIA 12–3 to NFPA 101, issued October 22, 2013. (iv) TIA 12–4 to NFPA 101, issued October 22, 2013. (2) NFPA 99, Standards for Health Care Facilities Code of the NFPA 99, 2012 edition, issued August 11, 2011. (i) TIA 12–2 to NFPA 99, issued August 11, 2011. (ii) TIA 12–3 to NFPA 99, issued August 9, 2012. (iii) TIA 12–4 to NFPA 99, issued March 7, 2013. (iv) TIA 12–5 to NFPA 99, issued August 1, 2013. (v) TIA 12–6 to NFPA 99, issued March 3, 2014. The materials that are incorporated by reference are available to interested parties and can be inspected at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org,* 1 (617) 770–3000. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.

The 2012 Edition of the Health Care Facilities Code

The 2012 edition of the NFPA 99, ''Health Care Facilities Code,'' addresses requirements for both health care occupancies and ambulatory care occupancies and serves as a resource for

those who are responsible for protecting health care facilities from fire and associated hazards. The purpose of this Code is to provide minimum requirements for the installation, inspection, testing, maintenance, performance, and safe practices for health care facility materials, equipment and appliances. This Code is a compilation of documents that have been developed over a 40-year period by NFPA, and is intended to be used by those persons involved in the design, construction, inspection, and operation of health care facilities, and in the design, manufacture, and testing of appliances and equipment used in patient care areas of health care facilities. It provides information on subjects, for example, medical gas and vacuum systems, electrical systems, electrical equipment, and gas equipment. The NFPA 99 applies specific requirements in accordance with the results of a risk-based assessment methodology. A risk-based approach allows for the application of requirements based upon the types of treatment and services being provided to patients or residents rather than the type of facility in which they are being performed. In order to ensure the minimum level of protection afforded by NFPA 99 is applicable to all patient and resident care areas within a health care facility, we are proposing to adopt the 2012 edition of NFPA 99, with the exception of chapters 7—Information Technology and Communications Systems for Health Care Facilities; 8—Plumbing; 12—Emergency Management; and 13—Security Management.

REH Proposed Requirements

At § 485.544(a) we propose that the REH be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. Specifically, we propose that the condition of the physical plant and the overall REH environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This would include emergency power and lighting in at least all areas serviced by the emergency supply source, including but not limited to, the operating, recovery, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source the REH would be required to have battery lamps and flashlights available. In addition, we propose to require the REH to have facilities for emergency gas and water supply and a safe and sanitary environment, that is properly constructed, equipped and maintained to protect the health and safety of all patients.

At § 485.544(b), we propose that the REH be required to maintain adequate facilities for its services that includes diagnostic and therapeutic facilities that are located in a manner that ensures the safety of patients. We also would require the REH to maintain facilities, supplies, and equipment in a manner that ensures an acceptable level of safety and quality. We propose further that the facility be designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice and that there must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

At § 485.544(c), we propose that REHs meet the provisions applicable to Ambulatory Health Care Occupancies in the 2012 edition of the LSC, regardless of the number of patients the facility serves. We believe the protection provided in the Ambulatory Health Care Occupancies chapter is necessary to protect the health and safety of patients who are incapable of caring for themselves at any point in time. We propose at § 485.544(c)(2) to implement requirements related to the Secretary's waiver authority for periods deemed appropriate, which would result in unreasonable hardship, but only if the waiver will not adversely affect the health and safety of patients. We propose at § 485.544(c)(3) that the provisions of the LSC would not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients. We also propose at § 485.544(c)(4) requirements related to protection against inappropriate access for alcohol-based hand rub dispensers. At § 485.544(c)(5), we propose to require that a REH with a sprinkler system that is out of service for more than 10 hours in a 24-hour period to evacuate the building or portion of the building affected by the system outage, or establish a fire watch until the system is back in service, notwithstanding the lower standard of the 2012 LSC.

Lastly, at § 485.544(d) we propose to require REHs to comply with the 2012 edition of the NFPA 99. We propose that chapters 7, 8, 12, and 13 would not apply to REHs. We also propose to allow for waivers of these provisions under the same conditions and procedures that we currently use for waivers of applicable provisions of the LSC.

23. Condition of Participation: Skilled Nursing Facility Distinct Part Unit (Proposed § 485.546)

Section 1861(kkk)(2)(D)(vi) of the Act allows REHs to establish a unit that is a distinct part licensed as a SNF to furnish post-REH or post-hospital (in the event the services were provided at a hospital or a CAH) extended care services (or SNF services). A distinct part SNF is an area that is separately licensed and certified to provide SNF services at all times. A distinct part SNF must be physically distinguishable from the REH, must be fiscally separate for cost reporting purposes, and the beds in the certified distinct part SNF unit of an REH must meet the requirements applicable to distinct part SNFs at 42 CFR part 483, subpart B. Medicare payment for SNF services furnished in these distinct part SNFs of an REH would be under the SNF prospective payment system as required under section 1834(x)(4) of the Act. We note that a distinct part SNF of an REH is not subject to the REH's length of stay limits of less than an annual per patient average of 24 hours.

According to a policy brief published by RUPRI Center for Rural Health Policy Analysis, there were 472 nursing home closures between 2008 and 2018 in nonmetropolitan counties in the U.S.[28] The policy brief noted that 10.1 percent of the country's nonmetropolitan counties had no nursing homes. Given the closures of rural nursing homes and the lack of nursing homes in rural communities, residents living in rural areas may not have adequate access to SNF services. The provision of these services in distinct part units of REHs may help address this access issue.

We highlight that a distinct part SNF unit is not the same as a CAH or hospital utilizing swing-beds. CAHs and hospitals may provide swing-bed services, allowing them to use their beds for acute inpatient care or for post-hospital or CAH SNF care. These facilities must be certified by CMS to provide swing-bed services. CAHs or hospitals utilizing swing-beds are not required to have their swing-beds in a special unit or area within the facility.

To implement that statutory provision allowing REHs to establish distinct part SNFs, we are proposing at § 485.546 to require REHs choosing to establish such a distinct part unit to meet the

[28] RUPRI Center for Rural Health Policy Analysis. (2021). Trends in Nursing Home Closures in Nonmetropolitan and Metropolitan Counties in the United States, 2008–2018. *https://rupri.public-health.uiowa.edu/publications/policybriefs/2021/Rural%20NH%20Closure.pdf.*

requirements for long-term care facilities at 42 CFR part 483, subpart B.

B. Proposed Changes for Critical Access Hospital Conditions of Participation

1. Condition of Participation: Status and Location (§ 485.610(c))

a. Adding the Definition of ''Primary Roads''

Generally, a CAH must meet certain criteria for designation, as outlined in section 1820(c)(2)(B) of the Act. These criteria specify certain ''distance requirements'' relative to other hospitals or CAHs, and specifically require that a CAH be (1) ''located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital'' or (2) ''certified before January 1, 2006, by the State as being a necessary provider of health care services to residents in the area''. The current regulatory requirement at § 485.610(c) sets forth the distance requirements for CAHs relative to other CAHs and hospitals, and specific definitions as related to the distance requirements are found in the SOM, Chapter 2, Section 2256A.

In 2013, the HHS OIG released a report entitled *Most Critical Access Hospitals Would Not Meet the Location Requirements If Required to Re-Enroll in Medicare* (OEI–05–12–00080) which found that approximately 63 percent of CAHs would not meet the distance requirement if required to re-enroll in Medicare. The report also found that CMS does not have the authority to decertify most of these CAHs based on failure to meet the distance requirement, as a majority of these CAHs are ''necessary provider'' CAHs and therefore exempt from the distance requirement as noted in section 1820(h)(3) of the Act. The report also included a recommendation for CMS to ensure that CAHs' compliance with the location-related CoPs is periodically reassessed. In response, CMS began evaluating its policies concerning the definitions of several key concepts used in enforcing the CAH regulations at § 485.610, which are further described in the SOM, Chapter 2, Section 2256A for enforcement of the distance requirements. The COVID–19 PHE put a hold on CAH certifications, and CMS has used this opportunity to work with interested parties to continue to review how it applies the distance requirements for CAH eligibility. In this proposed rule, CMS outlines how it will apply the CAH distance requirements as a result of its review. We recognize the impact of these criteria on rural communities and we aim to minimize any disruption to CAHs based on these requirements.

The distance requirements are uniquely important to CAH designations, as they must continually be met to maintain status as a CAH, by statutory design. As such, CMS anticipates certain facilities may lose or gain eligibility for CAH designation depending on the locations of hospitals and CAHs established within relevant distance of the CAH. Thus, CMS must continually verify the CAH distance requirements periodically to ensure that they are still met. CMS generally recertifies the distance requirements of CAHs every three years or upon a change of ownership as a component of initial certification or a recertification. If there is a change in distance and location that does not meet the requirements, CMS notifies the provider of its options for continued enrollment in the Medicare program.

CMS publishes guidance related to the distance requirements in the SOM, Chapter 2, Section 2256A. One of the distance criteria, as described in section 1820(c)(2)(B)(i) of the Act and set forth in § 485. 610(c), requires CMS to determine what constitutes a secondary road, and by extension a primary road. In 2015, CMS refined the definition of ''primary road'' in the SOM. The purpose of this refinement was, first, to make the definition of what constitutes a ''primary road'' more consistent across regions of the U.S., and, second, to make measuring the distances between facilities more consistent. It was not anticipated that this refinement in the definition of primary road would have any significant impact on the eligibility of existing CAHs to maintain their certification, but certain providers and interested parties raised concern in anticipation of their re-certification. Specifically, they were concerned about certain aspects of the 2015 refinements from the previous SOM update that would no longer afford them eligibility as a CAH, even though the existing CAH did not change location and there were no other CAHs or hospitals that moved within a relevant distance. Thus, CMS is further refining and codifying the definition to offer maximum flexibility to providers in meeting these distance criteria.

Presently, primary roads are defined as any U.S. highway, including; (1) any road in the National Highway System, as codified at 23 U.S.C. 103(b); or (2) in the Interstate System, as defined at 23 U.S.C. 103(c); or (3) which is a US-Numbered Highway (also called ''US Routes'' or ''US Highways'') as designated by the American Association of the State Highway and Transportation Officials (AASHTO), regardless of whether it is also part of the National Highway System. Currently, there is no regulatory language that references primary roads or outlines the definition of this term.

We propose to incorporate the definition of primary road in the CAH distance requirement regulations, both as part of the 35-mile drive requirement, and as applicable through the secondary roads definition for the 15-mile drive requirement. Specifically, we propose to revise § 485.610(c) to clarify that the location distance for a CAH is one for more than a 35-mile drive *on* primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH. In addition, at § 485.610(c)(2), we propose to specify that primary road of travel for determining the driving distance of a CAH and its proximity to other providers as a numbered Federal highway, including interstates, intrastates, expressways or any other numbered Federal highway; or a numbered state highway with two or more lanes each way. We are also soliciting comments regarding the description of a numbered Federal highway in this proposed definition. Specifically, we are interested in feedback on whether the definition of primary roads should include numbered Federal highways with two or more lanes, similar to the description of numbered state highways, and exclude numbered Federal highways with only one lane in each direction.

We believe that codifying the definition of primary roads in the regulations will provide clarity and consistency regarding the distance requirements.

Furthermore, if finalized, to support these proposed regulatory changes we are planning to establish a centralized, data-driven review procedure that focuses on hospitals being certified in proximity to a CAH, rather than focusing specifically on road classifications. CMS would review all hospitals and CAHs within a 50-mile radius of the CAH during each review of eligibility, and then subsequently on a 3-year cycle. Following the initial review of distance and location, further investigations would focus primarily on expanded healthcare capacity and access to care within the 35-mile radius of the CAH being examined and less on the actual roadway designations used in making the calculations. Those CAHs with no new hospitals within 50 miles would be immediately recertified. Those CAHs with new hospitals within 50 miles will receive additional review

based on the distance from the new hospital and the definitions for Primary Roads and Mountainous Terrain. To facilitate this review, the CAH Distance Analysis Committee and the CMS Survey Operations Group (SOG) Locations will utilize the geocoding of hospitals to identify those CAHs that are located within 50 miles of another certified hospital. Those CAHs that do not meet the regulatory distance and location requirements at the time of review would be identified as non-compliant and may face enforcement actions. We believe this change would help surveyors to make evidence-based and objective determinations of continued CAH eligibility. We expect the new distance review procedure, coupled with regulatory clarity on the proposed primary roads definition, would provide greater consistency in evaluating if CAHs meet the statutory 35 or 15-mile distance requirements from other acute care hospitals and CAHs as well greater adherence to statutory language by ensuring that CAHs operate under the CAH designation until, or unless, a hospital moves within 35 miles or 15 miles of the existing CAH.

2. Condition of Participation: Patient's Rights (§ 485.614)

We believe that it is imperative for patients to have the ability to exercise certain rights and protections while seeking and receiving necessary care and services at a CAH. Ensuring that patients and family members are aware of their rights and how to exercise them are vital components of improving overall CAH quality and patient satisfaction. We believe that having patient's rights requirements for CAHs creates transparency between the provider and patient. In addition, adding patient's rights requirements for CAHs is consistent with other providers and suppliers similar to CAHs, including those proposed in this rule for REHs. As previously mentioned, behavioral health is very important in the treatment and safety of patients and staff. Behavioral health is a challenge in rural areas, due to the accessibility, affordability, acceptability and availability of these services, therefore we believe it is important to have policies and procedures in place for CAHs and REHs in the event of a mental health crisis and the need for the use of restraints and seclusions.

We have received feedback from interested parties stating that CAHs should have patient rights requirements in place to protect the patient. Therefore, we are mirroring these proposed requirements for CAHs after the hospital patient's rights requirements found at § 482.13. However, we note that some of the provisions in this section for CAHs, and also for REHs (as discussed earlier) have requirements that are less prescriptive than those for hospitals because are proposing to allow for these providers to develop policies and procedures based on the scope of services they provide and patient populations they serve.

For example, we believe that CAHs will have a lower volume of patients than hospitals and the use of restraints and seclusion would not be as frequent as other providers. CAHs do not currently have any patient rights CoPs so our proposed requirements aim to increase accountability and provide patient protections in the event restraints and seclusion are used. We are specifically soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Specifically, we propose to establish a CoP for patient's rights at § 485.614 that would set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. This would include proposed requirements for the CAH to inform patients of and exercise their rights; address privacy and safety; adhere to the confidentiality of patient records; responsibilities for the use of restraint and seclusion; and adherence to patient visitation rights.

Notice of Rights

At § 485.614(a), we propose that a CAH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. This includes a proposal to require the CAH to establish a process for the oversight and prompt resolution of patient grievances and for informing each patient whom to contact to file a grievance.

Exercise of Rights

At § 485.614(b), we propose to specify those rights a patient has regarding their medical care, which includes the right to participate in the development and implementation of their plan of care, to make informed decisions regarding their care, to be fully informed about such care, and the right to request or refuse treatment, and finally the right to have a family member or representative of their choice and their own physician notified promptly of their admission to the hospital. We note that this right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. In addition, we propose to specify that the patient also has the right to formulate advance directives and to have CAH staff and practitioners who provide care in the CAH comply with these directives.

Privacy, Safety, and Confidentiality of Patient Records

At § 485.614(c), we propose to specify that the patient has the right to personal privacy, receive care in a safe setting, and be free from all forms of abuse or harassment. At § 485.614(d), we propose to specify that patients have the right to the confidentiality of their medical records and the right to access their medical records. When requested, we propose that the CAH must provide the patients with their records in a form and format requested by the requestor and within a reasonable timeframe, as not to frustrate the legitimate efforts of individuals to gain access to their own medical records.

Use of Restraints and Seclusion

At § 485.614(e), we propose those patient's rights relating to the use of restraints and seclusion. We are proposing requirements that are less burdensome than those existing restraint and seclusion requirements for hospitals because given the level of services provided by CAHs and their patient volume, we expect the likelihood of their need to utilize restraints and seclusion to be relatively low.

Specifically, we propose to specify that all patients have the right to be free from physical or mental abuse, and from corporal punishment and from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. We propose that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time. We propose to define restraint as any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. A restraint does not include devices, such as orthopedically

prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). We propose to define seclusion as the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

At § 485.614(e)(2), we propose to require that the restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm, and at § 485.614(e)(3) that the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm. At § 485.614(e)(4) we propose that the CAH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. These proposed requirements would allow for the CAH to use restraints and seclusion in the event that it is necessary and as a last resort to respond to immediate safety concerns, but lessens the burden and allows for more flexibility than the current hospital CoPs. We believe that allowing the CAH the flexibility to develop their own policies and procedures for restraints and seclusion based on the scope of services they provide is necessary given their patient volumes, populations, and access to resources. The policies and procedures that are developed need to be consistent with current standards of practice. As noted, we are soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Staff Training Requirements for the Use of Restraints or Seclusion

The following staff training requirements are not as prescriptive as the existing hospital requirements, and we are proposing these same requirements for REHs in this rule. At § 485.614(f) we propose to establish staff training requirements for the use of restraints and seclusion. Specifically, we propose that the patient has the right to safe implementation of restraint or seclusion by trained staff. We propose that the CAH must provide competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion. To ensure that the use of restraint and seclusion for patients receiving services in a CAH is respectful of, and responsive to, individual patient preferences, needs and values, we propose to require that the training be patient-centered. Additionally, to ensure that staff are educated and trained on using the least restrictive intervention necessary for the safety of the patients and CAH staff, we propose at § 485.614(f)(2) to require that the CAH train their staff in alternatives to the use of restraint and seclusion. For example, we believe that staff should have trauma-informed knowledge competencies and be aware of effective de-escalation techniques that can be used to avoid the use of restraint and seclusion so not to trigger any previous mental health issues because of the use of restraints and seclusion. Trained peer workers (people who share similar experiences of being diagnosed with mental health conditions, substance use disorders, or both) and CHWs may also serve a useful role in assisting patients and other staff. This could include helping to monitor use of restraint and seclusion, deescalating interactions with patients and contributing to a positive and supportive environment for patients, family members, and CAH staff. CAHs are encouraged to consider the use of peer workers and CHWs in their staffing plans. For further information, please see the 2007 guidance on use of peers in the Medicaid program (*https://www.medicaid.gov/federal-policy-guidance/downloads/SMD081507A.pdf*) and resources from the Substance Abuse and Mental Health Services Administration (*https://www.samhsa.gov/brss-tacs/recovery-support-tools/peers*). In addition, facilities are encouraged to consider any nutritional needs while a patient is restrained, such as a need to provide food and water.

Death Reporting Requirements

The following requirements are similar to the hospital requirements at § 482.13. At § 485.614(g), we propose to establish requirements that CAHs must follow when reporting deaths associated with the use of seclusion or restraint. Specifically, we propose to require that the CAH must report to CMS, by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day the following information— (1) Each death that occurs while a patient is in restraint or seclusion; (2) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; (3) Each death known to the CAH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. We note that ''reasonable to assume'' in this context would include, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

For instances when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the CAH staff must record in an internal log or other system, the following information—(1) Any death that occurs while a patient is in such restraints; (2) Any death that occurs within 24 hours after a patient has been removed from such restraints. Furthermore, we propose that staff must also document in the patient's medical record the date and time the death was reported to CMS or recorded in the internal log or other system. Also, for instances when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s),we propose to require that entries into the internal log or other system must be documented no later than seven days after the date of death of the patient, include the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es), and to be made available in either written or electronic form to CMS immediately upon request.

Patient Visitation Rights

We propose to redesignate § 485.635(f) as § 485.614(h). At § 485.614(h), we propose to establish requirements related to a patient's visitation rights. Specifically, we propose to require that a CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH

may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights, inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time, not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability, and ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

3. Condition of Participation: Staffing and Staff Responsibilities (§ 485.631)

Unified and Integrated Medical Staff for a CAH in a Multi-Facility System

In alignment the current standards for hospitals, we are proposing at § 485.631(e) to allow for either a unique medical staff for each CAH or for a unified and integrated medical staff shared by multiple hospitals, CAHs, and REHs within a health care system. We propose to hold a CAH responsible for showing that it actively addresses its use of a system unified and integrated medical staff model. We are also proposing to require that the medical staff members holding privileges at each separately certified CAH in the system have voted either to participate in a unified and integrated medical staff structure or to opt out of such a structure, and to maintain a CAH-specific separate and distinct medical staff for their respective CAH.

In addition, we propose to require that the unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified CAH (that is, all medical staff members who hold specific privileges to practice at that CAH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their CAH. We propose that the unified and integrated medical staff must be established in a manner that takes into account each CAH's unique circumstances, and any significant differences in patient populations and services offered in each CAH. Lastly, we propose that the unified and integrated medical staff give due consideration to the needs and concerns of members of the medical staff, regardless of practice or location, and the CAH has mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

In proposing this allowance for CAHs in the requirements here, we considered this past rulemaking experience with those multi-hospital systems using the single governing body and unified and integrated medical staff model for separately certified hospitals within their systems, as well as our decision to also propose this flexibility for REHs (as discussed in section II.A.7. of this rule), and applied the same model to CAHs within single governing body systems. As we continue to do with hospitals, we believe that it is in the best interest of CAHs, medical staff members, and patients to propose this requirement allowing for the use of a unified and integrated medical staff for a multi-facility system and its member CAHs, in order to enable the medical staff of each CAH to voluntarily integrate itself into a larger system medical staff. We welcome comments on the proposed applicability of these changes for CAHs.

4. Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs (§ 485.640)

Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs for a CAH in a Multi-Facility System

Similar to a standard in the hospital CoPs, we propose a standard at § 485.649(h) for CAHs that would allow for the governing body of a CAH that is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a single system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, to elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities, including any CAHs, after determining that such a decision is in accordance with all applicable state and local laws. The system's single governing body would be responsible for ensuring that each of its separately certified CAHs meets all of the requirements of this section. We note that each separately certified CAH subject to the system's single governing body would need to demonstrate that the unified and integrated infection prevention and control and antibiotic stewardship programs:

- Are established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH;
- Establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration; and
- Have mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

The CAH would also need to demonstrate that it has designated a qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship at the CAH to be responsible for:

- Communicating with the system's unified infection prevention and control and antibiotic stewardship programs;
- Implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs; and
- Providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to CAH staff.

5. Condition of Participation: Quality Assessment and Performance Improvement Program (§ 485.641)

Unified and Integrated QAPI Program for a CAH in a Multi-Facility System

Consistent with the standard included at § 482.21(f) in the hospital CoPs for QAPI programs, we are proposing at § 485.641(f) to allow CAHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program after determining that such a decision is in accordance with all applicable state and local laws. Specifically, we propose to specify that the system's governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets the proposed QAPI program requirements. We expect this allowance, if finalized, would be beneficial to CAHs that may lack time, resources, or staff to implement a QAPI program. The CAH would be able to

benefit from the resources and expertise of a multi-hospital system in implementing their QAPI program, as well as potentially reducing the time and labor investments required to enact and maintain the program.

We are interested in input from the public regarding unintended consequences that could occur as a result of allowing CAHs to participate in a unified and integrated QAPI program. We are interested in feedback regarding how the integrated health system's governing body will ensure that they take into account the CAH's unique circumstances and any significant differences in patient populations and services offered at the CAH. We also seek comments regarding how the integrated health system's governing body will ensure that a CAH participating in a unified and integrated QAPI program provides the appropriate level of care to patients being treated in the CAH, including being appropriately transferred to another facility when necessary.

C. Conforming Amendments and Technical Corrections

1. Technical Correction to § 485.635(b)(2)

We are proposing to make a technical correction to the laboratory services CAH CoP at § 485.635(b)(2). In the September 1, 1994, final rule entitled ''Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates'' (59 FR 45403), we revised the CAH laboratory services requirement to require the CAH laboratory services to meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). We inadvertently included an error in the referenced Public Health Service Act standard. The referenced standard at § 485.635(b)(2) should read, ''. . .353 of the Public Health Service Act (42 U.S.C. 263a).''

2. Conforming Amendments §§ 489.2(b) and 489.24(b)

The provider agreement and supplier approval requirements for Medicare-participating providers and suppliers are located at 42 CFR part 489. Section 489.2 sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare, with the providers that are subject to the provisions of this part listed at § 489.2(b). We are proposing to add REHs to the list of applicable providers at § 489.2(b) and therefore require REHs to adhere to the requirements for submittal and acceptance of provider agreements under Medicare as defined by § 489.3.

The requirements at 42 CFR part 489 also set forth requirements for Medicare hospitals in emergency cases. These provisions apply to hospitals that have emergency departments. Under this section, a hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act. The CAA amends Section 1867(e)(5) of the Act by including REHs, as defined in 1861(kkk)(2), as hospitals that have emergency departments. As a result, we are proposing to add REHs to the definitions at § 489.24(b) for Medicare hospitals in emergency cases under the hospital definition and to the definition of a participation hospital.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-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.

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):

A. Factors Influencing ICR Burden Estimates

Under this proposed rule, an REH's ICR may differ from that of a hospital or CAH, given that REHs would be providers of outpatient services and would not provide inpatient services. We based the ICRs for REHs on the ICRs for hospitals and CAHs in some cases because, in accordance with section 1861(kkk) of the Act, REHs must convert from either a rural hospital with not more than 50 beds or a CAH. In the discussion that follows, we rely heavily on the study of the North Carolina Rural Health Research Program's (NC RHRP's) study titled, ''How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?'' [29] This study examined data on existing rural hospitals (Medicare-funded through both the prospective payment system and cost-reimbursements to CAHs) to determine how many might meet three key criteria (1) three years of negative total financial margins; (2) average daily census of acute and swing beds of less than three persons; and (3) net patient revenue of less than $20 million annually. The study further assumed that all the statutory and regulatory requirements would be met by every REH. The NC RHRP study assumes that hospitals and CAHs meeting the necessary requirements would apply for election of coverage under the new REH program. The study did not address the potential caseload, cost, or revenue changes from electing conversion and implicitly assumed that the net effects would be positive.

We note that another study from consulting firm CLA also examines the number of facilities likely to convert to REHs titled, ''A Path Forward: CLA's Simulations on Rural Emergency Hospital Designation.'' [30] The CLA study estimated that between 11 and 600 CAHs would benefit from conversion to REH status—based on estimated REH reimbursement and several financial assumptions (estimated average facility payment, estimated outpatient fee schedule payment, estimated average skilled nursing facility payment rates by state, presence or loss of swing bed payments, and continuance or cessation of 340B eligibility) and four simulation methods. A key takeaway from both studies is that available data support a possible wide range of conversion decisions. In addition, we note that these results and the calculations on which they rely are subject to a wide range of uncertainty as illustratively shown in the CLA study's summary estimate and the NC RHRP study makes the same point in describing its central estimate set of results. In the analysis that follows, we use for simplicity of exposition the NC RHRP study results, which depend on data and calculations presented in the study at a level of detail that allows reader analysis and present our

[29] This study can be accessed here: *https://www.shepscenter.unc.edu/product/how-many-hospitals-might-convert-to-a-rural-emergency-hospital-reh/.*

[30] CLA, ''A Path Forward: CLA's Simulations on Rural Emergency Hospital Designation'', 2/8/22, at *https://www.claconnect.com/resources/articles/2022/a-path-forward-clas-simulations-on-rural-emergency-hospital-designation.*

summary estimates based on the NC RHRP study's central estimate.

In total, the NC RHRP study estimated that there are 1,673 hospitals (mostly CAHs) eligible to convert to an REH and of these, 68 would convert to REH status. The reasons why some would convert are presented in the NC RHRP study and include low levels of inpatient revenue, low levels of swing bed nursing care revenue, and negative financial margins over a period of years.

The finances of individual rural hospitals and CAHs vary widely, as do the local economic and demographic circumstances of the communities served by these facilities (for example some rural areas are gaining population even as most face declining populations). Competition from other hospitals either in the rural area or in nearby cities also varies widely, with the only certainty in forecasting REH conversion is that seemingly similar hospitals and CAHs will make widely different decisions. What the NC RHRP did, in essence, was predict that the hospitals and CAHs facing the most severe financial difficulties would be the most likely to convert.

For purposes of our analysis, we use the NC RHRP estimate of 68 conversions though acknowledge that the number of conversions could be less than or significantly greater than this estimate. In addition, when considering the PRA burden for REHs, given that the proposed CoPs align closely with existing standards, we considered both the existing burden estimates for CAHs and hospitals, as well as our ongoing experience with these provider types. We also considered that REHs would only be furnishing outpatient services, which would lessen their burden. We request comments on our estimates, particularly the conversion assumption. The final rule could utilize different estimates based on these comments.

B. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

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.[31] 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 1.

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TABLE 1: 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)	Physician	$105.22	$210
29-1141	Registered Nurses	Registered Nurse, Clinical Trainer	$39.27	$79
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Administrator, Medical director, Director of nursing	$61.22	$122
29-1071	Physician Assistants	Physician Assistant	$55.34	$111
29-1171	Nurse Practitioners	Nurse Practitioner	$53.51	$107
43-6013	Medical Secretaries and Administrative Assistants	Clerical Staff	$18.75	$38
11-3010	Administrative Services and Facilities Managers	Facilities Director	$51.98	$104
29-1000	Healthcare Diagnosing or Treating Practitioners	Mid-Level Practitioner	$50.58	$101

[31] 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.

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C. Rural Emergency Hospitals

1. ICRs Regarding Condition of Participation: Provision of Services (§ 485.514)

Proposed § 485.514(a) would require REHs to furnish health care services in accordance with appropriate written policies that are consistent with applicable state law. In addition, proposed § 485.514(b) would require REHs to develop the policies with the advice of members of the REH's professional health care staff, while § 485.514(d) would require REHs to conduct a biennial review of all its policies and procedures. We have not designated any specific process or format for REHs to use in developing their policies or conducting a review of their policies because we believe they need the flexibility to determine how best to accomplish these tasks.

In accordance with the section 1861(kkk)(3) of the Act, REHs must have been either a CAH or a rural hospital with not more than 50 beds as of the date of enactment of the CAA, December 27, 2020, to convert to an REH. We estimate that 68 facilities will convert to an REH and we believe that they will be developing REH-specific policies that are based on policies that were utilized when the facility was a rural hospital or CAH. As a result, we estimate that it would take an REH approximately 80 hours for administrative and clinical staff to develop policies. If there are 68 REHs to comply with the policy development requirement and each REH uses 80 hours to comply: (16 hours for a physician + 16 hours for an administrator + 16 hours for a mid-level practitioner + 16 hours for a nurse + 16 hours for a clerical staff person), then the burden hours are 5,440 (68 REHs × 80 hours). The cost is $8,800 per REH ($3,360 for a physician (16 hours × $210) + $1,952 for an administrator (16 hours × $122) + $1,616 for a mid-level practitioner (16 hours × $101) + $1,264 for a nurse (16 hours × $79) + $608 for a clerical staff person (16 hours × $38)). The total cost is 598,400 (68 REHs × $8,800). We estimate that it would take an REH's professional personnel 16 hours to review and make changes to policies and procedures biennially. Therefore, for all 68 REHs to comply with the policy review requirement it would require an estimated 16 burden hours biennially, or 8 hours annually (1.5 hours for a physician + 2 hours for an administrator + 1.5 hours for a mid-level practitioner + 1.5 hours for a nurse + 1.5 hours for a clerical staff person). The burden hours are 544 (8 hours × 68 REHs). The cost per REH is $886 ($315 for a physician (1.5 hours × $210) + $244 for an administrator (2 hours × $122) + $151.50 for a mid-level practitioner (1.5 hours × $101) + $118.50 for a nurse (1.5 hours × $79) + $57 for a clerical staff person (1.5 hours × $38)). The total cost is $60,248 ($886 × 68 REHs). Therefore, the total cost for each REH to comply with these requirements would be $658,648 annually and 5,984 burden hours.

2. ICRs Regarding Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs (§ 485.526)

COVID–19 and Seasonal Influenza Reporting

Consistent with the recent changes we made to the hospital and CAH infection control CoPs related to COVID–19 and the declared public health emergency (PHE), we are proposing to require REHs, after the conclusion of the current COVID–19 PHE, to report COVID–19 and seasonal influenza-related reporting. The proposed requirements would apply upon conclusion of the COVID–19 PHE and would continue until April 30, 2024, unless the Secretary establishes an earlier ending date. The proposed data elements align closely with those COVID–19 reporting requirements for long-term care (LTC) facilities that were finalized on November 9, 2021 (86 FR 62421), and are representative of the guidance provided to hospitals and CAHs for reporting. Therefore, we do not expect that these categories of data elements would require REHs to report any information beyond that which they have already been reporting as existing rural hospitals or CAHs. Furthermore, similar to the requirements for LTC facilities, this proposal would also allow for the scope and frequency of data collection to be reduced and limited responsive to the evolving clinical and epidemiological circumstances.

Based on our experience with those existing hospitals and CAHs and the current COVID–19 and related reporting requirements, we believe that this will primarily be the responsibility of a registered nurse and we have used this position in this analysis at an average hourly salary of $79. According to the most recent COVID–19 hospital reporting guidance (available at *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf*), hospitals are reporting COVID–19 and influenza-related data on a daily basis, with backdating permitted for weekends and holidays, except psychiatric and rehabilitation hospitals who report weekly. Some data element reporting fields are inactive for data collection, and therefore, hospitals can optionally report data for these fields. The inactive fields and active fields together reflect what is listed in this proposed rule for COVID–19 and influenza-related reporting as well as future reporting in the event of a declared PHE, which we discuss next. We do not expect, nor have we proposed, daily reporting for COVID–19 or influenza outside of a declared PHE.

If we were to assume a weekly reporting frequency, we would anticipate that there are reduced cases and fewer data elements (with no line level patient data) being reported. Based on these assumptions, we estimate that total annual burden hours for REHs to comply with these requirements would be 5,304 hours based on weekly reporting of the required information by 68 REHs × 52 weeks per year and at an average weekly response time of 1.5 hours for a registered nurse with an average hourly salary of $79. Therefore, the estimate for total annual costs for all hospitals and CAHs to comply with the required reporting provisions weekly would be $419,016 or approximately $6,162 per facility annually. We acknowledge that the data elements and reporting frequency could increase or decrease over the next two years, and those changes would impact this burden estimate.

We note that this estimate is assumed to be a one-day snapshot of reporting information as opposed to a cumulative weekly report accounting for information based on each day of that week. If we assumed a cumulative weekly account, we can assume reduced burden related to the actual reporting time, but anticipate that the estimate would be slightly higher to account for the need to track closely to daily reporting. We also acknowledge that respondents may have to track and invest in infrastructure in order to timely and accurately report on the specified frequency. Thus, respondents may face ongoing burdens associated with this collection even in the case of reduced frequency of submissions. We solicit comment on this potentiality.

Furthermore, we note that this estimate likely overestimates the costs associated with reporting because it assumes that all REHs will report manually. Efforts are underway to automate reporting that have the potential to significantly decrease reporting burden and improve reliability.

Future Reporting in the Event of a Future PHE Declaration

In addition, we are proposing to establish reporting requirements for future PHEs related to epidemics and pandemics by requiring REHs to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS–CoV–2/COVID–19, and other viral and bacterial pathogens or infectious diseases of pandemic or epidemic potential only when the Secretary has declared a PHE directly related to such specific pathogens and infectious diseases. Specifically, when the Secretary has declared a PHE, we propose to require REHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. Relevant to the declared PHE, the categories of data elements that this report would include are as follows: suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies; total REH bed and intensive care unit bed census, capacity, and capability; staffing shortages; vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

We are also proposing to require that, unless the Secretary specifies an alternative format by which a REH must report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients, unless the Secretary specifies an alternative format by which the REH would be required report these data elements. We are also proposing in this provision to limit any person-level, directly or potentially individually identifiable, information for affected patients and staff to items outlined in this section or otherwise specified by the Secretary. We note that the provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with sections 304, 306, and 308(d) of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m(d)). Lastly, we are proposing that a REH would provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or other CDC-supported surveillance systems as determined by the Secretary.

For purposes of this burden collection, we acknowledge the unknown and the ongoing burdens that may exist even if CMS is not collecting information outside of a declared PHE. We recognize that considerations such as building and maintaining the infrastructure to support readiness are necessary to ensure compliance with this requirement. Therefore, we are soliciting comment on the burden associated with these proposed requirements given the intended flexibility provided in reducing or limiting the scope and frequency of reporting based on the state of the PHE and ongoing circumstances. We are specifically asking for comment on the potential burden associated with the proposed reporting requirements as they might relate to any differences in the public health response to one specific pathogen or infectious disease versus another that would be directly related to the declared PHE. We are also interested in public comments addressing burden estimates (and the potential differences in those estimates) for variations in the required reporting response for a local PHE versus a regional PHE versus a national PHE that might be declared by the Secretary based on the specific circumstances at the time of the declaration.

CMS will pursue an emergency collection of information in the case of a declared PHE and use such burden estimate to inform its approach at that time. CMS will also publish an accompanying **Federal Register** Notice concurrent with its submission of a request to collect information, in addition to all other actions consistent with 5 CFR 1320.13. CMS commits to ensuring that respondents are well aware in advance of the intention to collect such information and solicits comment on the appropriate timeline and notification process for such actions.

3. ICRs Regarding Condition of Participation: Staffing and Staff Responsibilities (§ 485.528)

We proposed that the emergency department of the REH be staffed 24 hours a day, 7 days a week, and we propose this requirement at § 485.6528(a) and that a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant must be available to furnish services in the REH in the facility 24 hours a day. The burden associated with this requirement is the time it takes to review the REH's written policies and make appropriate changes or updates regarding its staffing and staff responsibilities for the services it furnishes. In conjunction with a mid-level practitioner, the physician develops, executes, and periodically reviews the REH's written policies governing the services it furnishes. We estimate that it will take the physician and mid-level practitioner 1 hour each to review the REH written policies and make the appropriate changes. We also estimate that a REH will utilize the services of one clerical person for half an hour to process any changes or updates, for a total of 2.5 burden hours and an estimated cost per REH of $ 330 ((1 hour × $210 for a physician) + (1 hour × $101 for a mid-level practitioner) + (0.5 hours × $38 for clerical staff)). Therefore, the burden associated with this requirement is an estimated 170 burden hours (2.5 hours × 68 REHs) at an estimated cost of $22,440 ($330 × 68 REHs).

4. ICRs Regarding Condition of Participation: Patient's Rights (§ 485.534) Standard: Notice of Rights: § 485.534(a)(1) and (2)

Proposed § 485.534(a) would require REHs to notify a patient of their rights and of whom to contact to file a grievance. We allow REHs the flexibility to use different approaches to meet this CoP. We have set forth general elements that should be common to all grievance processes, but have not delineated strategies and policies for implementing this system. We believe that in large

measure, REHs would be able to use existing systems for providing patients with information and handling complaints, and the elements listed in the regulation only serve to give basic assurance that these systems are responsive to patient grievances and act effectively. A less specific approach would permit a nominal, non-functional system that in essence did not serve the very purpose intended by the regulation. Costs associated with formalizing a process and modifying any existing notices or processes will most likely be partially offset by a reduction in patient-initiated lawsuits regarding care, and should provide a valuable tool for targeting internal quality assurance mechanisms.

We asked that the patient be provided with written notice containing a contact person's name, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. Steps taken on behalf of the patient need not include a detailed description of who was spoken to and when. It might merely be that the appropriate staff were interviewed and that records were reviewed to investigate the grievance, and that the investigation found the grievance to be either unsubstantiated or substantiated. Second, the figures represented are estimates. We know of no existing system that tracks how many complaints are lodged in aggregate in hospitals or CAHs each year; however, for REHs, we believe that the grievance response can largely rely on standardized language with only relevant information filled in, or could be created in a check-sheet format, or in many other ways.

Thus, the burden associated with this requirement is the time and effort necessary to modify any existing notices to include the proposed grievance process requirements. We believe that an office assistant may be tasked with drafting or updating the notices and distributing or posting, as appropriate, the information. We estimate that this would require no more than two hours of the clerical staff time. Based on this we estimate that this will create a one-time cost of $5,168 (68 REHs × 2 hours × $38 clerical staff hourly wage). In addition, we estimate that it will require the office assistant 2 minutes (.0333 hours) to provide the notice per REH patient on an annual basis. The number of notices required will depend on the number of patients received at the REH. Therefore, the per facility burden associated with providing the notice will vary based on the unique factors of the REH. According to an OIG report, there were 2,316,675 outpatient visits in 2011 at CAHs.[32] Based on this estimate, we assume that the REH will have an average of 1,743 outpatient/emergency department visits per year that would require informing each patient of their rights which would take 58 hours (.0333 hours × 1,743 notices). The cost is $149,872 ($38 clerical staff wage × 58 hours × 68 REHs).

In its resolution of a grievance, a REH must provide the patient with written notice of its decision that contains the name of the REH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each REH 15 minutes to develop and disseminate the required notice and estimate that an REH may have to provide 50 notices on an annual basis for a total annual burden. The burden hours would be 13 hours (0.25 hours × 50 notices). The total burden hours would be 884 hours (13 hours × 68 REHs) at the cost of $33,592 ($38 × 884 hours). Therefore, the total burden associated with this requirement is $188,632 ($5,168 to update notices, $149,872 to provide the notices, and $33,592 to provide the results of a grievance investigation).

Standard: Confidentiality of Patient Records (§ 485.534(d))

Proposed § 485.534(d), which sets forth the patient's right to access information in their records, will involve minimal burden as many states' existing laws cover this point. We have not proposed to require disclosure of all records, inasmuch as we recognize that there are situations where such a release could be harmful to the patient or another individual. Furthermore, we have not taken a prescriptive approach in specifying how quickly this information must be provided to the patient, or by setting a rate that the REH can charge. In the absence of state law, the REH should charge whatever is reasonable and customary in its community for duplication services (based on rates at local commercial copy centers, post offices, or other venues in which one could make photocopies). Therefore, while this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (3) because this requirement is considered standard industry practice and/or is required under state or local law.

Standard: Restraint and Seclusion (§ 485.534(e))

Section 485.534(e) requires that REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. While the requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, and effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities. These are reasonable and customary state practices based on current standards of practice and the state would impose this standard for efficient utilization of Medicare or Medicaid services in the absence of a Federal requirement. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

Standard: Restraint and Seclusion: Staff Training Requirements (§ 485.534(f))

Section 485.534(f) requires facilities to establish staff training requirements for the use of restraints and seclusion. The REH must provide competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion. While these information collection requirements are subject to the PRA, we believe the burden associated with them are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

Standard: Death Reporting Requirements (§ 485.534(g))

Section 485.534(g) requires the facility to report the death of a resident associated with restraint or seclusion to the CMS regional office. A report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

[32] *https://oig.hhs.gov/oei/reports/oei-05-12-00081.pdf.*

We estimate it will take 5 minutes to report each death to the CMS regional office and to document that report. We estimate fewer than 10 deaths annually for all 68 facilities. Five (5) minutes × 10 deaths annually would equate to a national burden of 50 minutes per year.

The hourly adjusted rate for a Medical and Health Service Manager responsible for notifying the CMS regional office of a death a documenting the report is $122/hour. Multiplying the total burden of 0.83 hours by the hourly wage yields an associated cost of about $101.67.

Standard: Patient Visitation Rights (§ 485.534(h))

Section 485.534(h) requires a REH to have written policies and procedures regarding the visitation rights of patients, including any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. Specifically, the written policies and procedures must contain the information listed in § 485.534(h)(1) through (4). Given that the statute requires a REH to have been either a CAH or rural hospital as of the date of enactment of the CAA, we expect these facilities to already have a visitation policy in accordance with the CAH and hospital CoPs at §§ 485.635(f) and 482.13(h), respectively. Therefore, the ICR burden associated with this requirement would be the time and effort necessary for a REH to review and make any necessary updates given its conversion to an REH and to distribute that information to patients. We expect that an office secretary or other clerical staff would update and distribute, or post as appropriate, the information and could accomplish this task in 15 minutes for an estimated one-time burden total of 17 hours (0.25 hours × 68 REHs) and at the cost of $646 ($38 × 17 hours).

5. ICRs Regarding Condition of Participation: Transfer Agreements (Proposed § 485.538)

At § 485.538, we propose that each REH must have a transfer agreement in effect with at least one certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. We estimate that it would require an REH administrator and a clerical person 2 hours each to develop the initial agreement and obtain the appropriate approvals. According to Table 1, the REH administrator's total hourly cost is $122 per hour. The clerical staff person's total hourly cost is $38. We estimate that for each REH to comply with the requirements in this section it would require 4 burden hours which would be a total of 272 hours (4 hours × 68 REHs). The cost is $320 ($244 (2 hours × $122 for an administrator) + $76 (2 hours × $38 for a clerical staff person)) for each REH. The total cost is $21,760 ($320 × 68 REHs). This is a one-time cost.

6. ICRs Regarding Condition of Participation: Medical Records (Proposed § 485.540)

There is no burden attributed to this task. The REH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable state law. The policies include a description of the services the REH furnishes directly and those furnished through agreement or arrangement; policies and procedures for emergency medical services and guidelines for medical management of health problems that include the conditions requiring medical consultation and/or patient referral and the maintenance of health care records.

We are not including burden associated with certain patient related activities such as health care plans, patient records, medical records, etc., because prudent institutions already incur this burden in the course of doing everyday business. As stated in 5 CFR 1320.3(b)(2), the burden associated with usual and customary business practices is exempt from the PRA. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH. Further, state laws require providers to maintain patient records. (For example, the annotated Code of Maryland (¶ 10.11.03.13) requires a provider to be responsible for maintaining patient records for services that it provides.) State law requires record information that should include: documentation of personal interviews; diagnosis and treatment recommendations; records of professional visits and consultations; and consultant notes which shall be appropriately initialed or signed.

7. ICRs Regarding Condition of Participation: Quality Assessment and Performance Improvement Program (QAPI) (Proposed § 485.536)

At proposed § 485.536, we require REHs to develop, implement, and maintain an effective, ongoing, REH-wide, data-driven quality assessment and performance improvement (QAPI) program. The REH's governing body must ensure that the program reflects the complexity of the REH's organization and services; involves all REH departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The REH must maintain and demonstrate evidence of its QAPI program for review by CMS. In addition, REHs must comply with all of the requirements set forth in proposed § 485.536(a) through (e). We believe that the REH QAPI leadership (consisting of a physician, and/or administrator, mid-level practitioner, and a nurse) would need to have at least one and potentially two meetings to ensure that the current QAPI program that the provider has established is in accordance with the proposed requirements at § 485.536. The first meeting would be to discuss the current QAPI program and what, if anything, needs to be revised based on the proposed QAPI requirements at § 485.536. The second meeting, if needed, would be to discuss strategies to update the current policies, and then to discuss the process for incorporating those changes. We believe that these meetings would take approximately 2 hours each. We estimate that the physician would have a limited amount of time, approximately 1 hour to devote to the QAPI activities. Additionally, we estimate these activities would require 4 hours of an administrator's time, 4 hours of a mid-level practitioner's time, 8 hours of a nurse's time, and 2 hours of a clerical staff person's time for a total of 19 burden hours. We believe that the REH's QAPI leadership would need to meet periodically to review and discuss the changes that would need to be made to their program. We also believe that a nurse would likely spend more time developing the program with the mid-level practitioner. The physician would likely review and approve the program. The clerical staff member would probably assist with the program's development and ensure that the program was disseminated to all of the necessary parties in the REH.

Based on these factors, we estimate that for each REH to comply with the requirements in this section it would require annually 19 burden hours (1 hour for a physician + 4 hours for an administrator + 4 hours for a mid-level practitioner + 8 hours for a nurse + 2 hours for a clerical staff person) at a cost of $1,810 ($210 for a physician (1 hour × $210) + $488 for an administrator (4 hours × $122) + $404 for a mid-level practitioner (4 hours × $101) + $632 for a nurse (8 hours × $79) + $76 for a

clerical staff person (2 hours × $38)). Therefore, for all 68 REHs to comply with these requirements, it would require 1,292 burden hours (19 hours × 68 REHs) at a cost of approximately $123,080 ($1,810 × 68 REHs).

8. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.542)

Section 485.542 sets forth the proposed emergency preparedness requirements for REHs. We note that these emergency preparedness standards are consistent national parameters that all Medicare and Medicaid participating providers and suppliers must meet. This includes both rural hospitals and CAHs and therefore facility that converts to an REH would have already incurred the costs to develop and implement their emergency preparedness plan. Based on this, the burden associated with these requirements would be the on-going costs to review, maintain and implement the emergency preparedness program to ensure ongoing compliance with the requirements and as such we have developed this collection of information (COI) section based largely on the existing COI burden for CAHs and hospitals.

Standard: Risk Assessment and Planning (§ 485.542(a))

We propose to require REHs to develop and maintain an emergency preparedness plan that must be reviewed and updated at least biennially. We expect that each REH facilities director ($104 per hour) would conduct a thorough risk assessment that will consider its location and geographical area; patient population, including those with special needs; and the type of services they have the ability to provide in an emergency (12 hours biennially or 6 hours annually) based on the services that they are now providing as an REH. They each would also need to review the measures needed to ensure continuity of its operation, including delegations and succession plans. We estimate that ongoing compliance with this requirement would require 6 burden hours annually (12 biennially) from the REH facilities director. Therefore, for all 68 REHs to comply with this requirement, it would require 408 burden hours (6 × 68 REHs) at a cost of approximately $42,432 (408 hours × $104).

Standard: Policies and Procedures (§ 485.542(b))

REHs are required to maintain emergency preparedness policies and procedures in accordance with their emergency plan, risk assessment, and communication plan. Each needs to review their emergency preparedness policies and procedures and revise, or in some cases, develop new policies and procedures that would ensure that the emergency preparedness plans address the specific requirements of the regulations.

We believe that the requirement for REHs to review and update their policies and procedures annually constitutes a usual and customary business practice and is not subject to the PRA in accordance with 5 CFR 1320.3(b)(2). However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

Standard: Communication Plan (§ 485.542(c))

REHs are required to develop and maintain an emergency preparedness communication plan that complies with both Federal and state law and must be reviewed and updated at least annually. The burden associated with this requirement would be the time and effort necessary to review, revise, and if necessary, develop a new communications plan to ensure that it complies with the requirements of this regulation. However, we believe that most REHs have some type of emergency preparedness communication plan based on their prior status as a CAH or rural hospital. It is standard practice in the health care industry to have and maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility, such as cell phones; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients.

If any revisions or additions are necessary to satisfy the requirements as an REH, we expect the revisions or additions would be those incurred during the course of normal business and thereby impose no additional burden. Thus, the ICRs related to the communication plan would constitute a usual and customary business practice as stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2) and we did not include this activity in the burden analysis. We are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

Standard: Training and Testing (§ 485.542(d))

REHs are required to develop and maintain an emergency preparedness training and testing program. The training program must include initial training in emergency preparedness policies and procedures for all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles and must be documented. The testing program must include participation in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If an actual natural or man-made emergency that requires activation of the emergency plan is experienced, then this requirement is exempt for 1 year following the onset of the actual event. In addition, the testing program must include one additional testing exercise, which may be determined by the REH. The training must be provided biennially and two testing exercises must be conducted annually.

We expect that all REHs will review their current training programs in their current capacity as hospitals or CAHs, and compare them to their risk assessments and emergency preparedness plans, emergency policies and procedures, and emergency communication plans. The CAHs will need to revise and, if necessary, develop new sections or materials to ensure their training and testing programs complied with our requirements. We anticipate that ongoing compliance with this requirement will require the involvement of an administrator, the mid-level practitioner, the facilities director, and clerical staff. We expect that a mid-level practitioner will perform the initial review of the training program (4 hours), brief the administrator and the director of facilities (2 hours), and clerical staff to revise or develop new sections for the training program (1 hour), based on the group's decisions, if necessary. This will result in a cost of $894 ($404 for a mid-level practitioner (4 hours × $101) + $244 for an administrator (2 hours × $122) + $208 for a director of facilities (2 hours × $104) + $38 for a clerical staff person (1 hour × $38)) for each REH. Therefore, for all REHs to comply with this requirement it will require an estimated 476 burden hours (7 hours × 68 REHs) at a cost of $60,792 ($894 × 68 REHs).

9. ICRs Regarding Conditions of Participation: Physical Environment (§ 485.544)

Standard: Life Safety Code (§ 485.544)

The REH must meet the applicable provisions of the 2012 edition of the Life Safety Code (LSC) of the National Fire Protection Association. If CMS finds that the state has a fire and safety code imposed by the state law that adequately protects patients, CMS may allow the state survey agency to apply the state's fire and safety code instead of the LSC if waiving the provisions of the LSC does not adversely affect the health and safety of patients. This regulation requires a REH to maintain written evidence of regular inspections and approval by state fire control agencies. We estimate that the burden associated with maintaining written evidence of state inspections and approval would be an average of 30 minutes for clerical personnel to file the documentation, for a total of 34 burden hours (0.5 hours × 68 REHs) and a cost of $1,292 (34 hours × $38). The burden will be accounted for in the Information Collection Request under OMB control number 0938–XXXX.

The table that follows summarizes our estimates of burden hours and costs for REHs. We emphasize that these estimates assume 68 conversions and that the number actually converting could be a fraction of this figure, or much higher, which as discussed earlier is an uncertainty addressed in both the NC RHRP and CLA study that estimated likely conversions. Our estimates of the cost per entity, however, would not be affected by the number of conversions.

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TABLE 2: Total COI Burden for Rural Emergency Hospitals

COI Requirement	Burden Hours	Costs
Condition of Participation: Provision of Services (§ 485.514)	5,984	$658,648
Condition of Participation: Infection prevention and control and antibiotic stewardship programs (§485.526)	5,304	$419,016
Condition of Participation: Staffing and Staff Responsibilities (§ 485.528)	170	$22,400
Standard: Notice of Rights: (§ 485.534(a)(1) and (2))	4,981	$188,632
Standard: Restraint and Seclusion (§485.534(e))	0	$0
Standard: Restraint and seclusion: Staff training requirements (§ 485.534(f))	0	$0
Standard: Death reporting requirements (§ 485.534(g))	0.83 hours	$101.67
Standard: Patient visitation rights (§ 485.534(h))	17	$646
Condition of participation: Agreements (Proposed § 485.538)	272	$21,760
Condition of Participation: Quality assessment and performance improvement program (QAPI) (Proposed § 485.536)	1292	$123,080
Standard: Risk Assessment and Planning (§485.542(a))	408	$42,432
Standard: Training and testing (§485.542(d))	476	$60,792
Standard: Life Safety Code (§ 485.544)	34	$1,292
TOTALS	18,939	$1,538,800

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D. Critical Access Hospitals

1. ICRs Regarding Condition of Participation: Patient's Rights (§ 485.614)

Standard: Notice of Rights: § 485.614(a)(1) and (2)

Proposed § 485.614(a) proposes to require CAHs to notify the patient of their rights and of whom to contact to file a grievance. We allow REHs the flexibility to use different approaches to meet this CoP. We have set forth general elements that should be common to all grievance processes, but have not delineated strategies and policies for implementing this system. We believe that in large measure, CAHs would be

able to use existing systems for providing patients with information and handling complaints, and the elements listed in the regulation only serve to give basic assurance that these systems are responsive to patient grievances and act effectively. A less specific approach would permit a nominal, non-functional system that in essence did not serve the very purpose intended by the regulation. Costs associated with formalizing a process and modifying any existing notices or processes will most likely be offset by a reduction in patient-initiated lawsuits regarding care, and should provide a valuable tool for targeting internal quality assurance mechanisms.

We propose that the patient be provided with written notice containing a contact person's name, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. Steps taken on behalf of the patient need not include a detailed description of who was spoken to and when. It might merely be that the appropriate staff were interviewed and that records were reviewed to investigate the grievance, and that the investigation found the grievance to be either unsubstantiated or substantiated. Second, the figures represented are estimates. We know of no existing system that tracks how many complaints are lodged in aggregate in CAHs each year; however, we believe that the grievance response can largely rely on standardized language with only relevant information filled in, or could be created in a check-sheet format, or in many other ways.

Thus, the burden associated with this requirement is the time and effort necessary to modify any existing notices to include the proposed grievance process requirements. We believe that an office assistant may be tasked with drafting or updating the notices and distributing or posting, as appropriate, the information. We estimate that this would require no more than two hours of the clerical staff time. The burden hours are 2,720 (2 hours × 1,360). Based on this we estimate that this will create a one-time cost of $103,360 (2,720 hours × $38). In addition, we estimate that it will require the office assistant 2 minutes (.0333 hours) to provide the notice per CAH patient on an annual basis. The number of notices required will depend on the number of patients received at the CAH. Therefore, the per facility burden associated with providing the notice will vary based on the unique factors of the CAH. According to a 2013 OIG report, there were approximately 1,753 patient visits per CAH in 2011.[33] Based on this estimate, the burden hours would be 58 hours (.0333 hours × 1,753 notices). The total burden hours would be 78,880 hours (58 hours × 1,360 CAHs). Therefore, we estimate that the CAH would have had to inform each of these patient of their rights at a cost of $2,997,440 ($38 × 78,880 hours).

In its resolution of a grievance, a CAH must provide the patient with written notice of its decision that contains the name of the CAH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each REH 15 minutes to develop and disseminate the required notice and estimate that a CAH may have to provide 50 notices on an annual basis. The burden hours for each CAH will be 12.5 (0.25 hour × 50 notices) for a total of 17,000 burden hours (12.5 hours × 1,360 CAHs). The total annual burden cost is $646,000 ($38 × 17,000).

Therefore, the total burden hours are 98,600 (78,880 + 17,000 + 2,720) and the total cost associated with this requirement is $3,746,800 ($103,360 to update notices, $2,997,440 to provide the notices, and $646,000 to provide the results of a grievance investigation).

Standard: Confidentiality of Patient Records (§ 485.614(d))

Proposed § 485.614(d), which sets forth the patient's right to access information in their records, will involve minimal burden as many states' existing laws cover this point. We have not proposed to require disclosure of all records, inasmuch as we recognize that there are situations where such a release could be harmful to the patient or another individual. Furthermore, we have not taken a prescriptive approach in specifying how quickly this information must be provided to the patient, or by setting a rate that the CAH can charge. In the absence of state law, the REH should charge whatever is reasonable and customary in its community for duplication services (based on rates at local commercial copy centers, post offices, or other venues in which one could make photocopies). Therefore, while this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (3) because this requirement is considered standard industry practice and/or is required under state or local law.

Standard: Restraint and Seclusion (§ 485.614(e))

Proposed § 485.614(e) requires that each CAH have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. While the requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, and effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities. These are reasonable and customary state practices and the state would impose this standard for efficient utilization of Medicare and Medicaid services in the absence of a Federal requirement. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden.

Standard: Restraint and Seclusion: Staff Training Requirements (§ 485.614(f))

Proposed § 485.614(f) requires facilities to establish staff training requirements for the use of restraints and seclusion. The CAH must provide competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion. While these information collection requirements are subject to the PRA, we believe the burden associated with them are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden.

Standard: Death Reporting Requirements (§ 485.614(g))

Proposed § 485.614(g) requires the facility to report the death of a resident associated with seclusion or restraint to the CMS regional office. A report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

We estimate it will take 5 minutes to report each death to the CMS regional

[33] *https://oig.hhs.gov/oei/reports/oei-05-12-00081.pdf.*

office and to document that report. We estimate fewer than 10 deaths annually for all 1,360 facilities. Five (5) minutes × 10 deaths annually would equate to a national burden of 50 minutes per year. The hourly adjusted rate for a Medical and Health Service Manager responsible for notifying the CMS regional office of a death a documenting the report is $122/hour. Multiplying the total burden of 0.83 hours by the hourly wage yields an associated cost of about $101.26.

TABLE 3: Total COI Burden for Critical Access Hospitals

COI Requirement	Burden Hours	Costs
Standard: Notice of Rights (§ 485.614(a)(1) and (2))	98,600	$3,746,800
Standard: Restraint and Seclusion (§ 485.614 (e))	0	$0
Standard: Restraint and seclusion: Staff training requirements (§ 485.614(f))	0	$0
Standard: Death reporting requirements (§ 485.614(g))	0.83 hours	$101
TOTALS	98,601	$3,746,901

The burden for the proposed CAH provisions will be accounted for in the Information Collection Request under OMB control number 0938–XXXX.

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 proposed rule.

Comments must be received by August 29, 2022.

IV. 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.

V. Regulatory Impact Statement

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 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). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule addresses the CoPs required for REH designation, which in accordance with the statute, may be sought by CAHs and small rural hospitals. It also proposes several new CAH requirements that we believe are appropriate under the existing program as well as to REHs. However, note that the costs of these CAH proposals are not attributable to the new REH program (except where such costs are experienced by entities that remain open due to the REH option but would have closed otherwise). The baseline for the estimates of REH costs is the status quo had the new program had not been created. Because the proposed CoPs for the new REH provider type are similar to those already met by the facilities that will potentially convert to REH status, and assuming that the estimated number of hospitals converting to the new program is approximately correct, the provisions of this proposed rule do not reach the economic threshold and thus it is not considered a major rule. This would remain the case if the number converting were to be significantly higher or lower. This is also an upper bound for these costs on a per facility basis, since for collection of information purposes we did not subtract offsetting savings from providers who would already meet these standards and who decide to make little change when updating their status. Payment policies for REHs will be developed under separately proposed rulemaking, and we expect that the total economic impact of the new program including both Conditions of Participation and payment costs will exceed the threshold for an economically significant impact, and will be addressed at that time.

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. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other healthcare providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We estimate that almost all of the new REH facilities, and the great majority of CAHs, are or would be small entities on the basis of legal status, revenues, or both. The North American Industry Classification System Code for the converting hospitals is 622110 (General Medical and Surgical Hospitals), and for the REHs to which they convert the closest Code is 621493 (Freestanding Ambulatory Surgical and Emergency Centers).

HHS uses an increase in costs or decrease in revenues of more than 3

percent as its threshold for ''significant economic impact''. Our collection of information estimates are that the 68 facilities converting to REH status (as estimated by the NC RHRP study referenced in the COI section) would face average annual costs of about $22,600 each (68 × $22,600 = $1,537,000 (COI burden estimate)). The North Carolina Rural Health Research Program estimated that the 68 hospitals it thought most likely to convert to REH status had average patient revenues of $7.3 million. For these facilities, the 3 percent threshold would be about $219,000, almost ten times our estimated cost of information collection. The CLA study does not present average facility revenues. However, we note that while it reaches a broad range of conversion estimates, we do not believe that it would have reached different conclusions had it presented such calculations. These relationships between revenues and costs would not be substantially different if the number of conversions was substantially fewer or substantially greater in number. More importantly, these facilities would be converting voluntarily to the new program. We expect that the costs any facility faces would be less than the anticipated gains of conversion, or it would not convert. This positive relationship of expected gains from conversion compared to current costs and revenues is explicit in the CLA modeling.

The effects of the proposed policy changes on CAHs are even smaller. The average annual cost per CAH for the new Conditions of Participation would be about $2,755 each (1,360 facilities × $2,755 = the $3,747,000 COI estimate), a tiny fraction of 1 percent of annual patient revenues estimated in the NC RHRP study at about $24 million a year. Moreover, the proposed change in the definition of primary roads could prevent the loss of the CAH designation for 3 to 4 CAHs. We note that we propose no change in rural hospital standards, so they are not directly regulated by this proposed rule.

For these reasons, an Initial Regulatory Flexibility Analysis (IRFA) is not required. Furthermore, as described provision by provision earlier in this preamble, we carefully sought to keep regulatory burdens on REH providers to a reasonable minimum, taking into account our obligation to reduce health care inequities, their small size, and the statutory and practical limitations on their status as providers. For example, we propose to allow systems composed of multiple and separately certified hospitals, CAHs, and/or REHs to have unified or integrated governing bodies, unified infection prevention and control and antibiotic stewardship programs, and unified and integrated medical staff. Taking all these factors into account, this analysis and the preamble as a whole meet the scope and content required for IRFAs.

Accordingly, we are not preparing an analysis under the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities. We do, however, request comments on our estimates and analysis, and on any alternatives that would reduce unnecessarily costly effects.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This proposed rule would not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $165 million in any 1 year.

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. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 9, 2022.

List of Subjects

42 CFR Part 485

Grant programs—health, Health facilities, Incorporation by reference, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 1. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Subpart E is added to read as follows:

Subpart E—Conditions of Participation: Rural Emergency Hospitals (REHs)

Sec.

485.500 Basis and scope.
485.502 Definitions.
485.504 Basic requirements.
485.506 Designation and certification of REHs.
485.508 Condition of participation: Compliance with Federal, state, and local laws and regulations.
485.510 Condition of participation: Governing body and organizational structure of the REH.
485.512 Condition of participation: Medical staff.
485.514 Condition of participation: Provision of services.
485.516 Condition of participation: Emergency services.
485.518 Condition of participation: Laboratory services.
485.520 Condition of participation: Radiologic services.
485.522 Condition of participation: Pharmaceutical services.
485.524 Condition of participation: Additional outpatient medical and health services.
485.526 Condition of participation: Infection prevention and control and antibiotic stewardship programs.
485.528 Condition of participation: Staffing and staff responsibilities.
485.530 Condition of participation: Nursing services.
485.532 Condition of participation: Discharge planning.
485.534 Condition of participation: Patient's rights.
485.536 Condition of participation: Quality assessment and performance improvement program.

485.538 Condition of participation: Agreements.
485.540 Condition of participation: Medical records.
485.542 Condition of participation: Emergency preparedness.
485.544 Condition of participation: Physical environment.
485.546 Condition of participation: Skilled nursing facility distinct part unit.

Subpart E—Conditions of Participation: Rural Emergency Hospitals (REHs)

§ 485.500 Basis and scope.

Section 1861(kkk) of the Act requires the Secretary to establish the conditions REHs must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients receiving services at these entities.

§ 485.502 Definitions.

As used in this subpart, *Rural Emergency Hospital* or *REH* means an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. The entity must not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-REH or post-hospital extended care services.

§ 485.504 Basic requirements.

Participation as an REH is limited to facilities that—

(a) Meet the definition in § 485.502.

(b) Have in effect a provider agreement as defined at § 489.3 of this chapter to provide services.

(c) Meet the conditions of participation set out in this subpart.

§ 485.506 Designation and certification of REHs.

CMS certifies a facility as an REH if the facility was, as of December 27, 2020—

(a) A critical access hospital; or

(b) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1886(d)(2)(D) of the Act); or

(c) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in § 412.103 of this chapter as of December 27, 2020.

§ 485.508 Condition of participation: Compliance with Federal, state, and local laws and regulations.

(a) The REH must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The REH must be located in a state that provides for the licensing of such hospitals under state or applicable local law; and is

(1) Licensed in the state as an REH; or

(2) Approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.

(c) The REH must assure that personnel are licensed or meet other applicable standards that are required by state or local laws to provide services within the applicable scope of practice.

§ 485.510 Condition of participation: Governing body and organizational structure of the REH.

There must be an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. If an REH does not have an organized governing body, the person or persons legally responsible for the conduct of the REH must carry out the functions specified in this subpart that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

(1) Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

(3) Ensure that the medical staff has bylaws.

(4) Approve medical staff bylaws and other medical staff rules and regulations.

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

(i) Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The REH grants privileges in accordance with recommendations from qualified medical personnel.

(ii) Medical staff privileges must be periodically reappraised by the REH. The scope of procedures performed in the REH must be periodically reviewed and amended as appropriate.

(iii) If the REH assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the REH dependent solely upon certification, fellowship, or membership in a specialty body or society.

(8) Ensure that, when telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with § 485.512(a)(3), grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

(9) Ensure that when telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the REH and as such, in accordance with paragraph (b) of this section, furnishes the contracted services in a manner that permits the REH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with § 485.512(a)(4), grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such REH's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the REH's medical staff, or their designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the REH. For a multi-facility

system, including a multi-hospital or multi-REH system, using a single governing body, the single multi-facility or multi-REH system governing body must consult directly with the individual responsible for the organized medical staff (or their designee) of each hospital or REH within its system in addition to the other requirements of this paragraph (a).

(b) *Standard: Contracted services.* The governing body must be responsible for services furnished in the REH whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the REH to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The REH must maintain a list of all contracted services, including the scope and nature of the services provided.

§ 485.512 Condition of participation: Medical staff.

The REH must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the REH.

(a) *Standard: Eligibility and process for appointment to medical staff.* The medical staff must be composed of doctors of medicine or osteopathy. In accordance with state law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at paragraph (c)(1) of this section) and non-physician practitioners who are determined to be eligible for appointment by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with state law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

(3) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the REH whose patients are receiving the telemedicine services, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the REH's patients and all complaints the REH has received about the distant-site physician or practitioner.

(4) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with paragraph (d) of this section, permit the REH to comply with all applicable conditions of participation for the contracted services. The REH's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at § 485.510(a)(1) through (7) and paragraphs (a)(1) and (2) of this section.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the REH with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the REH whose patients are receiving the telemedicine services, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the REH's patients, and all complaints the REH has received about the distant-site physician or practitioner.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathy.

(ii) A doctor of dental surgery or dental medicine, when permitted by state law of the state in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by state law of the state in which the hospital is located.

(4) If an REH is part of a system consisting of multiple separately certified hospitals, critical access hospitals, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, critical access hospitals, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified REH must demonstrate that:

(i) The medical staff members of each separately certified REH in the system (that is, all medical staff members who hold specific privileges to practice at that REH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective REH;

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified REH (that is, all medical staff members who hold specific privileges to practice at that REH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their REH;

(iii) The unified and integrated medical staff is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH; and

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (for example, active, courtesy, etc.).

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the REH, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in § 485.510(a)(8) and (9) and paragraphs (a)(3) and (4) of this section.

§ 485.514 Condition of participation: Provision of services.

(a) The REH's health care services must be furnished in accordance with appropriate written policies that are consistent with applicable state law.

(b) The policies must be developed with the advice of members of the REH's professional health care staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.528(b)(1).

(c) The policies must include the following:

(1) A description of the services the REH furnishes, including those furnished through agreement or arrangement.

(2) Policies and procedures for emergency medical services.

(3) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the REH.

(4) Policies and procedures that address the post-acute care needs of patients receiving services in the REH.

(d) The policies must be reviewed at least biennially by the group of professional personnel required under paragraph (b) of this section and updated as necessary by the REH.

§ 485.516 Condition of participation: Emergency services.

The REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* The emergency services of the REH must be—(1) Organized under the direction of a qualified member of the medical staff; and

(2) Integrated with other departments of the REH.

(b) *Standard: Personnel.* There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

(c) *Standard: Compliance with CAH requirements.* The REH must meet the requirements specified in § 485.618, with respect to:

(1) 24-hour availability of emergency services (§ 485.618(a)).

(2) Equipment, supplies, and medication (§ 485.618(b)).

(3) Blood and blood products (§ 485.618(c)).

(4) Personnel (§ 485.618(d)).

(5) Coordination with emergency response systems (§ 485.618(e)).

§ 485.518 Condition of participation: Laboratory services.

The REH must provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized standards of care for emergency services. The REH must ensure that—

(a) Laboratory services are available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(b) Emergency laboratory services are available 24 hours a day.

§ 485.520 Condition of participation: Radiologic services.

The REH must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, the therapeutic services, as well as the diagnostic services, must be furnished by the REH and provided by personnel qualified under state law. The REH must ensure that REH patients or personnel are not exposed to radiation hazards.

(a) *Standard: Radiologic services.* The REH must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services,

particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with state law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) The REH must have a full-time, part-time, or consulting qualified radiologist, or other personnel qualified under State law, to interpret only those radiologic tests that are determined by the medical staff to require specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of their interpretations.

(2) The REH must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

§ 485.522 Condition of participation: Pharmaceutical services.

The REH must have pharmaceutical services that meet the needs of its patients. The REH must have a pharmacy or a drug storage area that is directed by a registered pharmacist or other qualified individual in accordance with state scope of practice laws. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the REH's registered pharmacist or other qualified individual.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles and in accordance with state and Federal laws.

(1) A pharmacist or competent individual in accordance with state scope of practice laws must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacist or competent individual in accordance with state law and scope of practice must be available for a sufficient time to provide oversight of the REH's pharmacy services based on the scope and complexity of the services offered at the REH.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services for the provision of all services provided by the REH.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* Drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and state law, to ensure patient safety.

(1) All compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or competent individual in accordance with state law and scope of practice and performed consistent with state and Federal laws.

(2) All drugs and biologicals must be kept in a secure area, and locked when appropriate.

(i) All drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 *et seq.*) must be kept locked within a secure area.

(ii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) Drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and state law.

(c) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood transfusions, blood products, and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or other authorized prescriber.

(4) There must be an REH procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§ 485.524 Condition of participation: Additional outpatient medical and health services.

If the REH provides outpatient medical and health services in addition to providing emergency services and observation care, the medical and health services must be appropriately organized and meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Patient services.* The REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. If the REH provides outpatient and medical health diagnostic and therapeutic items and services, those items and services must align with the health needs of the community served by the REH. If the REH provides outpatient medical and health services in addition to providing emergency services, the REH must—

(1) Provide items and services based on nationally recognized guidelines and standards of practice.

(2) Have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate.

(3) Have effective communication systems in place between the REH and the patient (or responsible individual) and their family, ensuring that the REH is responsive to their needs and preferences.

(4) Have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH.

(5) Have personnel providing the services in paragraphs (a)(1) through (4) of this section who meet the requirements in paragraph (b) of this section.

(b) *Standard: Personnel for additional outpatient and medical health services.* The REH must—

(1) Assign one or more individuals to be responsible for outpatient services.

(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

(3) For any specialty services offered at the REH, have a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant providing services with experience and training in the specialty service area and in accordance with their scope of practice.

(c) *Standard: Orders for outpatient medical and health services.* Outpatient medical and health services must be ordered by a practitioner who meets the following conditions:

(1) Is responsible for the care of the patient.

(2) Is licensed in the state where they provide care to the patient.

(3) Is acting within their scope of practice under state law.

(4) Is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

(i) All practitioners who are appointed to the REH's medical staff and who have been granted privileges to order the applicable outpatient services.

(ii) All practitioners not appointed to the medical staff, but who satisfy the requirements of paragraphs (c)(1) through (4) of this section for authorization by the medical staff and the REH for ordering the applicable outpatient services for their patients.

(d) *Standard: Surgical services.* If the REH provides outpatient surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the REH in accordance with the designation requirements under paragraph (a) of this section.

(1) *Designation of qualified practitioners.* The REH designates the practitioners who are allowed to perform surgery for REH patients, in accordance with its approved policies and procedures, and with state scope of practice laws. Surgery is performed only by—

(i) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(ii) A doctor of dental surgery or dental medicine; or

(iii) A doctor of podiatric medicine.

(2) *Anesthetic risk and evaluation.* (i) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(ii) A qualified practitioner, as specified in paragraph (d)(3) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(iii) Before discharge from the REH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (d)(3) of this section.

(3) *Administration of anesthesia.* The REH designates the person who is allowed to administer anesthesia to REH patients in accordance with its approved policies and procedures and with state scope-of-practice laws.

(i) Anesthesia must be administered by only—

(A) A qualified anesthesiologist;

(B) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(C) A doctor of dental surgery or dental medicine;

(D) A doctor of podiatric medicine;

(E) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(F) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or

(G) A supervised trainee in an approved educational program, as described in § 413.85 or §§ 413.76 through 413.83 of this chapter.

(ii) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(4) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(5) *Standard: State exemption.* (i) An REH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (d)(3) of this section, if the state in which the REH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that they have consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the state and has concluded that it is in the best interests of the state's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with state law.

(ii) The request for exemption and recognition of state laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

§ 485.526 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The REH must have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the facility-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The REH must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the REH and between the REH and other health care settings;

(3) The infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and

(4) The infection prevention and control program reflects the scope and complexity of the services furnished by the REH.

(b) *Standard: Antibiotic stewardship program organization and policies.* The REH must demonstrate that—

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

(2) The facility-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the REH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

(ii) Documents the evidence-based use of antibiotics in all departments and services of the REH; and

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(4) The antibiotic stewardship program reflects the scope and complexity of the services furnished by an REH.

(c) *Standard: Leadership responsibilities.* (1) The governing body, or responsible individual, must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the REH's QAPI leadership.

(2) The infection prevention and control professional(s) are responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the REH's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of infection prevention and control guidelines, policies and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by REH personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the REH's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

(d) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-facility systems.* If a REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the REH as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

(e) *COVID–19 and Seasonal Influenza reporting.* Beginning at the conclusion of the COVID–19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (e), the REH must electronically report information about COVID–19 and seasonal influenza in a standardized format specified by the Secretary.

(1) Related to COVID–19, to the extent as required by the Secretary, this report must include the following data elements:

(i) Suspected and confirmed COVID–19 infections among patients and staff.

(ii) Total COVID–19 deaths among patients and staff.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies.

(v) Total patient census and capacity.

(vi) Staffing shortages.

(vii) COVID–19 vaccine administration data of patients and staff.

(viii) Relevant therapeutic inventories or usage, or both.

(2) Related to seasonal influenza, to the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients and staff.

(ii) Total influenza deaths among patients and staff.

(iii) Confirmed co-morbid influenza and COVID–19 infections among patients and staff.

(f) *Standard: Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential.* The REH must electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS–CoV–2/COVID–19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency (PHE), as defined in § 400.200 of this chapter, directly related to such specific pathogens and infectious diseases. The requirements of this paragraph (f) will be applicable to local, state, regional, or national PHEs as declared by the Secretary.

(1) The REH must electronically report information about the infectious disease pathogen, relevant to the declared PHE, in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include, the following:

(i) Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff.

(ii) Total deaths attributed to the relevant infectious disease pathogen among patients and staff.

(iii) Personal protective equipment and other relevant supplies in the REH.

(iv) Capacity and supplies in the REH relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies.

(v) Total patient census, capacity, and capability.

(vi) Staffing shortages.

(vii) Vaccine administration data of patients and staff for conditions monitored under this section and where a specific vaccine is applicable.

(viii) Relevant therapeutic inventories or usage, or both.

(ix) Isolation capacity, including airborne isolation capacity.

(x) Key co-morbidities or exposure risk factors, or both, of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

(2) Unless the Secretary specifies an alternative format by which the REH must report these data elements, the REH must report the applicable infection (confirmed and suspected) and vaccination data in a format that provides person-level information, which must include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. Facilities must not report any directly or potentially individually-identifiable information for affected patients (for example, name, social security number) that is not set out in this section or otherwise specified by the Secretary.

(3) The REH must provide the information specified in this paragraph (f) on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network or other CDC-supported surveillance systems as determined by the Secretary.

(g) *Standard: COVID–19 Vaccination of REH staff.* Until November 4, 2024, unless the Secretary specifies an earlier end date for the requirements of this paragraph (g), the REH 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 REH staff, who provide any care, treatment, or other services for the REH and/or its patients:

(i) REH employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the REH and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following REH staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the REH 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 REH that are performed exclusively outside of the REH 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 REH 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 REH 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 REH'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.

§ 485.528 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Emergency department staffing.* The emergency department of the REH must be staffed 24 hours a day, 7 days a week to receive patients and activate the appropriate medical resources.

(b) *Standard: Staffing.* (1) The REH must have a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the REH.

(4) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the REH has one or more patients receiving emergency care or observation care.

(c) *Standard: Responsibilities of the doctor of medicine or osteopathy.* (1) The doctor of medicine or osteopathy must—

(i) Provide medical direction for the REH's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participate in developing, executing, and periodically reviewing the REH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically review the REH's patient records, provide medical orders, and provide medical care services to the patients of the REH.

(iv) Periodically review and sign a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent where state law requires record reviews or co-signatures, or both, by a collaborating physician.

(2) A doctor of medicine or osteopathy must be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the REH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

(d) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the REH's staff must—

(i) Participate in the development, execution and periodic review of the written policies governing the services the REH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the REH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the REH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is placed in observation care at the REH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the REH is notified of the patient's status.

(e) *Standard: Periodic review of clinical privileges and performance.* The REH requires that—

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the REH must be evaluated by a member of the REH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the REH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the REH must be evaluated by one of the following—

(i) One Quality Improvement Organization (QIO) or equivalent entity.

(ii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patient under an agreement between the REH and a distant-site hospital, the distant-site hospital; or

(iii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patients under a written agreement between the REH and a distant-site telemedicine entity, one Quality Improvement Organization (QIO) or equivalent entity.

(3) The REH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

§ 485.530 Condition of participation: Nursing services.

The REH must have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care. The nursing services must be furnished and supervised by a registered nurse. Nursing services must meet the needs of patients.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice.

(b) *Standard: Nursing leadership.* The director of the nursing service must be a licensed registered nurse. The individual is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the REH.

§ 485.532 Condition of participation: Discharge planning.

An REH must have an effective discharge planning process that focuses

on the patient's goals and treatment preferences and includes the patient and their caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and their treatment preferences, ensure an effective transition of the patient from the REH to post-discharge care, and reduce the factors leading to preventable hospital admissions or readmissions.

(a) *Standard: Discharge planning process.* The REH's discharge planning process must identify, at an early stage of the provision of services, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-REH care will be made before discharge and to avoid unnecessary delays in discharge.

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate services following those furnished by the REH, including, but not limited to, hospice care services, post-REH extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(4) Upon the request of a patient's physician, the REH must arrange for the development and initial implementation of a discharge plan for the patient.

(5) Any discharge planning evaluation or discharge plan required under this paragraph (a) must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(6) The REH's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(7) The REH must assess its discharge planning process on a regular basis. The assessment must include ongoing periodic review of a representative sample of discharge plans.

(8) The REH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH) data on quality measures and data on resource use measures. The REH must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(b) *Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information.* The REH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

§ 485.534 Condition of participation: Patient's rights.

An REH must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) An REH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The REH must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The REH's governing body or responsible individual must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The REH must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the REH.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the REH must provide the patient with written notice of its decision that contains the name of the REH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* The patient has the right to—

(1) Participate in the development and implementation of their plan of care.

(2) Make informed decisions regarding their care, including being informed of their health status, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) Formulate advance directives and to have REH staff and practitioners who provide care in the REH comply with these directives, in accordance with §§ 489.100, 489.102, and 489.104 of this chapter.

(c) *Standard: Privacy and safety.* The patient has the right to—

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of their medical records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request.

(i) The records must be provided in the form and format requested by the individual, if it is readily producible in such form and format. This includes in an electronic form or format when such medical records are maintained electronically or if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual.

(ii) The records must be provided within a reasonable time frame. The REH must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or

seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1)(i) A *restraint* is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The REH must provide patient-centered competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion.

(2) The training must include alternatives to the use of restraint/seclusion.

(g) *Standard: Death reporting requirements.* REHs must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the REH must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the REH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the REH staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) *Standard: Patient visitation rights.* An REH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights under this section.

(2) Inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

§ 485.536 Condition of participation: Quality assessment and performance improvement program.

The REH must develop, implement, and maintain an effective, ongoing, REH-wide, data-driven quality assessment and performance improvement (QAPI) program. The REH's governing body must ensure that the program reflects the complexity of the REH's organization and services; involves all REH departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The REH must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The REH must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, REH service and operations.

(b) *Standard: Program data collection and analysis.* The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.

(c) *Standard: Program activities.* (1) The REH must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the REH. An *adverse patient event* means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. *Medical error* means an error that occurs in the delivery of health care services.

(3) The REH must take actions aimed at performance improvement and, after implementing those actions, the REH must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Executive responsibilities.* The REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the REH-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the REH's performance and reducing risk to patients.

(e) *Standard: Unified and integrated QAPI program for an REH in a multi-facility system.* If an REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that—

(1) The unified and integrated QAPI program is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed.

§ 485.538 Condition of participation: Agreements.

The REH must have in effect an agreement with at least one certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH that is—

(a) Licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the state; and

(b) Licensed or designated by the state or local government authority as level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

§ 485.540 Condition of participation: Medical records.

(a) *Standard: Records system.* (1) The REH must maintain a medical records system in accordance with written policies and procedures.

(2) The records must be legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the REH must maintain a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information.* (1) The REH must maintain the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) The REH must have written policies and procedures that govern the use and removal of records from the REH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records must be retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

(d) *Standard: Electronic notifications.* If the REH utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the REH must demonstrate that—

(1) The system's notification capacity is fully operational and the REH uses it in accordance with all state and Federal statutes and regulations applicable to the REH's exchange of patient health information.

(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

(3) To the extent permissible under applicable Federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of the patient's registration in the REH's emergency department.

(4) To the extent permissible under applicable Federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time the patient's discharge or transfer from the REH's emergency department.

(5) The REH has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

(i) The patient's established primary care practitioner;

(ii) The patient's established primary care practice group or entity; or

(iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for their care.

§ 485.542 Condition of participation: Emergency preparedness.

The REH must comply with all applicable Federal, state, and local emergency preparedness requirements. The REH must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The REH must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the REH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, state, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The REH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to—

(i) Food, water, medical, and pharmaceutical supplies; and

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the REH's care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the REH must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the REH, which includes the following:

(i) Consideration of care and treatment needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the REH.

(5) A system of medical documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

(6) The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of state and federally designated health care professionals to address surge needs during an emergency.

(7) The role of the REH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The REH must develop and maintain an emergency preparedness communication plan that complies with Federal, state, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, state, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) REH's staff.

(ii) Federal, state, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the REH's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the REH's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The REH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program.* The REH must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the REH must conduct training on the updated policies and procedures.

(2) *Testing.* The REH must conduct exercises to test the emergency plan at least annually. The REH must do the following:

(i) Participate in a full-scale exercise that is community-based every 2 years.

(A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or

(B) If the REH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the REH is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the REH's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the REH's emergency plan, as needed.

(e) *Emergency and standby power systems.* The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (National Fire Protection Association (NFPA) 99 and Technical Interim Amendments (TIA) 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6), Life Safety Code (NFPA 101 and TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The CAH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) *Emergency generator fuel.* CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If an REH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the REH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2) through (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) *Incorporation by reference.* The material listed in this paragraph (g) is approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the CMS must publish a document in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* The material may be obtained from: National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169; phone: (617) 770–3000; *www.nfpa.org.*

(1) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(2) Technical interim amendment (TIA) 12–2 to NFPA 99, issued August 11, 2011.

(3) TIA 12–3 to NFPA 99, issued August 9, 2012.

(4) TIA 12–4 to NFPA 99, issued March 7, 2013.

(5) TIA 12–5 to NFPA 99, issued August 1, 2013.

(6) TIA 12–6 to NFPA 99, issued March 3, 2014.

(7) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(8) TIA 12–1 to NFPA 101, issued August 11, 2011.

(9) TIA 12–2 to NFPA 101, issued October 30, 2012.

(10) TIA 12–3 to NFPA 101, issued October 22, 2013.

(11) TIA 12–4 to NFPA 101, issued October 22, 2013.

(12) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

§ 485.544 Condition of participation: Physical environment.

The REH must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall REH environment must be developed and maintained in such a manner that the safety and well-being of patients are ensured.

(1) There must be emergency power and lighting in at least the operating, recovery, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(3) The REH must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(b) *Standard: Facilities.* The REH must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in patient care, pharmaceutical, food preparation, and other appropriate areas.

(c) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the REH must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4).

(2) In consideration of a recommendation by the state survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an REH, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients in an REH.

(4) An REH may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(5) When a sprinkler system is shut down for more than 10 hours, the REH must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service; or

(ii) Establish a fire watch until the system is back in service.

(d) *Standard: Building safety.* Except as otherwise provided in this section, the REH must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99 and TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an REH.

(2) If application of the Health Care Facilities Code required under paragraph (d) of this section would result in unreasonable hardship for the REH, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(e) *Incorporation by reference.* The material listed in this paragraph (e) is approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the CMS must publish a document in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* The material may be obtained from: National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169; phone: (617) 770–3000; *www.nfpa.org.*

(1) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(2) TIA 12–2 to NFPA 99, issued August 11, 2011.

(3) TIA 12–3 to NFPA 99, issued August 9, 2012.

(4) TIA 12–4 to NFPA 99, issued March 7, 2013.

(5) TIA 12–5 to NFPA 99, issued August 1, 2013.

(6) TIA 12–6 to NFPA 99, issued March 3, 2014.

(7) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(8) TIA 12–1 to NFPA 101, issued August 11, 2011.

(9) TIA 12–2 to NFPA 101, issued October 30, 2012.

(10) TIA 12–3 to NFPA 101, issued October 22, 2013.

(11) TIA 12–4 to NFPA 101, issued October 22, 2013.

§ 485.546 Condition of participation: Skilled nursing facility distinct part unit.

If the REH provides skilled nursing facility services in a distinct part unit, the services furnished by the distinct part unit must comply with the requirements of participation for long-term care facilities specified in part 483, subpart B, of this subchapter.

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

■ 3. Section 485.610 is amended by revising paragraph (c) to read as follows:

§ 485.610 Condition of participation: Status and location.

* * * * *

(c) *Standard: Location relative to other facilities or necessary provider certification.* (1) The CAH is located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

(2) Primary roads of travel for determining the driving distance of a CAH and its proximity to other providers is defined as:

(i) A numbered Federal highway, including interstates, intrastates, expressways, or any other numbered Federal highway; or

(ii) A numbered State highway with 2 or more lanes each way.

* * * * *

■ 4. Section 485.614 is added to read as follows:

§ 485.614 Condition of participation: Patient's rights.

A CAH must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective

operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of their plan of care.

(2) The patient or their representative (as allowed under State law) has the right to make informed decisions regarding their care. The patient's rights include being informed of their health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §§ 489.100, 489.102, and 489.104 of this chapter.

(4) The patient has the right to have a family member or representative of their choice and their own physician notified promptly of their admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of their clinical records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1)(i) A *restraint* is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The CAH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The CAH must provide patient-centered, trauma informed competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion.

(2) The training must include alternatives to the use of restraint/seclusion.

(g) *Standard: Death reporting requirements.* Hospitals must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) *Standard: Patient visitation rights.* A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

■ 5. Section 485.631 is amended by adding paragraph (e) to read as follows:

§ 485.631 Condition of participation: Staffing and staff responsibilities.

* * * * *

(e) *Standard: Unified and integrated medical staff for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable State and local laws, each separately certified CAH must demonstrate that:

(1) The medical staff members of each separately certified CAH in the system (that is, all medical staff members who hold specific privileges to practice at that CAH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective CAH;

(2) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified CAH (that is, all medical staff members who hold specific privileges to practice at that CAH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their CAH;

(3) The unified and integrated medical staff is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH; and

(4) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

§ 485.635 [Amended]

■ 6. Section 485.635 is amended—

■ a. In paragraph (b)(2) introductory text by removing the reference ''42 U.S.C. 236a'' and adding in its place the reference ''42 U.S.C. 263a''; and

■ b. By removing paragraph (f).

■ 7. Section 485.640 is amended by adding paragraph (g) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(g) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the CAH as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to CAH staff.

■ 8. Section 485.641 is amended by adding paragraph (f) to read as follows:

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(f) *Standard: Unified and integrated QAPI program for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated QAPI program is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 9. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 10. Section 489.2 is amended by adding paragraph (b)(11) to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) * * *

(11) Rural emergency hospitals (REHs).

* * * * *

■ 11. Section 489.24 is amended in paragraph (b) by revising the definitions of ''Hospital'' and ''Participating hospital'' to read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

* * * * *

(b) * * *

Hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act and a rural emergency hospital as defined in section 1861(kkk)(2).

* * * * *

Participating hospital means:

(1) A hospital;

(2) A critical access hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act; or

(3) A rural emergency hospital as defined in section 1861(kkk)(2) of the Act.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–14153 Filed 6–30–22; 4:15 pm]

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Part III

Department of Education

34 CFR Chapter II

Final Priorities, Requirements, Definitions, and Selection Criteria—Expanding Opportunity Through Quality Charter Schools Program (CSP)—Grants to State Entities (State Entity Grants); Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools (CMO Grants); and Grants to Charter School Developers for the Opening of New Charter Schools and for the Replication and Expansion of High-Quality Charter Schools (Developer Grants); Final Rule

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED–2022–OESE–0006]

Final Priorities, Requirements, Definitions, and Selection Criteria—Expanding Opportunity Through Quality Charter Schools Program (CSP)—Grants to State Entities (State Entity Grants); Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools (CMO Grants); and Grants to Charter School Developers for the Opening of New Charter Schools and for the Replication and Expansion of High-Quality Charter Schools (Developer Grants)

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

ACTION: Final priorities, requirements, definitions, and selection criteria.

SUMMARY: The Department of Education (Department or ED) announces priorities, requirements, definitions, and selection criteria for CSP State Entity Grants, Developer Grants, and CMO Grants, Assistance Listing Numbers (ALNs) 84.282A, 84.282B, 84.282E, and 84.282M. We may use one or more of these priorities, requirements, definitions, and selection criteria for grant competitions under these programs in fiscal year (FY) 2022 and later years.

DATES: These priorities, requirements, definitions, and selection criteria are effective August 5, 2022.

FOR FURTHER INFORMATION CONTACT: Porscheoy Brice, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E209, Washington, DC 20202–5970. Telephone: (202) 260–0968. Email: *charterschools@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action: These priorities, requirements, definitions, and selection criteria are aimed at ensuring that all students have access to excellent schools that deliver the highest quality education. We take this action to ensure that Federal CSP funds support the creation, replication, and expansion of high-quality charter schools that promote positive student outcomes, educator and community empowerment, and promising practices; and to promote school diversity. We also seek to promote greater fiscal and operational transparency and accountability for CSP-funded charter schools. We believe the policies and strategies reflected in this regulatory action can serve as a model for all charter schools.

Summary of the Major Provisions of This Regulatory Action: Through this regulatory action, we establish two priorities, three application requirements, and two selection criteria for CMO Grants and Developer Grants; six application requirements and one selection criterion for State Entity Grants; and several assurances, definitions, and selection criteria applicable to CSP State Entity Grants, CMO Grants, and Developer Grants. These final priorities, requirements, definitions, and selection criteria supplement the provisions in Title IV, Part C of the Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (ESEA); and the priorities, requirements, definitions, and selection criteria in: Final Priorities, Requirements, Definitions, and Selection Criteria—Expanding Opportunity Through Quality Charter Schools Program; Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools (CMO NFP), published in the **Federal Register** on November 30, 2018 (83 FR 61532), and Final Priorities, Requirements, Definitions, and Selection Criteria—Expanding Opportunity Through Quality Charter Schools Program; Grants to Charter School Developers for the Opening of New Charter Schools and for the Replication and Expansion of High-Quality Charter Schools (Developer NFP), published in the **Federal Register** on July 3, 2019 (84 FR 31726).

Costs and Benefits: In accordance with Executive Order 12866, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

We believe the benefits of this regulatory action outweigh any associated implementation costs for State Entity Grant applicants and subgrant applicants, CMO Grant applicants, and Developer Grant applicants. We also believe this regulatory action will strengthen accountability for the use of Federal funds in the CSP by helping to ensure that CSP grants and subgrants are awarded to those entities most capable of successfully implementing their proposed projects and meeting the needs of the students and families they serve.

Purposes of Programs: State Entity Grants, CMO Grants, and Developer Grants support various activities critical to the successful creation and implementation of charter schools. The major purposes of the CSP are to expand opportunities for all students, particularly underserved students, to attend charter schools and meet challenging State academic standards; provide financial assistance for the planning, program design, and initial implementation of charter schools; increase the number of high-quality charter schools available to students across the United States; evaluate the impact of charter schools on student achievement, families, and communities; share best practices between charter schools and other public schools; aid States in providing facilities support to charter schools; and support efforts to strengthen the charter school authorizing process.

State Entity Grants (ALN 84.282A) comprise the largest portion of CSP funds. These competitive grants are awarded to State entities (SEs) that, in turn, award subgrants to eligible applicants on a competitive basis for the purpose of opening and preparing for the operation of new charter schools and replicated high-quality charter schools and expanding high-quality charter schools. Eligible applicants are charter school developers that have applied to an authorized public chartering agency to operate a charter school and have provided adequate and timely notice to that authority. A developer is an individual or group of individuals (including a public or private nonprofit organization), which may include teachers, administrators, and other school staff; parents; or other members of the local community in which a charter school project will be carried out.[1] For-profit organizations are ineligible to apply for grants or subgrants under the CSP.

In addition to awarding subgrants to eligible applicants to enable them to open new charter schools and to replicate or expand high-quality charter schools, State entity grantees may use grant funds to provide technical assistance to eligible applicants and authorized public chartering agencies in opening and preparing for the operation of new charter schools and replicated high-quality charter schools, and

[1] Section 4310(5) and (6) of the ESEA (20 U.S.C. 7221i(5) and (6)) (*www.congress.gov/114/plaws/publ95/PLAW-114publ95.pdf*).

expanding high-quality charter schools; and to work with authorized public chartering agencies in the State to improve authorizing quality, including developing capacity for, and conducting, fiscal oversight and auditing of charter schools. State entities may also use up to 3 percent of grant funds for administration, which may include technical assistance and monitoring of subgrants for performance and fiscal and regulatory compliance, as required under 2 CFR 200.332(d).

If a State does not have an active CSP State Entity Grant, the Department may award Developer Grants (ALNs 84.282B and 84.282E) to eligible applicants in the State on a competitive basis to enable them to open and prepare for the operation of new charter schools and replicated high-quality charter schools, or to expand high-quality charter schools.

Through CMO Grants (ALN 84.282M), the Department provides funds to nonprofit charter management organizations (CMOs) on a competitive basis to enable them to replicate or expand one or more high-quality charter schools.

CSP State Entity Grants, Developer Grants, and CMO Grants are intended to support charter schools that serve elementary or secondary school students. Funds may also be used to serve students in early childhood education programs or postsecondary education programs.

Section 4310 of the ESEA defines ''replicate'' as opening a new charter school, or a new campus of a high-quality charter school, based on the educational model of an existing high-quality charter school; and ''expand'' as significantly increasing enrollment or adding one or more grades to a high-quality charter school (20 U.S.C. 7221i(9) and (7)). Section 4310 defines ''high-quality charter school,'' in pertinent part, as a charter school that shows evidence of strong academic results, which may include strong student academic growth, as determined by a State; has no significant issues in the areas of student safety, financial and operational management, or statutory or regulatory compliance; and has demonstrated success in significantly increasing student academic achievement, including graduation rates where applicable, for all students served by the charter school and for each of the subgroups of students defined in section 1111(c)(2) of the ESEA (20 U.S.C. 7221i(8)).

Program Authority: Title IV, part C of the ESEA (20 U.S.C. 7221–7221j).

We published a notice of proposed priorities, requirements, definitions, and selection criteria for CSP State Entity Grants, CMO Grants, and Developer Grants in the **Federal Register** on March 14, 2022 (NPP) (87 FR 14197). That document contained background information and our reasons for proposing the particular priorities, requirements, definitions, and selection criteria. We also published an extension notice in the **Federal Register** on April 12, 2022 (87 FR 21644), extending the deadline for interested parties to submit public comments on the NPP from April 13, 2022, to April 18, 2022.

There are important differences between the proposed priorities, requirements, definitions, and selection criteria and the final priorities, requirements, definitions, and selection criteria established in this NFP, as discussed in the *Analysis of Comments and Changes* section in this document.

Public Comment: In response to our invitation in the NPP, 26,586 parties submitted comments on the proposed priorities, requirements, definitions, and selection criteria. A large proportion of those comments appear to have been part of organized letter-writing campaigns and addressed the same issues and concerns. Approximately 5,770 of the total comments received were unique comments. These comments also raised similar issues either in support of, or expressing concerns about, the proposed priorities, requirements, definitions, and selection criteria.

We group major issues according to subject. We discuss other substantive issues under the title of the item to which they pertain. Generally, we do not address technical and other minor changes. In addition, we do not address general comments that raised concerns not directly related to any of the proposed priorities, requirements, definitions, or selection criteria in the NPP.

Analysis of Comments and Changes: An analysis of the comments and changes in the priorities, requirements, definitions, and selection criteria since publication of the NPP follows.

General Comments

Comments: A majority of commenters expressed general support for the proposed priorities, requirements, definitions, and selection criteria. Many of these commenters, however, but also recommended that the Department modify some of the proposed priorities, requirements, definitions, and selection criteria to strengthen their purpose and intent and to clarify the language.

One commenter who expressed general support for the proposed priorities, requirements, definitions, and selection criteria, for example, stated that the Department should address teacher licensure requirements in charter schools. The commenter noted that some teachers in charter schools do not have appropriate State teaching licenses or credentials, despite extensive research indicating that highly qualified educators improve student achievement. The commenter encouraged the Department to issue regulations under the ESEA to reduce the reliance on what the commenter described as unqualified teachers in charter schools, which the commenter argued adversely impacts student achievement, undermines the teaching profession, and hinders union organization efforts in charter schools.

Another commenter stated that the proposed actions are a positive development for America's children and, if fully implemented, will advance equity and help restore charter schools to their original purpose by integrating them into the broader education community. This commenter also suggested that we require applicants to certify that they will remain neutral in any union organizing effort for the term of the grant award, noting that charter-district collaborations can benefit when charter school and district teachers belong to the same union.

Discussion: We agree with the vast majority of commenters that these priorities, requirements, definitions, and selection criteria will improve the overall quality of CSP-funded charter schools. We agree with the commenter that research shows that highly qualified educators improve student achievement and that all students should be taught by teachers who are fully certified in the area they are assigned to teach. As a general matter, however, State law governs the licensure and credentialing requirements for teachers in public schools, including public charter schools. Therefore, the Department believes the issue of teacher licensure should be addressed at the State level. Additionally, while we acknowledge that teacher unions can play an important role in charter schools as well as traditional public schools, we believe the issue of union organizing is outside the scope of this regulatory action.

Changes: None.

Comments: With respect to the peer review of CSP grants and subgrants, one commenter recommended that review teams include at least one reviewer representative of the district public school community. This commenter also recommended that a minimum point threshold be established for an award, and that applications be checked

for factual accuracy and posted for public review and comment for a period of no less than 45 days before award decisions are made.

Discussion: The Department considers a number of factors when selecting peer reviewers, including their knowledge and experience relevant to the competition for which they are reviewing applications, and any possible conflicts of interest that might affect their ability to be objective when reviewing grant applications. While some peer review panels may include district employees, it would be impractical, and possibly impede timely grant award decisions, to require each peer review team to include one representative from any particular school district community. In an effort to expand our peer reviewer pool, increase peer reviewer diversity, and ensure that grant applications are evaluated by individuals with up-to-date and relevant knowledge in a variety of learning settings, we published a notice in the **Federal Register** on May 20, 2022, inviting interested persons to apply to serve as peer reviewers for upcoming grant competitions in the Department's Office of Elementary and Secondary Education, Office of Postsecondary Education, and Office of Special Education and Rehabilitative Services. A link to this notice in the **Federal Register** can be found here: *https://www.federalregister.gov/documents/2022/05/20/2022-10834/peer-review-opportunities-with-the-us-department-of-educations-office-of-elementary-and-secondary.*

Further, while the Department checks all applications for accuracy prior to making a grant award, we believe it would be impractical and lead to unnecessary delays to require applications to be posted for at least 45 days before award decisions are made. Currently, the Department posts on the CSP website copies of all CSP applications that are approved for funding as well as their overall scores and peer reviewers' comments. Even after an award is made, projects must continue to meet program requirements and can be subject to administrative actions, including possible termination, if they do not comply with applicable statutory and regulatory requirements and the terms of the approved application.

Although State entity grantees must award subgrants on a competitive basis, State entity grantees generally establish their own procedures for reviewing subgrant applications, consistent with the program statute and applicable regulations. With respect to grants awarded by the Department, we believe it would be impractical to establish a minimum funding threshold, as such decisions are driven by several factors (*e.g.,* total amount of funds available, number of applications received, overall quality of the applications received) that may vary from one competition to the next. We are confident that the statutory requirements concerning the peer review of CSP grants and subgrants, the notice we published in the **Federal Register** on May 20, 2022, and the actions taken in this NFP combined will lead to further improvements in the quality of our peer review processes.

Changes: None.

Comments: Some commenters expressed concern that the proposed regulations empower Federal and State peer reviewers to question decisions that are central to the charter school authorizing process, such as whether there is sufficient demand for a school to be financially viable. These commenters contend that charter school authorizers are best positioned to determine whether requirements under State law have been met and evaluate the data and analyses that applicants are required to produce. These commenters recommended that we remove the community impact analysis requirement.

Discussion: We understand that the charter school authorizing process is governed by State law and agree with the commenters that charter school authorizers are better positioned than the Department to determine whether a particular proposed charter school meets State law requirements. On the other hand, the Department is responsible for administering the CSP and ensuring that CSP funds are used properly to support the highest quality applications that have the greatest likelihood of success. Given that peer reviews inform funding decisions involving the award of more than $400 million annually under the CSP, we believe it is necessary for peer reviewers to have access to as much information as possible in order to assess the viability of proposed charter schools. This peer review process is not merely an academic exercise; since 2001, seven years after the CSP was first authorized in 1994, approximately 930 CSP-funded charter schools and proposed charter schools (approximately 14.5 percent) either never opened or closed prior to the end of the grant period. These charter school closures and failures to open cost more than $174 million in Federal resources provided through CSP; are disruptive for communities, particularly for students and families directly affected by school closures; and potentially undermine the effectiveness of charter schools.[2] Moreover, assessing the need for Federal funding, including in the context of how well a particular proposal addresses local needs, is a standard consideration for peer reviewers in many Department discretionary grant programs, such as ''Promise Neighborhoods'' and ''Full-Service Community Schools.''

Changes: See the discussion of changes we have made to the requirements related to a community impact analysis, including changing this requirement to a ''needs analysis'' to align with other Department programs, under the *Requirements Applicable to CMO Grants and Developer Grants, Requirement 1* section of this Analysis of Comments and Changes.

Comments: Some commenters expressed concern about specific charter school practices that may exclude certain students from charter schools. A few commenters stated that charter schools should be required to disclose information about their student application, selection, turnover, backfilling, and disciplinary practices. One commenter stated that applicants should certify that application materials are available in all languages spoken in the community, that charter schools do not cap for admission the number of students with disabilities (or students with a particular type of disability), and that charter schools do not charge an application fee. The commenter further recommended that we require applicants that currently operate charter schools to disclose annual student turnover figures for the past 5 years and whether they use admissions tests, consider students' past academic or behavioral issues during admissions, and backfill student vacancies created as a result of withdrawals or expulsions during the school year. The commenter added that applicants should also be required to disclose how they have recruited students from diverse populations within their communities.

Discussion: We agree that transparency regarding student recruitment and enrollment practices of charter schools is important, including ensuring that charter schools implement enrollment practices that attract students from all different backgrounds. Accordingly, under the *Final Application Requirements, Requirements Applicable to CMO Grants and Developer Grants, Requirement 1* and *Requirements Applicable to State Entity Grants, Requirement 1,* grant and subgrant applicants must conduct a needs analysis that addresses the need for the

[2] WestED, Data Collection Form, 2012.

project and includes a robust family and community engagement plan that, among other things, describes how the charter school's recruitment, enrollment, and retention processes will engage and accommodate families from various backgrounds. As part of the needs analysis, applicants must include details about the school's common enrollment and retention practices that include, as part of the enrollment process, how it will disclose to families and community members policies or requirements (*e.g.,* discipline policies, purchasing and wearing specific uniforms and other fees, or family participation), and any services that are or are not provided, that could impact a family's ability to enroll or remain enrolled (*e.g.,* transportation services or participation in the National School Lunch Program). Accordingly, we believe the needs analysis requirement is sufficient to obtain information from applicants necessary to address the commenters' concerns, without being overly burdensome.

Changes: None.

Comments: Some commenters expressed general concern about how CSP funding is allocated to charter schools and recommended ways to strengthen accountability and oversight of the grants. For example, one commenter noted that the CSP authorizing statute has a provision that prohibits a State from having more than one active State Entity Grant at a time and suggested that the Department impose a similar restriction under the CMO Grant program. The commenter further suggested that the Department should not award a grant to any charter management organization with an active CMO Grant that exceeds $25 million, citing the potential misuse of grant funds by grantees as an example of why such a provision is needed. Two other commenters recommended that the Department require a forensic audit for any charter school applying for CSP funding. These commenters also stated that charter schools that do not operate as classroom-based entities or that are operated by for-profit entities should be barred from receiving CSP funds. Another commenter requested that we require all federally funded charter schools and charter school authorizers to comply with State freedom of information and open meetings laws.

Discussion: We agree that transparency and accountability regarding the use of Federal funds are important and believe these priorities, requirements, definitions, and selection criteria will enhance transparency and accountability under the CSP. With respect to the State Entity Grant program, the commenter is correct that the CSP statute prohibits the Department from awarding a grant to a State entity in a State where there is already an active State Entity Grant. The commenter also is correct that the CSP statute does not impose a restriction on the number of CMO Grants that can be awarded in a specific State. Where there is interest from multiple State entities within a State to apply for a State Entity Grant and be responsible for awarding subgrants to eligible applicants, we believe the statutory limit of one active State Entity Grant per State can help encourage partnerships and, thereby, eliminate the need for State entities to compete against each other for a limited pool of prospective high-quality charter school subgrantees. This context does not exist for the CMO Grant program, as CMO grantees generally manage the charter schools that they fund and do not fund their charter schools through subgrants. Likewise, while we appreciate the commenter's concerns about the possible misuse of CSP funds, we believe that imposing a blanket prohibition against CMOs with active CMO grants that exceed $25 million from receiving new CMO Grants would be counter-productive. For instance, large CMOs that manage multiple high-quality charter schools and have demonstrated that they have the capacity and resources to administer their CMO grant effectively and efficiently could be prevented from receiving the funds they need to implement their projects successfully. Furthermore, prior to awarding a grant to any entity—particularly, an entity that has an existing grant—the Department takes appropriate steps to mitigate the risk of program funds being misspent, including conducting a risk analysis and ensuring that the applicant is in compliance with all program requirements and has the capacity and resources to administer the grant effectively and efficiently.

Regarding State freedom of information and open meetings laws, under the CSP statute, applicants for State Entity Grants are required to describe how charter schools are addressed in the open meetings and open records laws in their State. In addition, this NFP requires applicants for Developer Grants to hold or participate in a public hearing to obtain information and feedback on the impact of the proposed project and, in the case of an applicant for a State Entity Grant or CMO Grant, each charter school that it funds must hold or participate in such a hearing. We do not address State freedom of information laws in these final priorities, requirements, definitions, and selection criteria because that issue is outside the scope of this regulatory action. Further, Assurance (c) of the *Final Assurances, Assurances Applicable to State Entity Grants, CMO Grants, and Developer Grants* requires applicants to provide an assurance that they will post on their websites information regarding any management contract between the charter school and a for-profit management organization, and the *Final Assurance Applicable to State Entity Grants and CMO Grants* requires applicants to post on their websites information regarding the charter schools slated to receive CSP funds.

Regarding comments that charter schools that do not operate as classroom-based entities should be barred from receiving CSP funds, we presume that the commenters were referring to virtual charter schools. Although the CSP statute does not specifically prohibit virtual charter schools from receiving CSP funds, the Department typically awards direct grants to ''brick and mortar'' charter schools and not to virtual charter schools. Because virtual charter schools in a few states may have received CSP funds indirectly through State educational agency (SEA) or State entity grantees, however, the Department has issued nonregulatory guidance to ensure that SEA and State entity grantees understand the inherent risks associated with the use of CSP funds by virtual charter schools and implement appropriate safeguards to mitigate the risks, particularly in the areas of student attendance and assessments. Finally, for-profit entities are ineligible to receive direct grants or subgrants under the CSP, although CSP grantees and subgrantees may enter into contracts with for-profit entities for the provision of goods and services. A grantee or subgrantee that enters into a contract for goods or services with any entity, including a for-profit management organization, must comply with the Federal procurement standards at 2 CFR 200.317–200.327, and applicable conflict of interest requirements. Further, Requirement 2 applicable to CMO Grants and Developer Grants and Requirement 2 applicable to State Entity Grants in the *Final Application Requirements* section of this notice require CSP grantees and subgrantees to provide detailed information about any management contracts they enter with for-profit management organizations, and Assurances (a) and (b) applicable to State Entity Grants, CMO Grants, and Developer Grants in the *Final*

Assurances section of this notice require applicants to provide assurances that they will not relinquish full or substantial administrative control of their CSP grants or subgrants to a for-profit management organization and that any management contract with a for-profit management organization will contain specific provisions to mitigate the risks associated with such contracts.

Changes: None.

Comments: Numerous commenters strongly recommended the continued use of the priorities, requirements, definitions, and selection criteria established in the CMO NFP published in the **Federal Register** on November 30, 2018 (83 FR 61532), and the Developer NFP published in the **Federal Register** on July 3, 2019 (84 FR 31726). These commenters stated that these regulations are critical to the success of charter schools and the inclusion of all students in charter schools.

Discussion: We agree that the priorities, requirements, definitions, and selection criteria established in the CMO NFP and Developer NFP should remain available for use in future competitions. Accordingly, as stated in the *Executive Summary* section of this notice and in the NPP, these regulations supplement, and do not supersede, the CMO NFP and the Developer NFP.

Changes: None.

Comments: Some commenters requested that the Department delay publishing the NFP or withdraw the actions proposed in the NPP to allow additional time for the Department to engage in meaningful discussions with the charter school community about the proposed changes to the programs.

Discussion: The Department received recommendations prior to the publication of the notice from numerous organizations and provided a public comment period to support further engagement with the field. As demonstrated by the significant number of comments, the Department has had the opportunity to hear directly from those who would be most impacted by this regulatory action. The Department carefully reviewed each of these comments. As stated in the *Purpose of Regulatory Action* section of this notice, we believe these final priorities, requirements, definitions, and selection criteria are critical to ensuring that CSP funds support the creation, replication, and expansion of high-quality charter schools that are fiscally and operationally transparent and accountable. Given the Biden-Harris Administration's commitment to ensuring that all students attending charter schools have access to a high-quality education, we decline to delay publishing the NFP or to withdraw the NPP.

Changes: None.

Priorities Applicable to CMO Grants and Developer Grants

Priority 1—Promoting High-Quality Educator- and Community-Centered Charter Schools To Support Underserved Students

Comments: A number of commenters expressed support for Priority 1 and its focus on creating community-centered charter schools and consideration of community assets. One commenter stated that there is value in having parents, educators, and community members take an active role in the creation and governance of charter schools, but recommended making the priority a competitive preference priority rather than an absolute priority. The commenter also recommended broadening the parameters for educator involvement and removing the requirement for a timetable with milestones to reflect that a community-centered approach should be an ongoing effort.

Discussion: We agree that community involvement in the creation and governance of charter schools should be considered a best practice and increases the likelihood of a charter school's success. The priority is not intended to limit the ways educators can be involved in the development of high-quality charter school models, and we are revising the priority to clarify this. We also are removing the requirement for a ''timetable with milestones'' to clarify that we do not believe efforts to engage the community should have an end date. Rather, we seek a timeline for the applicant's plans to implement key activities under the priority. Further, when establishing a priority for use in a program, we generally do not identify the priority as absolute, competitive preference or invitational, to allow the Department flexibility to determine how the priority should be used in any future competition.

Changes: In paragraph (a)(1) of Priority 1, we clarified that applicants may propose educator involvement in activities other than the enumerated activities. Additionally, in paragraph (b), we revised the requirement to require applicants to provide a timeline to clarify that while there should be milestones, a grantee's community engagement efforts and community-centered approach should be ongoing. We also made corresponding changes to the language in Requirement 6 applicable to State Entity Grants to align with the changes to paragraph (a)(1) of Priority 1.

Priority 2—Charter School and Traditional Public School or District Collaborations That Benefit Students and Families

Comments: Many commenters expressed support for Priority 2 given its goal to foster greater collaboration between traditional public schools and public charter schools. One commenter stated that it is important for organizations and stakeholders, particularly those responsible for ensuring school quality, to listen and learn from one another to develop improved practices for implementing community-responsive schooling. While supportive of the priority, the commenter recommended making Priority 2 an invitational priority as opposed to a competitive preference priority, noting that the proposed priority might discourage applications from charter schools that are not able to engage in such collaborations, such as rural charter schools.

Another commenter expressed support for Priority 2 but requested that we require all applicants to certify that they will not use nondisclosure agreements or noncompete agreements at their schools and will void any such existing agreements during the grant period. The commenter asserted that nondisclosure agreements and noncompete agreements create barriers to fostering charter-district collaborations because such agreements prohibit teachers in charter schools from taking jobs in traditional public schools for a fixed period of time or within a specific geographic area that is close to the charter school following the termination of employment.

Several commenters recommended making the priority less prescriptive by allowing applicants to determine the nature of their collaborations with traditional school districts rather than including a menu of activities. These commenters also recommended allowing applicants to provide evidence of an existing collaboration or an intent to collaborate with a traditional school district if such collaboration is not already underway. Another commenter suggested that the Department add services to meet the needs of students with disabilities and English learners to the list of services on which the applicant may propose to collaborate with a traditional public school or school district.

One commenter recommended that we require grantees to provide evidence of the collaboration within 180 days of receiving a CSP grant award.

A relatively large number of commenters opposed this priority for varying reasons. Some commenters noted that while they are generally supportive of school collaborations and the sharing of best practices between charter schools and traditional public schools, they are skeptical that this priority will lead to true partnerships between charter schools and traditional public schools and school districts because of the tensions that exist between charter schools and traditional public schools in some communities.

Other commenters expressed concern that many eligible applicants may be blocked from receiving funding and opening new charter schools and, thus, may be discouraged from applying for a grant or subgrant if traditional public schools and school districts are unwilling to partner with charter schools; these commenters argued that traditional school districts often resist attempts to foster cooperation and collaboration with charter schools. One commenter stated that this priority has the potential to give traditional school districts additional leverage to reject the creation of new charter schools if the priority is implemented as an absolute priority or competitive preference priority.

Another commenter stated that requiring the district to sign a memorandum of understanding (MOU) could be labor-intensive, with significant legal fees, and noted that a newly elected school board could revoke the MOU in a subsequent year.

Other commenters stated that requiring State entities to give priority to eligible applicants that propose charter-district collaborations would diminish the role of states in the development and administration of their charter school programs by forcing states to re-orient grant-awarding priorities in their subgrant application process for peer review.

Discussion: We agree that charter schools and traditional public schools and school districts should listen and learn from one another to develop improved practices for implementing programs and services that are responsive to student, family, and community needs, which we believe can lead to improved academic outcomes for all students. We also agree that applicants should have flexibility regarding not only whether they respond to the priority, but also, how they respond to this priority, particularly if they have an existing collaboration with a traditional public school or school district. Likewise, we recognize that significant benefit could derive from collaborations between character schools and traditional public schools or school districts (also referred to as ''charter-traditional collaborations'' in this notice) focused on supporting students with disabilities and English learners. In response to these comments, we have revised the priority to clarify that applicants have flexibility to choose the collaborations they propose, modified elements of the description of the collaboration to reflect that collaborations may be proposed or existing, and added collaborations focused on serving students with disabilities and English learners to the list of examples of collaborations that applicants may choose to propose. We also acknowledge that it may take significant time for applicants to establish such collaborations, and that implementing the priority as an absolute priority could make it more difficult for some charter schools to qualify for CSP subgrants. To be clear, the purpose of this priority is to encourage, but not require, collaborations between charter schools and traditional public schools or school districts in ways that benefit students and families in charter schools and traditional public schools. Some of the most successful charter school networks have collaborated with traditional public schools and school districts, and there is evidence that these types of collaborations can improve the quality of educational opportunities and outcomes for students in charter schools and traditional public schools, including by sharing instructional materials, creating joint professional learning opportunities, developing principal pipeline programs, and more.[3]

For example, an analysis of collaborations between charter schools and traditional public schools in the District of Columbia identified over 60 examples of how charter schools and traditional public schools were able to partner in mutually beneficial ways.[4] These collaborations included shared professional development, scaling innovative practices, and research development. A similar collaboration exists in Boston, Massachusetts, where a compact among traditional public schools, charter schools, and Catholic schools was created to coordinate and share best practices.

Perhaps more importantly, these types of partnerships can help improve services and supports for educationally disadvantaged students, including students with disabilities and English learners, enrolled in charter schools. For example, according to a report by the Center for American Progress (CAP),[5] developing the expertise to successfully serve students with disabilities can be particularly challenging for charter schools that may not enroll many students with low-incidence disabilities and who require highly specialized services and supports. Collaboration with the district can help charter schools access expertise that would help improve student services and outcomes. CAP also published a report with the Center for Learner Equity (CLE) that profiled examples of districts and charter schools pursuing similar efforts.[6] Such partnerships can provide charter schools with additional expertise and supports to help meet the needs of all students, particularly students with disabilities and English learners.

The CAP report also found that these partnerships can improve economies of scale for small charter school operators, as many charter schools are not able to access the same pricing for curricula, supplies, support services, and technology as larger districts and networks. This frees up resources for charter schools to invest elsewhere in their programs to ensure that they are meeting the needs of their students.

We also know that charter schools often foster innovation in public education, which is a major purpose of the CSP. These kinds of partnerships can provide opportunities for charter schools to share their best practices with traditional public schools that can learn from these efforts.

This priority reflects the research on how these mutually beneficial partnerships can improve educational opportunities for students enrolled in charter schools as well as traditional public schools. We have seen successful outcomes for students and communities

[3] See *e.g.,* Putting Students First: *Profiles of District-Charter Collaborations in the District of Columbia and Massachusetts,* Mid-Atlantic Comprehensive Center, WestEd, Putting Students First: Profiles of District-Charter Collaboration in the District of Columbia and Massachusetts (*wested.org*), 2019; Passing Notes: *Learning from Efforts to Share Instructional Practices Across District-Charter Lines,* CRPE, Passing Notes: Learning from Efforts to Share Instructional Practices Across District-Charter Lines—Center on Reinventing Public Education (*crpe.org*), February 2018.

[4] DC Public School and DC Public Charter School Collaboration, EdSight, EdSight Cross Sector Collaboration FINAL.pdf (*dc.gov*), October 2019.

[5] Improving Outcomes for Students with Disabilities: *Negotiating Common Ground for District and Charter School Collaboration,* Center for American Progress, Improving Outcomes for Students with Disabilities—Center for American Progress, January 2017.

[6] A Secondary Analysis of the Most Recent Civil Rights Data Collection to Inform Policy and Practice, Center for Learner Equity, A Secondary Analysis of the Most Recent Civil Rights Data Collection to Inform Policy and Practice—The Center for Learner Equity, November 2021.

when there is collaboration between charter schools and traditional public schools and hope to encourage more of it. Under no circumstances should this priority be implemented in a manner that creates barriers for eligible applicants seeking to obtain approval of a charter application or an application for CSP funding to support the creation, replication, or expansion of a high-quality charter school.

In response to the commenter's concerns about the use of noncompete and nondisclosure agreements in charter schools, we agree that the use of such agreements could impede charter-district collaborations to the extent that they restrict a teacher's ability to work at, or to share best practices with, another public school, and that non-compete agreements undermine the ability of all students to have access to qualified teachers. The issue of noncompete and nondisclosure agreements in charter schools, however, is outside the scope of this regulatory action. Nevertheless, the Department will explore options for collecting data in this area that might inform future activities.

Finally, while the Department has discretion to designate the priority as invitational, competitive preference, or absolute in any given competition, for the reasons noted above, we do not intend to use this priority as an absolute or competitive preference priority in FY 2022, and it is unlikely that we would use the priority as an absolute priority in future years. Therefore, in the FY 2022 CSP CMO Grant and Developer Grant competitions, applicants will not be required to collaborate with a traditional public school or school district to be eligible for funding. Further, as discussed below, we have revised Priority 2 to clarify the Department's intent and to help ensure that this priority is not implemented in a manner that would make it more difficult for eligible applicants to obtain charter approval or to qualify for CSP funding. Also, as discussed below, we have amended Requirement 6 applicable to State Entity Grants to require State entity applicants to describe how they will ''encourage, but not require,'' eligible applicants to propose projects that include charter-traditional collaborations.

We also acknowledge the commenter's concern that requiring the district to sign an MOU could be labor-intensive and result in significant legal fees, only to be revoked at a later date. Putting in place an MOU is not required in order for applicants to address this priority but is one example of the various types of information that may be provided. Nevertheless, to avoid confusion, we have removed the reference to an MOU in the priority. In addition, as discussed below, we have extended the time period within which an applicant must provide evidence of the existence of a collaboration. Having an MOU in place, or having a traditional public school or district ''sign off'' on the application, is not a requirement of this priority.

Changes: We changed the name of this priority to Collaborations between Charter Schools and Traditional Public Schools or Districts that Benefit Students and Families across Schools. In paragraph (a) of Priority 2, we clarified that applicants can meet the priority not only by proposing a new collaboration, but also by proposing to continue an existing collaboration. We also revised the priority to provide more examples of the types of collaborations applicants may propose. We also clarified, in paragraph (a), that the collaboration must be designed to benefit students or families served by at least one member of the collaboration and lead to increased educational opportunities and improved academic outcomes for students served by at least one member of the collaboration. The proposed priority referred to improved *student* outcomes and required the activity to benefit ''students and families served by each member of the collaboration.'' Additionally, in paragraph (a)(1), we revised the priority to allow applicants to implement, among other examples, co-developed or shared curricular and instructional resources or academic course offerings. We moved the example describing ''policies and practices to create safe, supportive, and inclusive learning environments'' to paragraph (a)(4) and replaced ''including'' with ''such as'' in reference to systems of positive behavioral intervention and support. We also added paragraph (a)(7) to include as an example of a charter-traditional collaboration any shared special education collaborative designed to address a significant barrier or challenge faced by participating charter schools and traditional public schools in improving academic and developmental outcomes and services for students with disabilities. Similarly, we added paragraph (a)(8), which allows applicants to describe implementation of this priority by including details of a shared English learner collaborative designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in improving student outcomes for English learners. We moved the reference to ''other collaborations designed to address a significant barrier or challenge faced by charter schools and traditional public schools'' to paragraph (a)(9), clarified that the collaboration must address a significant barrier or challenge faced by participating schools, and added as an example the sharing of innovative and best practices. In paragraph (b), we modified the priority to require applicants to describe the collaboration, and in paragraph (b)(1), we deleted the requirement to provide evidence of the collaboration at the time the application is submitted, and added that applicants must describe each member of the collaboration and indicate whether the collaboration would be a new or existing commitment. In paragraph (b)(3), we removed the requirement to identify key staff responsible for completing specific tasks and required applicants to describe the ''anticipated'' roles and responsibilities of each member of the collaboration. Lastly, we revised the priority to require applicants to provide evidence of the collaboration within 120 days of receiving a CSP grant or subgrant award, or within 120 days of the date the collaboration is scheduled to begin, whichever is later; and made it clear that an MOU is not required. We also made corresponding changes in Requirement 6 applicable to State Entity Grants to align with the changes in Priority 2, and revised Requirement 6 to require State entities to describe how they will encourage, but not require, eligible applicants to propose projects that include a new or existing collaboration with a traditional public school or school district.

Requirements Applicable to CMO Grants and Developer Grants

Requirement 1 for CMO Grants and Developer Grants

Comments: A number of commenters expressed support for the community impact analysis requirement, noting various reasons why it is needed in the CSP. Some commenters suggested that low student enrollment in specific charter schools is one of the leading factors associated with a significant number of charter school closures. For this reason, these commenters expressed strong support for this requirement and the idea of bringing greater transparency, careful planning, and better judgment to the process of awarding CSP grants.

One commenter expressed support for this requirement given its intent to ensure due diligence in the selection of qualified, well-meaning grantees, but recommended requiring applicants to

include demographic information on students with disabilities and English learners in the community of the proposed project, along with an assurance that the applicant will provide the full range of services that meet the needs of such students. This commenter also recommended that applicants be required to provide a fiscal impact report and a signed affidavit provided by a district or State education department official attesting to the accuracy of the information provided in the grant application.

Another commenter noted that this requirement is a move in the right direction, stating CSP programs have long ignored the economic reality of charter school growth and how such growth impacts the resources available to traditional public schools. This same commenter recommended that the Department require applicants to state, as part of the community impact analysis, whether a credit rating agency has identified charter school growth as a credit negative for the districts from which the proposed charter school intends to draw its students.

Other commenters expressed strong support for the requirement given its emphasis on desegregation and diversity. One commenter stated that one of the most concerning features of urban charter schools is their potential to accelerate the concentration of the poorest and highest need students in the traditional public schools from which charter schools draw students, and that the community impact analysis would address this issue.

Another commenter stated that the community impact analysis is necessary because charter schools have been ''magnets for white flight'' from integrated traditional public schools, and some charter schools attract high-achieving students while discouraging students with special needs from attending. This commenter noted further that the information requested by the Department under this requirement is reasonable and will help peer reviewers make sound decisions.

Many commenters expressed significant concerns about this requirement and requested that the Department remove it, as they do not believe it is necessary. One commenter stated that the requirement will subject charter schools to a standard to which traditional public schools are not held accountable. This commenter, along with several others, cited concerns that paragraph 1(e) of the requirement implies that charter schools should only open in districts where the public schools are overcrowded, and that such a requirement does not take into consideration other factors, such as the number of seats in high-quality schools accessible to all students, possible shifts of students from private schools into charter schools, or the availability of enrollment data. One commenter recommended that the Department encourage the opening of charter schools in communities where children attend low-performing schools and do not have high-quality public school options, regardless of the traditional school district's capacity.

Another commenter opposed to this requirement contended that enrollment figures remain below pre-pandemic numbers in some of the Nation's largest school districts and that the limited availability of enrollment data may hinder an applicant from providing a complete or accurate analysis. This same commenter also stated that requiring a community impact analysis would hold charter schools responsible for maintaining diverse student populations, without clearly defining the meaning of the term ''diverse,'' even in communities that are not ethnically diverse, such as those affected by historical neighborhood ''red lining.''

Relatedly, one commenter suggested that the requirement is intended to prioritize integrated school models exclusively. According to this commenter, the requirement may have a chilling effect on a community or families of color who may seek to open or enroll in a different mission-oriented school, such as a school offering a pedagogical model that is in high demand by families of color in the community but that may not attract a sufficient number of White students to satisfy paragraph 1(b). According to this commenter, an applicant seeking to serve these families and communities of color may be deterred from applying for CSP funds, even though these monies often provide supports essential to opening a successful charter school. The commenter stated further that, if such an applicant chose to apply for CSP funds, instead of having an equal chance at funding to support planning and opening the charter school, the applicant would be at a competitive disadvantage when its application is evaluated by peer reviewers. The commenter stated that the charter school would face heightened barriers to opening, and that the families and ''community of color'' that the school intends to serve could be disproportionately negatively impacted.

Two commenters recommended revising the name of the requirement to ''Community Benefit Analysis'' to emphasize the available data and evidence regarding how a proposed project may benefit the community where it intends to locate. Additionally, one commenter stated that, if the Department keeps the requirement, grant and subgrant applicants should be allowed to decide what information to include in the analysis so that they can provide data and evidence that is applicable to their proposed project.

Lastly, some commenters raised concerns that the proposed requirement would increase burden hours and administrative costs for applicants, claiming that hiring a firm to conduct a community impact analysis could cost a charter school operator $15,000 or more—funds a small charter school operator would not have access to without receiving a CSP grant or subgrant.

Discussion: The goal of this requirement is to ensure that CSP applicants clearly address in their applications the need for their proposed projects and the anticipated benefits to the community in which the charter school is or would be located. As stewards of taxpayers' dollars, we hold a fundamental belief that all applicants for Federal financial assistance should be able to articulate the need for their proposed project and its potential impact on the community that it would serve. The idea of requiring grant and subgrant applicants to address the need for the proposed project is not unique to the CSP. Many notices inviting applications for new awards under the Department's discretionary grant programs require applicants to address project need and the potential impact of the project on the community, including several school choice and place-based discretionary grant programs, such as the Magnet Schools Assistance and Full-Service Community Schools programs.

Furthermore, through this requirement, we ultimately seek to support the creation, expansion, and replication of high-quality charter schools that effectively meet the needs of their communities and that remain open. As noted above, data from the Department's Charter School Programs Office show that 930 prospective charter schools and charter schools funded as subgrantees under the Department's CSP State Educational Agency [7] (CSP SEA) and State Entity Grant programs from 2001 to 2020, never opened or closed prior to the end of the grant period primarily due to low student

[7] In December 2015, Congress enacted the Every Student Succeeds Act (ESSA), which reauthorized the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001 (NCLB). The CSP SEA program was originally authorized under NCLB but was replaced with the CSP State Entity program under ESSA.

enrollment. We believe the proposed requirement can help reduce the number of CSP-funded charter schools that never open or close prematurely by directing Federal resources to high-quality, well-planned charter schools.

Contrary to concerns expressed by some commenters, the community impact analysis is not intended to require applicants to show evidence of over-enrollment in other public schools; nor is the requirement intended to restrict CSP-funded charter schools to opening only in districts whose traditional public schools are overcrowded. Therefore, the Department has revised the requirement to clarify that its intent is to require applicants to demonstrate need for the proposed project. District over-enrollment is one of several possible factors that an applicant may cite to evince the need for the proposed charter school. To be clear, applicants may use their discretion in identifying relevant information or data to demonstrate need for the project and that projected enrollment targets will be met. Applicants also may provide other information or data to demonstrate need and support estimates of projected enrollment, including, but not limited to, information on waiting lists for the proposed charter school or existing charter schools in the community; data on access to seats in high-quality schools in the community; and proposed specialized programs and student and family interest in those specialized programs.

In response to commenters who expressed concern that conducting a community impact analysis will create additional burden hours and administrative costs for applicants, we acknowledge that it may take considerable time for an applicant to conduct a thoughtful and thorough needs analysis depending on the size and scale of the proposed project. However, we also believe the benefits of such analysis far outweigh any additional burden. Many high-quality charter school authorizers already require charter applicants to present data on academic achievement, demographics, and enrollment and retention rates of students in the surrounding public schools of a proposed project. We also note that consideration of need for the project is a common factor the Department considers when determining whether to fund a proposed project and to appropriately direct resources to communities that would derive the most benefit from program funds in alignment with the purposes of the program. Thus, requiring a needs analysis is a best practice that helps ensure that CSP grant and subgrant applicants are aware of, and prepared to address, issues related to need for a proposed charter school project, including providing evidence of thoughtful planning to support a student population that is racially and socio-economically diverse.

We disagree with the comment that the community impact analysis requirement requires charter schools to maintain diverse student populations even in communities that are not ethnically diverse and, thus, fails to acknowledge that some communities are not ethnically diverse due to historical neighborhood redlining. To clarify the purpose of the requirement, we revised Requirement 1(b) now subpart (c) applicable to CMO Grants and Developer Grants (and Requirement 1(b) now subpart (c) applicable to State Entity Grants) to require the needs analysis to include an analyses of the proposed charter school's projected student demographics and a description of the demographics of students attending public schools in the local community in which the charter school would be located and, how the applicant plans to establish and maintain a racially and socio-economically diverse student body, including proposed strategies (consistent with applicable legal requirements) to recruit, admit, enroll, and retain a diverse student body. As revised, this requirement clarifies that an applicant that is unlikely to establish and maintain a racially or socio-economically diverse student body due to its specific educational mission or because the proposed charter school would be located in a racially or socioeconomically segregated or isolated community would not be at a competitive disadvantage. The revised language requires such an applicant to describe (i) why it is unlikely to establish and maintain a racially and socio-economically diverse student body at the proposed charter school; (ii) how the anticipated racial and socio-economic makeup of the student body would promote the purposes of the CSP, including to provide high-quality educational opportunities to underserved students, which may include a specialized educational program or mission; and (iii) the anticipated impact of the proposed charter school on the racial and socio-economic diversity of the public schools and school districts from which students would be drawn to attend the charter school. For example, a proposed charter school that enrolls 90 percent Native American students—either because the student population of the public schools or school districts from which the charter school draws students is generally Native American, or because the charter school's educational mission focuses on Native American languages and heritage would not be at a competitive disadvantage due to this requirement.

To clarify, peer reviewers do not assign points to an application based on the quality of an applicant's response to all application requirements. The overall quality of an application, and whether it is recommended for funding, is evaluated by peer reviewers based on an applicant's responses to the specific selection criteria and any competitive preference priorities established for the competition.

Likewise, an applicant that proposes to operate or manage a charter school in a racially or socio-economically segregated or isolated community would not be at a competitive disadvantage simply due to community demographics. This is true even if the proposed charter school itself would not have a racially or socio-economically diverse student body. For example, a proposed charter school in a community in which 95 percent of the students are Latino, and that draws students from school districts with roughly 95 percent Latino students both before and after the creation of the proposed charter school, would not be at a competitive disadvantage due to this requirement because the proposed charter school would not increase the racial or socio-economic segregation or isolation in the schools from which the students are, or would be, drawn to attend the charter school. The Administration is committed to supporting State and local efforts to increase student diversity and reduce racial and socio-economic isolation, including preventing Federal funds from being used to support efforts counter to these purposes. Racially and socio-economically diverse schools have positive benefits for all students, including higher graduation rates, improved academic outcomes, and increased levels of college enrollment for students of all races.

Lastly, we agree that the data provided by applicants should emphasize the main benefits that a proposed new, replicated, or expanded charter school may bring to the community it intends to serve. The community impact analysis requirement allows applicants flexibility to present relevant and applicable data most suitable for the types of projects they are proposing. For these reasons, we decline to require applicants to submit

information regarding the demographics of students with disabilities and English learners, a fiscal impact report and a signed affidavit provided by the district or SEA attesting to the accuracy of the information submitted in the grant application, or evidence that a credit rating agency has identified charter school growth as a credit negative for the districts from which the charter school would likely draw students.

Changes: We changed the requirement from a ''community impact analysis'' to a ''needs analysis'' to emphasize the main purpose of the requirement is to ensure that CSP applicants address the need for their proposed projects, including the anticipated benefits to the community. Referring to the analysis as a needs analysis also aligns with approaches used in other Department grant programs like the Full-Service Community Schools and Magnet Schools Assistance programs. We also added, in the lead-in sentence, that applicants must provide a needs analysis and describe the need for the proposed project, including how the proposed project would serve the interests and meet the needs of students and families in communities the charter school intends to serve. We also clarified that the needs analysis may consist of information and documents previously submitted to an authorized public chartering agency to address need.

Additionally, we streamlined and simplified the requirement. We revised paragraph (a) to require that applicants include descriptions of the community support for the charter school, benefits to the community, and other evidence of demand for the charter school that demonstrates a strong likelihood that the charter school will achieve and maintain its enrollment projections. We clarified that such information may include information on waiting lists for the proposed charter school or traditional public schools, data on access to seats in high-quality public schools in the districts from which the charter school expects to draw students; or evidence of family interest in specialized instructional approaches proposed to be implement at the charter school. These changes make it clear that over-enrollment of schools in the districts or communities an applicant proposes to serve is not a requirement of the program. Applicants that propose to serve students in a district or community with declining enrollment are eligible to apply to participate in the program.

We streamlined paragraph (b) to require applicants to provide information on the proposed charter school's projected enrollment and evidence to support such projected enrollment based on the needs analysis and other relevant data and factors. We also moved the request for applicants to describe how they plan to establish and maintain racially and socio-economically diverse student bodies to paragraph (c) and eliminated the request for applicants to address diverse staff populations.

In paragraph (c), we also ask applicants for an analyses of the proposed charter school's projected student demographics and a description of the demographics of students attending public schools in the local community in which the proposed charter school would be located. We also added to this paragraph that an applicant that is unlikely to establish and maintain a racially and socio-economically diverse student body at the proposed charter school because the charter school would be located in a racially or socio-economically segregated or isolated community, or because of the charter school's specific educational mission (*e.g.,* serving underserved students), must describe why it is unlikely to maintain a racially and socio-economically diverse student body, how the anticipated racial and socio-economic makeup of the student body would promote the purposes of the CSP to provide high-quality educational opportunities to underserved students, and the anticipated impact of the proposed charter school on the racial and socio-economic diversity of the public schools and school districts from which students would be drawn to attend the charter school.

We also revise paragraph (c) so that it no longer requires applicants to include analyses of publicly available information and enrollment trends of students attending schools in the community in which the proposed charter school would be located and the school districts from which students are, or will be, drawn to attend the charter school.

Finally, we have modified paragraph (f)(4) to require applicants to describe how the charter school's recruitment, admissions, enrollment, and retention policies and practices will engage and accommodate families from diverse backgrounds. We also made corresponding changes to Requirement 1 applicable to State Entity Grants to align with the changes in Requirement 1 applicable to CMO Grants and Developer Grants.

Requirement 2 for CMO Grants and Developer Grants

Comments: The overwhelming majority of comments received regarding this requirement were supportive of the Department's efforts to increase transparency for CSP applicants that enter into contracts with for-profit management organizations. One commenter expressed strong support for prohibiting charter schools operated by for-profit management organizations from receiving CSP grant or subgrant funds. Another commenter recommended that we add the phrase ''and its related entities'' wherever references to for-profit organizations appear in the language to capture the caveat that many for-profit organizations operate by steering business to their nonprofit related entities. Another commenter expressed support for the requirement's focus on increasing transparency but stated that the extent to which the proposed rules build on existing CSP guidance or set an entirely new standard is unclear. This commenter recommended that we remove ''substantial'' from the requirement where it suggests that arrangements under which a for-profit entity, including a nonprofit CMO operated by or on behalf of a for-profit entity, exercises full or ''substantial'' administrative control over the charter school because the commenter believes such a restriction is not permissible under CSP-funded projects.

Discussion: We agree with the commenters that it is important for CSP grantees and subgrantees to exercise fiscal and operational transparency by disclosing their contractual relationships with for-profit management organizations. For this reason, the proposed requirements and assurances included the phrase, ''including a nonprofit management organization operated by or on behalf of a for-profit entity,'' after references to for-profit management organization, where appropriate. In addition, we are adding the phrase, ''or its related entities,'' where appropriate, to ensure that this provision applies to those applicants with related for-profit arms that access CSP funds through their non-profit related entities. Furthermore, as stated in the NPP, this requirement is based, in part, on Federal regulations at 34 CFR 75.701 and 76.701, which require grantees and subgrantees, respectively, to directly administer or supervise the administration of their projects. It builds on existing non-regulatory guidance and is not intended to establish a new standard but rather to further clarify an existing standard. The

term ''substantial'' refers to the management organization's control over the charter school. We believe it is important to distinguish between control over the charter school and control over the CSP project, as a management organization could control certain aspects of the charter school without controlling the CSP grant or subgrant. The use of the term ''substantial'' in this context is intended to put grantees and subgrantees on notice that, in most cases, a management organization that exercises ''substantial'' control over a charter school would be considered to be exercising an impermissible amount of control over the CSP project.

Changes: We changed the first paragraph of Requirement 2 applicable to CMO and Developer Grants to cover ''related entities'' of for-profit management organizations as well as the management organizations themselves. Additionally, to ease the burden on applicants, we clarified that applicants can meet the requirement by providing equivalent information that they have submitted to the authorized public chartering agency.

We modified paragraph (a) to require applicants either to submit a copy of the existing contract with a for-profit management organization or to describe the terms of such contract. We also streamlined the requirement by combining paragraphs (a) and (b), and paragraphs (d) and (e). Additionally, we revised the provision to require, in addition to the name and contact information for each member of the governing board of the charter school, a list of the management organization's officers, chief administrator, other administrators, and any staff involved in approving or executing the management contract. Finally, we added paragraph (d) requiring applicants to describe how they will ensure that members of the governing board of the charter school are not selected, removed, controlled or employed by the management organization and that the charter school's legal, accounting, and auditing services will be procured independently from the management organization. We also made corresponding changes to Requirement 2 applicable to State Entity Grants to align with the changes in Requirement 2 applicable to CMO Grants and Developer Grants.

Requirement 3 for CMO Grants and Developer Grants

Comments: We received minimal comments in response to this requirement, but the majority of commenters offered general support for requiring applicants to provide more information regarding the approval status of their charter application from an authorized public chartering agency. One commenter recommended changing the language to request the dates the charter application was submitted and approved by the authorized public chartering agency rather than requiring a signed copy of the school's charter application. The commenter also recommended requiring applicants to identify the authorized public chartering agency to which they submitted the charter application and to provide proof that the application was submitted. Finally, the commenter recommended adding the leading phrase, ''In its budget,'' to paragraph (d), which requires applicants to submit documentation on planning costs.

Discussion: Under section 4310(6) of the ESEA, an applicant that has applied (and provided adequate and timely notice of its CSP application) to an authorized public chartering agency is eligible to apply for and receive CSP planning funds, even if the charter application has not yet been approved. Given the Department's interest in collecting more information regarding the status of grantees' charter applications, particularly as it relates to applicants that receive funding before obtaining charter approval, we believe that requiring applicants to submit this information is warranted and have revised the requirement based on all the recommended changes previously noted. We hope to gain greater insight into the charter authorizing process from this data.

Changes: We changed paragraph (a) to cover all applicants. We changed paragraph (a)(1) to request the name and address of the authorized public chartering agency that issued the applicant's approved charter or, in the case of an applicant that has not yet received an approved charter, the authorized public chartering agency to which the applicant has applied. We removed the proposed requirement for an applicant to provide a timeline from the authorized public chartering agency for providing a final decision on the charter application, and changed paragraph (a)(2) to request the date on which an applicant that has not yet received an approved charter submitted its charter application to the authorized public chartering agency and an estimated date by which the authorized public chartering agency will issue its final decision on the charter application. Additionally, we changed paragraph (a)(3) to require applicants to provide documentation that they have provided notice to the authorized public chartering agency that they have applied for a CSP grant. Lastly, we changed paragraph (a)(4) to require applicants to include in their proposed budgets a description of any post-award planning costs, including planning costs expected to be incurred prior to the date the authorized public chartering agency issues a decision on the charter application.

Requirements Applicable to State Entity Grants

Requirements 1 and 2 for State Entity Grants

For comments, discussion, and changes applicable to these requirements, see the above discussion for *Requirement 1 for CMO Grants and Developer Grants* and *Requirement 2 for CMO Grants and Developer Grants,* which include parallel requirements within the context of those programs.

Requirement 3 for State Entity Grants

Comments: While some commenters expressed general support for the requirement for State Entity applicants to provide a detailed description of how they will review applications from eligible applicants, slightly more commenters opposed the requirement. Some of the commenters who opposed the requirement questioned the Secretary's authority to create the requirement given that the program statute provides flexibility for State Entity applicants to describe how they will review subgrant applications. One commenter said the requirement may inhibit the ability of developers to propose new high-quality charter schools by discouraging CSP grant applications for State Entity review. Another commenter stated that paperwork to process a subgrant for review would increase as a result of the proposed requirement, discouraging schools from applying, especially single site and community schools. Another commenter noted that some State statutes conflict with the proposed requirement. This commenter asserted that, given the likely timing of the release of the NFP, the Department would have very little time to provide guidance on reconciling subgrant application requirements with State law requirements, further narrowing the ability for charter school developers to apply for CSP grants and subgrants and to open schools.

Discussion: We agree with some commenters that the program statute offers some flexibilities to State entity applicants regarding the development and implementation of their CSP subgrant programs, including the review of subgrant applications. Under the CSP,

State Entity grantees are given flexibility to design and implement their subgrant programs in a manner that enables them to achieve their policy goals and objectives, consistent with CSP requirements. Requirement 3 Applicable to State Entity Grants merely requires SE applicants to explain how they will review applications; it does not limit a State Entity's flexibility in developing the review process or adhering to State statutes. Thus, while grantees and subgrantees must comply with the CSP authorizing statute, applicable regulations, and their approved applications, the Department believes State entities are in the best position to establish the standards and guardrails that are necessary for their subgrantees to create, replicate, and expand high-quality charter schools that meet the educational needs of their students and comply with CSP requirements. Requirement 3 applicable to State Entity Grants holds State entities accountable for designing and implementing high-quality subgrant programs and, we believe, enhances the overall quality of charter school subgrantees in the areas of transparency, oversight, and accountability. We also do not believe this requirement will inhibit or discourage charter school subgrantees from applying to the State entity for funding as the requirement does not add any burden to charter school subgrant applicants. Therefore, we decline to eliminate or change the requirement.

Changes: None.

Requirement 4 for State Entity Grants

Comments: Commenters generally expressed support for this requirement for State Entity Grant applicants to provide a detailed description of how the SE will monitor and report on subgrant performance. One commenter recommended that the Department modify the language slightly to encourage collaboration between the State entity and authorized public chartering agency of a given school to eliminate unnecessary duplication of oversight activities. That commenter noted that high-quality charter school authorizers should already be conducting some level of operational and fiscal oversight of such entities. Two commenters suggested that the Department require subgrantee monitoring review teams to include at least one reviewer representative from the traditional school district in the community.

Discussion: The purpose of this requirement is to ensure that CSP State entity grantees implement high-quality compliance monitoring reviews that address and mitigate subgrantee risk. We also recognize that, in many instances, charter school authorizers are required to monitor and oversee the charter schools they authorize for operational and fiscal management and agree that such monitoring and oversight should be conducted widely across all authorized public chartering agencies in tandem with State entity subgrantee monitoring. It should be noted, however, that charter school authorizers generally monitor their charter schools for compliance with the terms of the charter, which may include compliance with State and Federal laws, while State entity grantees are responsible for monitoring their subgrantees to ensure compliance with CSP requirements. Nevertheless, the Department agrees with this recommendation and deems such collaboration between charter school authorizers and State entity grantees to be a best practice for ensuring the quality and effectiveness of CSP grants and subgrants. We do not, however, agree with the recommendation to require State entity grantees to include at least one representative from a traditional school district on the monitoring review team for the charter school as the district representative would not necessarily have the expertise to ensure compliance with CSP requirements; therefore, we decline to make this change.

Changes: We added a reference to ''subgrant activities'' to the introductory paragraph and, to avoid duplication, removed the prior paragraph (d) regarding monitoring for progress and compliance. We added paragraph (h) that requires applicants for State Entity Grants to describe how they will work with authorized public chartering agencies to share information regarding the monitoring of subgrantees, including in areas related to fiscal protocols and organizational governance, for the purpose of reducing the reporting burden on charter schools.

Requirement 5 for State Entity Grants

Comments: None.

Changes: None.

Requirement 6 for State Entity Grants

For comments, discussion, and changes applicable to this requirement, see the above discussions for *Priority 1—Promoting High-Quality Educator- and Community-Centered Charter Schools to Support Underserved Students* and *Priority 2—Charter School and Traditional Public School or District Collaborations that Benefit Students and Families,* which establish priorities for CMO Grants and Developer Grants that are parallel to what a State entity prioritizes and encourages under this requirement when awarding subgrants.

Assurances Applicable to State Entity Grants, CMO Grants, and Developer Grants

Assurance (a) for State Entity Grants, CMO Grants, and Developer Grants

Comments: None.

Changes: We added a parenthetical to Assurance (a) to clarify that State entity and CMO grantees must ensure that charter schools that they fund meet the requirement.

Assurance (b) for State Entity Grants, CMO Grants, and Developer Grants

Comments: None.

Changes: We added a parenthetical to Assurance (b) to clarify that State entity and CMO grantees must ensure that charter schools that they fund meet the requirement.

Assurance (c) for State Entity Grants, CMO Grants, and Developer Grants

For comments, discussion, and changes applicable to this assurance, see the above discussion for *Requirement 2 for CMO Grants and Developer Grants,* which include parallel requirements within the context of those programs.

Assurance (d) for State Entity Grants, CMO Grants, and Developer Grants

Comments: None.

Changes: We added a parenthetical to Assurance (d) to clarify that State entity and CMO grantees must ensure that charter schools that they fund meet the requirement.

Assurance (e) for State Entity Grants, CMO Grants, and Developer Grants

Comments: One commenter expressed support for Assurance (e), which requires CMO Grant and Developer Grant applicants, and subgrant applicants under the State Entity Grant program, to provide an assurance that they (or, in the case of an applicant for a CMO Grant, each charter school it proposes to fund) will hold or participate in a public hearing in the community where the charter school will be located to obtain information and feedback regarding the potential impact of the charter school, including the steps the applicant has taken or will take to ensure that the proposed charter school would not negatively affect any desegregation efforts in the public school districts from which students would be drawn to attend the charter school and to ensure that the proposed charter school would not otherwise increase racial or socioeconomic segregation or isolation in such schools.

However, the commenter recommended that the Department modify the language to expand the focus of such public hearing to include multiple topics relevant to the affected community. The commenter expressed concern that the assurance language, as written, is too restrictive regarding the nature of the public hearings and the topics that must be covered.

Discussion: The main purposes of Assurance (e) are to ensure transparency regarding the creation, replication, and expansion of proposed charter schools and to ensure that the applicant engages the community in the planning and implementation of CSP-funded charter schools. The assurance requires the applicant to obtain ''information and feedback'' from the community regarding the potential impact of the charter school. The applicant must also obtain information and feedback regarding the steps it has taken or will take to ensure that the proposed charter school does not negatively affect any desegregation efforts or otherwise increase racial or socioeconomic segregation or isolation in the public school districts from which students are, or would be, drawn to attend the charter school. We agree with the commenter that the hearing, which may take place as part of or concurrent with a public hearing in which the applicant participates or conducts for other purposes (*e.g.,* as part of a pre-opening requirement of a charter school authorizer or under State-law), also should cover other topics related to the charter school project that are of interest to the community.

Changes: We added a parenthetical to Assurance (e) to clarify that State entity and CMO grantees must ensure that charter schools that they fund meet the requirement. We also modified Assurance (e) to specify that the public hearing must include a discussion of how the proposed charter school will increase the availability of high-quality public school options for traditionally underserved students in the local community in which the charter school would be located; promote racial and socio-economic diversity in such community, be located in a racially or socio-economically segregated of isolated community, have a specific educational mission, for example, serving targeted underserved students; and not increase racial or socio-economic segregation or isolation in the school districts from which students would be drawn to attend the charter school.

Assurance (f) for State Entity Grants, CMO Grants, and Developer Grants

Comments: Some commenters expressed support for Assurance (f), which requires State Entity, CMO Grant, and Developer Grant applicants, and subgrant applicants under the State Entity Grant program, to provide an assurance that they will not use or provide CSP ''implementation'' funds for a charter school until after the charter school has received a charter from an authorized public chartering agency and has obtained a facility in which to operate. One commenter recommended that we keep the assurance but clarify its purpose. Another commenter noted the significance of the assurance to prevent waste, fraud, and abuse under the CSP and provided statistics regarding the percentage of previous recipients of CSP ''planning'' funds between 2006 and 2015 that never opened the proposed charter school and the number of charter schools that opened and received CSP funds but have since closed. Another commenter recommended imposing a spending cap on the use of implementation funds before a prospective new charter school is authorized or secures a facility, rather than prohibiting the use of CSP funds if these milestones are not met right away. Similarly, several other commenters recommended imposing a $10,000 cap on the amount of CSP funds an applicant may use for planning purposes and releasing the remaining planning funds when the charter is approved. Another commenter supported continuing to allow funds for planning and program design to be provided to applicants even if they have not yet secured a facility given the challenges many charter schools face when trying to obtain a new site in various communities.

A number of commenters strongly opposed Assurance (f), citing concerns that the assurance will create a standard that is very difficult for CMO Grant applicants to meet. The commenters stated that research indicates that it sometimes takes up to 5 years for a new charter school to gain approval and, thus, a CMO Grant applicant might have to wait several years before they are eligible to apply for CSP funding.

Discussion: Under section 4310(6) of the ESEA, a charter school developer that has applied to an authorized public chartering agency for approval to operate a charter school is eligible to apply for a CSP grant or subgrant, even if the developer has not yet received an approved charter or secured a facility. Under the CSP, planning funds may be used to cover post-award costs associated with planning and designing the educational program of the charter school before it opens, and implementation funds are used to cover costs associated with the initial implementation of the charter school after it opens. Planning funds can be used, for example, for hiring and compensating teachers, school leaders, and specialized instructional support personnel; providing training and professional development to staff; or other critical activities that need to occur prior to opening. The CSP statute limits grantees and subgrantees to no more than 18 months for planning activities. Assurance (f) requires State Entity Grant, CMO Grant, and Developer Grant applicants, and subgrant applicants under the State Entity Grant program, to provide an assurance that they will not use CSP ''implementation'' funds for a charter school until after the charter school has received a charter from an authorized public chartering agency and has obtained a facility in which to operate. Assurance (f) is consistent with how previous administrations have addressed this issue by distinguishing between planning funds and implementation funds and restricting the use of implementation funds to costs related to operating the charter school. As stated above, a CSP applicant may receive ''planning'' funds before charter approval is obtained or a facility is secured. Assurance (f) does not restrict the use of planning funds beyond what is prescribed in the statute, but rather, is intended to clarify expectations for charter school developers to obtain charter approval and secure a facility during the 18-month planning period of the grant or subgrant. We also believe this assurance will help to mitigate the risk of CSP implementation funds being used to support charter schools that never open because the charter was not approved or the applicant was unable to secure a facility in a timely manner. The Department recognizes that the charter approval process may exceed the 18-month planning period for CSP grants and subgrants, as prescribed under section 4303(d)(1)(B) of the ESEA. In such a case, applicants may request approval from the Department or the State entity to amend their application to request an extension of the 18-month planning period. Under section 4303(d)(5) of the ESEA, the Secretary, in his discretion, may waive any statutory or regulatory requirement over which he exercises administrative authority, except the requirements related to the definition of ''charter school'' in section

4310(2), provided that the waiver is requested in an approved application and the Secretary determines that granting the waiver will promote the purposes of the CSP. It is also worth noting that a grantee may request approval from the Department, and a State entity subgrantee may request approval from the State entity, to amend its approved application and budget to cover additional planning costs that it may incur due to an unexpected delay in the charter approval process or for other reasons.

Changes: We amended Assurance (f) to remove the requirement that applicants provide an assurance that they will not ''use or provide'' implementation funds for a charter school until after the eligible applicant has received an approved charter and secured a facility, so that applicants are required only to provide an assurance that they will not ''use'' implementation funds prior to receiving an approved charter and securing a facility. We also added a parenthetical to clarify that State entity and CMO grantees must ensure that charter schools that they fund meet the requirement. Additionally, we added language specifying some of the allowable uses of planning funds, stating that consistent with sections 4303(b)(1), 4303(h)(1)(B), and 4310(6) of the ESEA, an eligible applicant may use CSP planning funds for post-award planning and design of the educational program of a proposed new or replicated high-quality charter school that has not yet opened, which may include hiring and compensating teachers, school leaders, and specialized instructional support personnel; providing training and professional development to staff; and other critical planning activities that need to occur prior to the charter school opening when such costs cannot be met from other sources.

Assurance Applicable to State Entity Grants and CMO Grants

Comments: One commenter expressed support for the assurance that requires State entity and CMO grantees, and subgrantees under the State Entity Grant program, to post specific information regarding the proposed charter schools on their respective websites within 30 days of receiving the grant or subgrant award notification. The commenter recommended changing the time limit to 120 days to align with the timing of grant administration activities by the Department and the multi-year way that CMO grantees make decisions about where to allocate funds to individual charter schools. The same commenter recommended revising the assurance to require State Entity Grant and CMO Grant applicants to assure that they will update annually the list of charter schools slated to receive CSP funds, including charter schools that have been approved to receive CSP planning funds but do not yet have a campus or facility identified.

Discussion: We agree that a 120-day time limit would allow more efficient timing for award recipients to post the required information on their websites after making decisions about how to allocate their grant funds. We also agree that CMO grantees should update their lists of charter schools approved to receive CSP funding at least once per year. In addition, we believe CMO grantees should be transparent regarding the anticipated number of charter schools likely to receive CSP planning funds prior to having a facility or campus identified. Since the assurance requires State entity grantees to post information regarding the subgrants they award after each local subgrant competition, depending on the number of subgrant competitions a State entity holds during the year, the State entity could be required to post such information more frequently than once a year.

Changes: We deleted the reference to ''subgrantee'' so that only State entity and CMO grantees are required to post the required information regarding the charter schools funded under their grants, since subgrantees are unlikely to have access to the required information for all subgrants awarded by the State entity. We increased from 30 days to 120 days after award notification the time period within which State Entity Grant and CMO Grant recipients must post the required information on their websites. We also added a paragraph (b) to this assurance that requires CMO applicants to assure that they will update their lists of charter schools that have been approved for funding at least annually and include on the list the charter schools that will receive CSP planning funds prior to securing a facility. Finally, in paragraph (a)(6), we added the phrase, ''For State entity grantees,'' and deleted ''grant or'' from the phrase, ''grant or subgrant,'' to clarify that only State entity grantees are required to post peer review materials on their website since CMO grantees do not hold local subgrant competitions. The Department posts such information regarding CMO Grants on the CSP website.

Selection Criteria Applicable to CMO Grants and Developer Grants

Comments: We received relatively few comments that addressed the selection criteria or that provided specific recommendations for changes; however, of the comments received, most offered general support for the proposed selection criteria. One commenter who expressed support for the selection criteria specifically noted the focus on requiring applicants for State Entity Grants to address how they will estimate the number of subgrants they intend to provide.

Discussion: We agree with the one commenter that it is important to hold applicants accountable for providing realistic estimates of the number of subgrants they plan to award. The selection criteria are designed to provide peer reviewers with clear and measurable parameters to identify the best quality applications that are most likely to succeed in supporting the development and implementation of high-quality charter schools, and that are driven by the needs of families and their communities. We revise the Quality of Needs Analysis criterion to align with the revisions made to the needs analysis requirement and its emphasis on ensuring that an applicant's needs analysis demonstrates a clear need for the proposed charter school.

Changes: We changed the title of the Quality of the Community Impact Analysis criterion to Quality of Needs Analysis to align with corresponding changes to the Needs Analysis application requirements and assurance. We also revised the third subpart of Quality of Needs Analysis a(1), replacing ''and will not otherwise increase racial or socio-economic segregation or isolation in the schools from which the students are, or would be, drawn to attend the charter school'' to ''demonstrates sufficient demand for the charter school.''

Definitions Applicable to State Entity Grants, CMO Grants, and Developer Grants

Comments: A few commenters recommended that the Department establish definitions for ''diverse,'' ''racial isolation,'' and ''substantial.'' Similarly, a commenter stated that because the term ''racial isolation'' is not defined in the notice, applicants may have difficulty determining whether a school is segregated under Requirement 1 applicable to CMO Grants and Developer Grants and Requirement 1 applicable to State Entity Grants. Some commenters also expressed support for providing a definition for ''community asset,'' noting that many stakeholders believe a community-centered approach is

necessary to ensure quality charter school authorizing.

Discussion: We understand that the meanings of the terms ''diverse,'' ''racial isolation,'' and ''substantial'' are somewhat broad. Because of the universal nature of these terms, however, we do not believe it is necessary to define them. For these reasons, we decline to define ''diverse,'' ''racial isolation,'' and ''substantial.'' The definition for the term ''community assets'' that was proposed in the NPP is included in the final Definitions applicable to State Entity Grants, CMO Grants, and Developer Grants.

Changes: To simplify the definition of ''community assets'' we removed the reference to ''political assets''. FINAL PRIORITIES, REQUIREMENTS, DEFINITIONS, AND SELECTION CRITERIA: The Department establishes the following priorities, requirements, definitions, and selection criteria for use in any future CSP grant competitions.

Final Priorities

Priorities Applicable to CMO Grants and Developer Grants

Priority 1—Promoting High-Quality Educator- and Community-Centered Charter Schools to Support Underserved Students.

(a) Under this priority, an applicant must propose to open a new charter school, or to replicate or expand a high-quality charter school, that is developed and implemented—

(1) With meaningful and ongoing engagement with current or former teachers and other educators; and

(2) Using a community-centered approach that includes an assessment of community assets, informs the development of the charter school, and includes the implementation of protocols and practices designed to ensure that the charter school will use and interact with community assets on an ongoing basis to create and maintain strong community ties.

(b) In its application, an applicant must provide a high-quality plan that demonstrates how its proposed project would meet the requirements in paragraph (a) of this priority, accompanied by a timeline for key milestones that span the course of planning, development, and implementation of the charter school.

Priority 2—Collaborations between Charter Schools and Traditional Public Schools or Districts that Benefit Students and Families across Schools.

(a) Under this priority, an applicant must propose a new collaboration, or the continuation of an existing collaboration, with at least one traditional public school or traditional school district that is designed to benefit students or families served by at least one member of the collaboration, is designed to lead to increased or improved educational opportunities for students served by at least one member of the collaboration, and includes implementation of one or more of the following—

(1) Co-developed or shared curricular and instructional resources or academic course offerings.

(2) Professional development opportunities for teachers and other educators, which may include professional learning communities, opportunities for teachers to earn additional certifications, such as in a high-need area or national board certification, and partnerships with educator preparation programs to support teaching residencies.

(3) Evidence-based (as defined in section 8101 of the ESEA) practices to improve academic performance for underserved students.

(4) Policies and practices to create safe, supportive, and inclusive learning environments, such as systems of positive behavioral intervention and support.

(5) Transparent enrollment and retention practices and processes that include clear and consistent disclosure to families of policies or requirements (*e.g.,* discipline policies, purchasing and wearing specific uniforms and other fees, or family participation), and any services that are or are not provided, that could impact a family's ability to enroll or remain enrolled in the school (*e.g.,* transportation services or participation in the National School Lunch Program).

(6) A shared transportation plan and system that reduces transportation costs for at least one member of the collaboration and takes into consideration various transportation options, including public transportation and district-provided or shared transportation options, cost-sharing or free or reduced-cost fare options, and any distance considerations for prioritized bus services.

(7) A shared special education collaborative designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in improving academic and developmental outcomes and services for students with disabilities (as defined in section 8101 of the ESEA);

(8) A shared English learner (as defined in section 8101 of the ESEA) collaborative designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in providing educational programs to improve academic outcomes for English learners;

(9) Other collaborations, such as the sharing of innovative and best practices, designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in providing educational programs to improve academic outcomes for all students served by members of the collaboration.

(b) In its application, an applicant must provide a description of the collaboration that—

(1) Describes each member of the collaboration and whether the collaboration would be a new or existing commitment;

(2) States the purpose and duration of the collaboration;

(3) Describes the anticipated roles and responsibilities of each member of the collaboration) ;

(4) Describes how the collaboration will benefit one or more members of the collaboration, including how it will benefit students or families affiliated with a member and lead to increased educational opportunities for students, and meet specific and measurable, if applicable, goals;

(5) Describes the resources members of the collaboration will contribute; and

(6) Contains any other relevant information.

(c) Within 120 days of receiving a grant award or within 120 days of the date the collaboration is scheduled to begin, whichever is later, provide evidence of participation in the collaboration (which may include, but is not required to include, an MOU).

Types of Priorities

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

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)). Depending on the grant competition, applicants may have the option to choose one or more of several absolute priorities.

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit

that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

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

Final Application Requirements

Requirements Applicable to CMO Grants and Developer Grants

Requirement 1:

Each applicant must provide a needs analysis and describe the need for the proposed project, including how the proposed project would serve the interests and meet the needs of students and families in the communities the charter school intends to serve. The needs analysis, which may consist of information and documents previously submitted to an authorized public chartering agency to address need, must include, but is not necessarily limited to, the following:

(a) Descriptions of the local community support, including information that demonstrates interest in, and need for, the charter school; benefits to the community; and other evidence of demand for the charter school that demonstrates a strong likelihood the charter school will achieve and maintain its enrollment projections. Such information may include information on waiting lists for the proposed charter school or existing charter schools or traditional public schools; data on access to seats in high-quality public schools in the districts from which the charter school expects to draw students; or evidence of family interest in specialized instructional approaches proposed to be implemented at the charter school.

(b) Information on the proposed charter school's projected student enrollment, and evidence to support the projected enrollment based on the needs analysis and other relevant data and factors, such as the methodology and calculations used.

(c) An analysis of the proposed charter school's projected student demographics and a description of the demographics of students attending public schools in the local community in which the proposed charter school would be located and the school districts from which students are, or would be, drawn to attend the charter school; a description of how the applicant plans to establish and maintain a racially and socio-economically diverse student body, including proposed strategies (that are consistent with applicable legal requirements) to recruit, admit, enroll, and retain a diverse student body. An applicant that is unlikely to establish and maintain a racially and socio-economically diverse student body at the proposed charter school because the charter school would be located in a racially or socio-economically segregated or isolated community, or due to the charter school's specific educational mission, must describe—

(i) why it is unlikely to establish and maintain a racially and socio-economically diverse student body at the proposed charter school;

(ii) how the anticipated racial and socio-economic makeup of the student body would promote the purposes of the CSP, including to provide high-quality educational opportunities to underserved students, which may include a specialized educational program or mission; and

(iii) the anticipated impact of the proposed charter school on the racial and socio-economic diversity of the public schools and school districts from which students would be drawn to attend the charter school.

(d) A robust family and community engagement plan designed to ensure the active participation of families and the community that includes the following:

(1) How families and the community were, are, or will be engaged in determining the vision and design for the charter school, including specific examples of how families' and the community's input was, is, or is expected to be incorporated into the vision and design for the charter school.

(2) How the charter school will meaningfully engage with both families and the community to create strong and ongoing partnerships.

(3) How the charter school will foster a collaborative culture that involves the families of all students, including underserved students, in ensuring their ongoing input in school decision-making.

(4) How the charter school's recruitment, admissions, enrollment, and retention policies and practices will engage and accommodate students and families from diverse backgrounds, including English learners, students with disabilities, and students of color, including holding enrollment and recruitment events on weekends or during non-standard work hours, making interpreters available, and providing enrollment and recruitment information in widely accessible formats (*e.g.,* hard copy and online in multiple languages; as appropriate, large print or braille for visually-impaired individuals) through widely available and transparent means (*e.g.,* online and at community locations).

(5) How the charter school has engaged or will engage families and the community to develop an instructional model to best serve the targeted student population and their families, including students with disabilities and English learners.

(e) How the plans for the operation of the charter school will support and reflect the needs of students and families in the community, including consideration of district or community assets and how the school's location, or anticipated location if a facility has not been secured, will facilitate access for the targeted student population (*e.g.,* access to public transportation or other transportation options, the demographics of neighborhoods within walking distance of the school, and transportation plans and costs for students who are not able to walk or use public transportation to access the school).

(f) A description of the steps the applicant has taken or will take to ensure that the proposed charter school (1) would not hamper, delay, or negatively affect any desegregation efforts in the local community in which the charter school would be located or in the public school districts from which students are, or would be, drawn to attend the charter school, including efforts to comply with a court order, statutory obligation, or voluntary efforts to create and maintain desegregated public schools,; and (2) to ensure that the proposed charter school would not otherwise increase racial or socio-economic segregation or isolation in the schools from which the students are, or would be, drawn to attend the charter school.

Requirement 2:

For any existing or proposed contract with a for-profit management organization (including a nonprofit management organization operated by or on behalf of a for-profit entity), without regard to whether the management organization or its related entities exercise full or substantial administrative control over the charter school or the CSP project, the applicant must provide the following information or equivalent information that the applicant has submitted to the authorized public chartering agency—

(a) A copy of the existing contract with the for-profit management organization or a description of the terms of the contract, including the name and contact information of the management organization; the cost (*i.e.,* fixed costs and estimates of any ongoing costs), including the amount of CSP

funds proposed to be used toward such cost, and the percentage such cost represents of the school's total funding; the duration; roles and responsibilities of the management organization; and steps the applicant will take to ensure that it pays fair market value for any services or other items purchased or leased from the management organization, makes all programmatic decisions, maintains control over all CSP funds, and directly administers or supervises the administration of the grant in accordance with 34 CFR 75.701;

(b) A description of any business or financial relationship between the charter school developer and the management organization, including payments, contract terms, and any property owned, operated, or controlled by the management organization or related individuals or entities that will be used by the charter school;

(c) The name and contact information for each member of the governing board of the charter school and list of the management organization's officers, chief administrator, and other administrators, and any staff involved in approving or executing the management contract; and a description of any actual or perceived conflicts of interest, including financial interests, and how the applicant resolved or will resolve any actual or perceived conflicts of interest to ensure compliance with 2 CFR 200.318(c);

(d) A description of how the applicant will ensure that members of the governing board of the charter school are not selected, removed, controlled, or employed by the management organization and that the charter school's legal, accounting, and auditing services will be procured independently from the management organization;

(e) An explanation of how the applicant will ensure that the management contract is severable, severing the management contract will not cause the proposed charter school to close, the duration of the management contract will not extend beyond the expiration date of the school's charter, and renewal of the management contract will not occur without approval and affirmative action by the governing board of the charter school; and

(f) A description of the steps the applicant will take to ensure that it maintains control over all student records and has a process in place to provide those records to another public school or school district in a timely manner upon the transfer of a student from the charter school to another public school, including due to closure of the charter school, in accordance with section 4308 of the ESEA.

Requirement 3:

(a) Each applicant must provide—

(1) The name and address of the authorized public chartering agency that issued the applicant's approved charter or, in the case of an applicant that has not yet received an approved charter, the authorized public chartering agency to which the applicant has applied;

(2) A copy of the approved charter or, in the case of an applicant that has not yet received an approved charter, a copy of the charter application that was submitted to the authorized public chartering agency, including the date the application was submitted, and an estimated date by which the authorized public chartering agency will issue its final decision on the charter application;

(3) Documentation that the applicant has provided notice to the authorized public chartering agency that it has applied for a CSP grant; and

(4) A proposed budget, including a detailed description of any post-award planning costs and, for an applicant that does not yet have an approved charter, any planning costs expected to be incurred prior to the date the authorized public chartering agency issues a decision on the charter application.

Requirements Applicable to State Entity Grants

Requirement 1:

Each applicant must certify that it will require each subgrant applicant to provide a needs analysis and describe in its subgrant application the need for the proposed project, including how the proposed project would serve the interests and meet the needs of students and families in the communities the charter school intends to serve. The needs analysis, which may consist of information and documents previously submitted to an authorized public chartering agency to address need, must include, but is not necessarily limited to, the following:

(a) Descriptions of the local community support, including information that demonstrates interest in, and need for, the charter school; benefits to the community; and other evidence of demand for the charter school that demonstrates a strong likelihood the charter school will achieve and maintain its enrollment projections. Such information may include information on waiting lists for the proposed charter school or existing charter schools or traditional public schools; data on access to seats in high-quality public schools in the districts from which the charter school expects to draw students; or evidence of family interest in specialized instructional approaches proposed to be implemented at the charter school.

(b) Information on the proposed charter school's projected student enrollment, and evidence to support the projected enrollment based on the needs analysis and other relevant data and factors, such as the methodology and calculations used.

(c) An analysis of the proposed charter school's projected student demographics and a description of the demographics of students attending public schools in the local community in which the proposed charter school would be located and the school districts from which students are, or would be, drawn to attend the charter school; a description of how the applicant plans to establish and maintain a racially and socio-economically diverse student body, including proposed strategies (that are consistent with applicable legal requirements) to recruit, admit, enroll, and retain a diverse student body. An applicant that is unlikely to be able to establish and maintain a racially and socio-economically diverse student body at the proposed charter school because the charter school would be located in a racially or socio-economically segregated or isolated community, or due to the charter school's specific educational mission must describe—

(i) why it is unlikely to establish and maintain a racially and socio-economically diverse student body at the proposed charter school;

(ii) How the anticipated racial and socio-economic makeup of the student body would promote the purposes of the CSP, including to provide high-quality educational opportunities to underserved students, which may include a specialized educational program or mission; and

(iii) The anticipated impact of the proposed charter school on the racial and socio-economic diversity of the public schools and school districts from which students would be drawn to attend the charter school.

(d) A robust family and community engagement plan designed to ensure the active participation of families and the community that includes the following:

(1) How families and the community were, are, or will be engaged in determining the vision and design for the charter school, including specific examples of how families' and the community's input was, is, or is expected to be incorporated into the vision and design for the charter school.

(2) How the charter school will meaningfully engage with both families

and the community to create strong and ongoing partnerships.

(3) How the charter school will foster a collaborative culture that involves the families of all students, including underserved students, in ensuring their ongoing input in school decision-making.

(4) How the charter school's recruitment, admissions, enrollment, and retention policies and practices will engage and accommodate students and families from diverse backgrounds, including English learners, students with disabilities, and students of color, including by holding enrollment and recruitment events on weekends or during nonstandard work hours, making interpreters available, and providing enrollment and recruitment information in widely accessible formats (*e.g.,* hard copy and online in multiple languages; as appropriate, large print or braille for visually-impaired individuals) through widely available and transparent means (*e.g.,* online and at community locations).

(5) How the charter school has engaged or will engage families and the community to develop an instructional model to best serve the targeted student population and their families, including students with disabilities and English learners.

(e) How the plans for the operation of the charter school will support and reflect the needs of students and families in the community, including consideration of district or community assets and how the school's location, or anticipated location if a facility has not been secured, will facilitate access for the targeted student population (*e.g.,* access to public transportation or other transportation options, the demographics of neighborhoods within walking distance of the school, and transportation plans and costs for students who are not able to walk or use public transportation to access the school).

(f) A description of the steps the applicant has taken or will take to ensure that the proposed charter school would not hamper, delay, or negatively affect any desegregation efforts in the public school districts from which students are, or would be, drawn or in which the charter school is or would be located, including efforts to comply with a court order, statutory obligation, or voluntary efforts to create and maintain desegregated public schools, and that it would not otherwise increase racial or socio-economic segregation or isolation in the schools from which the students are, or would be, drawn to attend the charter school.

Requirement 2:

For any existing or proposed contract between a charter school and a for-profit management organization (including a nonprofit management organization operated by or on behalf of a for-profit entity), without regard to whether the management organization or its related entities exercise full or substantial administrative control over the charter school or the CSP project, each applicant must certify that it will require subgrant applications to include the following information or equivalent information that the applicant has submitted to the authorized public chartering agency—

(a) A copy of the existing contract with the for-profit management organization or a description of the terms of the contract, including the name and contact information of the management organization; the cost (*i.e.,* fixed costs and estimates of any ongoing costs), including the amount of CSP funds proposed to be used toward such cost, and the percentage such cost represents of the school's overall funding; the duration; roles and responsibilities of the management organization; and steps the applicant will take to ensure that it pays fair market value for any services or other items purchased or leased from the management organization, makes all programmatic decisions, maintains control over all CSP funds, and directly administers or supervises the administration of the grant in accordance with 34 CFR 75.701;

(b) A description of any business or financial relationship between the charter school developer and the management organization, including payments, contract terms, and any property owned, operated, or controlled by the management organization or related individuals or entities that will be used by the charter school;

(c) The name and contact information for each member of the governing board of the charter school and a list of the management organization's officers, chief administrator, other administrators, and any staff involved in approving or executing the management contract; and a description of any actual or perceived conflicts of interest, including financial interests, and how the applicant resolved or will resolve any actual or perceived conflicts of interest to ensure compliance with 2 CFR 200.318(c);

(d) A description of how the applicant will ensure that members of the governing board of the charter school are not selected, removed, controlled, or employed by the management organization and that the charter school's legal, accounting, and auditing services will be procured independently from the management organization;

(e) An explanation of how the applicant will ensure that the management contract is severable, severing the management contract will not cause the proposed charter school to close, the duration of the management contract will not extend beyond the expiration date of the school's charter, and renewal of the management contract will not occur without approval and affirmative action by the governing board of the charter school; and

(f) A description of the steps the applicant will take to ensure that it maintains control over all student records and has a process in place to provide those records to another public school or school district in a timely manner upon the transfer of a student from the charter school to another public school, including due to closure of the charter school, in accordance with section 4308 of the ESEA.

Requirement 3:

Each applicant must provide a detailed description of how it will review applications from eligible applicants, including—

(a) How eligibility will be determined;

(b) How peer reviewers will be recruited and selected, including efforts the applicant will make to recruit peer reviewers from diverse backgrounds and underrepresented groups;

(c) How subgrant applications will be reviewed and evaluated;

(d) How cost analyses and budget reviews will be conducted to ensure that costs are necessary, reasonable, and allocable to the subgrant;

(e) How applicants will be assessed for risk (*i.e.,* fiscal, programmatic, and compliance); and

(f) How funding decisions will be made.

Requirement 4:

Each applicant must provide a detailed description, including a timeline, of how the State entity will monitor subgrant activities and report on subgrant performance in accordance with 2 CFR 200.329, and address and mitigate subgrantee risk, including—

(a) How subgrantees will be selected for in-depth monitoring, including factors that indicate higher risk (*e.g.,* charter schools that have management contracts with for-profit management organizations, virtual charter schools, and charter schools with a history of poor performance);

(b) How identified subgrantee risk will be addressed;

(c) How subgrantee expenditures will be monitored;

(d) How monitors will be trained;

(e) How monitoring findings will be shared with subgrantees;

(f) How corrective action plans will be used to resolve monitoring findings;

(g) How the State entity will ensure transparency so that monitoring findings and corrective action plans are available to families and the public; and

(h) How the State entity will work with authorized public chartering agencies to share information regarding the monitoring of subgrantees, including in areas related to fiscal protocols and organizational governance, for the purpose of reducing the reporting burden on charter schools.

Requirement 5:

Each applicant must provide evidence to support the requested funds and projected enrollment, such as explanations for the methodology and calculations.

Requirement 6:

Each applicant must describe how, in awarding subgrants to eligible applicants, the State entity will—

(a)(1) Give priority to eligible applicants that propose projects that include the creation, replication, or expansion of a high-quality charter school that is developed and implemented—

(i) With meaningful and ongoing engagement with current or former teachers and other educators; and

(ii) Using a community-centered approach that includes an assessment of community assets, informs the development of the charter school, and includes the implementation of protocols and practices designed to ensure that the charter school will use and interact with community assets on an ongoing basis to create and maintain strong community ties.

(2) In its application, an applicant must provide a high-quality plan that demonstrates how its proposed project would meet the requirements in paragraph (a)(1) of this priority, accompanied by a timeline for key milestones that span the course of planning, development, and implementation of the charter school.

(b)(1) Encourage, but not require, eligible applicants to propose projects that include a new collaboration, or the continuation of an existing collaboration, with at least one traditional public school or traditional school district that is designed to benefit students or families served by at least one member of the collaboration, is designed to lead to increased and improved educational opportunities for students served by at least one member of the collaboration, and includes implementation of one or more of the following—

(i) Co-developed or shared curricular and instructional resources or academic course offerings.

(ii) Professional development opportunities for teachers and other educators, which may include professional learning communities, opportunities for teachers to earn additional certifications, such as in a high-need area or national board certification, and partnerships with educator preparation programs to support teaching residencies.

(iii) Evidence-based (as defined in section 8101(21) of the ESEA) practices to improve academic performance for underserved students.

(iv) Policies and practices to create safe, supportive, and inclusive learning environments, such as systems of positive behavioral intervention and support.

(v) Transparent enrollment and retention practices and processes that include clear and consistent disclosure to families of policies or requirements (*e.g.,* discipline policies, purchasing and wearing specific uniforms and other fees, or family participation), and any services that are or are not provided that could impact a family's ability to enroll or remain enrolled (*e.g.,* transportation services or participation in the National School Lunch Program).

(vi) A shared transportation plan and system that reduces transportation costs for members of the collaboration and takes into consideration various transportation options, including public transportation and district-provided or shared transportation options, cost-sharing or free or reduced-cost fare options, and any distance considerations for prioritized bus services.

(vii) A shared special education collaborative designed to address a significant barrier or challenge faced by participating charter schools and traditional public schools in improving academic or developmental outcomes and services for students with disabilities (as defined in section 8101 of the ESEA);

(viii) A shared English learner collaborative designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools in improving academic outcomes for English learners (as defined in section 8101 of the ESEA); or

(ix) Other collaborations, such as the sharing of innovative and best practices, designed to address a significant barrier or challenge faced by participating charter schools or traditional public schools and designed to improve academic outcomes for all students served by members of the collaboration.

(2) The State entity must certify that it will ask each eligible applicant that proposes a project that includes such a collaboration to—

(A) Provide in its subgrant application a description of the collaboration that—

(i) Describes each member of the collaboration and whether the collaboration would be a new or existing commitment;

(ii) States the purpose and duration of the collaboration;

(iii) Describes the anticipated roles and responsibilities of each member of the collaboration;

(iv) Describes how the collaboration will benefit one or more members of the collaboration, including how it will benefit students or families affiliated with a member and lead to increased or improved educational opportunities for students, and meet specific and measurable, if applicable, goals;

(v) Describes the resources members of the collaboration will contribute; and

(vi) Contains any other relevant information; and

(B) Within 120 days of receiving a subgrant award or within 120 days of the date the collaboration is scheduled to begin, whichever is later, provide evidence of participation in the collaboration (which may include, but is not required to include, an MOU).

Final Assurances

Assurances Applicable to State Entity Grants, CMO Grants, and Developer Grants:

(a) Each applicant for a State Entity Grant, CMO Grant, or Developer Grant must provide an assurance that it (or, in the case of an applicant for a State Entity Grant or CMO Grant, each charter school that it funds) has not and will not enter into a contract with a for-profit management organization, including a nonprofit management organization operated by or on behalf of a for-profit entity, under which the management organization, or its related entities, exercises full or substantial administrative control over the charter school and, thereby, the CSP project.

(b) Each applicant for a State Entity Grant, CMO Grant, or Developer Grant must provide an assurance that any management contract between the charter school (or, in the case of an applicant for a State Entity Grant or CMO Grant, each charter school that it funds) and a for-profit management organization, including a nonprofit CMO operated by or on behalf of a for-profit entity, guarantees or will guarantee that—

(1) The charter school maintains control over all CSP funds, makes all programmatic decisions, and directly administers or supervises the administration of the grant or subgrant;

(2) The management organization does not exercise full or substantial administrative control over the charter school (and, thereby, the CSP project), except that this does not limit the ability of a charter school to enter into a contract with a management organization for the provision of services that do not constitute full or substantial control of the charter school project funded under the CSP (*e.g.,* food or payroll services) and that otherwise comply with statutory and regulatory requirements;

(3) The charter school's governing board has access to financial and other data pertaining to the charter school, the management organization, and any related entities; and

(4) The charter school is in compliance with applicable Federal and State laws and regulations governing conflicts of interest, and there are no actual or perceived conflicts of interest between the charter school and the management organization.

(c) Each applicant for a State Entity Grant, CMO Grant, or Developer Grant must provide an assurance that it (or, in the case of an applicant for a State Entity Grant or CMO Grant, each charter school that it funds) will post on its website, on an annual basis, a copy of any management contract between the charter school and a for-profit management organization, including a nonprofit management organization operated by or on behalf of a for-profit entity, and report information on such contract to the Department (or, in the case of a charter school that receives CSP funding through a State Entity Grant, to the State Entity), including—

(1) A copy of the existing contract with the for-profit management organization or description of the terms of the contract, including the name and contact information of the management organization, the cost (*i.e.,* fixed costs and estimates of any ongoing costs), including the amount of CSP funds proposed to be used toward such costs, and the percentage such cost represents of the charter school's total funding, the duration, roles and responsibilities of the management organization, the steps the charter will take to ensure that it pays fair market value for any services or other items purchased or leased from the management organization, and the steps the charter school is taking to ensure that it makes all programmatic decisions, maintains control over all CSP funds, and directly administers or supervises the administration of the grant or subgrant in accordance with 34 CFR 75.701 and 76.701;

(2) A description of any business or financial relationship between the charter school developer or CMO and the management organization, including payments, contract terms, and any property owned, operated, or controlled by the management organization or related individuals or entities to be used by the charter school;

(3) The names and contact information for each member of the governing boards of the charter school, and a list of management organization's officers, chief administrator, and other administrators, and any staff involved in approving or executing the management contract; and a description of any actual or perceived conflicts of interest, including financial interests, and how the applicant resolved or will resolve any actual or perceived conflicts of interest to ensure compliance with 2 CFR 200.318(c); and

(4) A description of how the charter school ensured that such contract is severable and that a change in management companies will not cause the proposed charter school to close.

(d) Each applicant for a State Entity Grant, CMO Grant, or Developer Grant must provide an assurance that it (or, in the case of an applicant for a State Entity Grant or CMO Grant, each charter school that it funds) will disclose, as part of the enrollment process, any policies and requirements (*e.g.,* purchasing and wearing specific uniforms and other fees, or requirements for family participation), and any services that are or are not provided, that could impact a family's ability to enroll or remain enrolled in the school (*e.g.,* transportation services or participation in the National School Lunch Program).

(e) Each applicant for a State Entity Grant, CMO Grant, or Developer Grant must provide an assurance that it (or, in the case of an applicant for a State Entity Grant or CMO Grant, each charter school that it funds) will hold or participate in a public hearing in the local community in which the proposed charter school would be located to obtain information and feedback regarding the potential benefit of the charter school, which shall at least include how the proposed charter school will increase the availability of high-quality public school options for underserved students, promote racial and socio-economic diversity in such community or have an educational mission to serve primarily underserved students, and not increase racial or socio-economic segregation or isolation in the school districts from which students would be drawn to attend the charter school (consistent with applicable laws). Applicants must ensure that the hearing (and notice thereof) is accessible to individuals with disabilities and limited English proficient individuals as required by law, actively solicit participation in the hearing (*i.e.,* provide widespread and timely notice of the hearing), make good faith efforts to accommodate as many people as possible (*e.g.,* hold the hearing at a convenient time for families or provide virtual participation options), and submit a summary of the comments received as part of the application. The hearing may be conducted as part of the charter authorizing process, provided it meets the requirements above.

(f) Each applicant for a State Entity Grant, CMO Grant, or Developer Grant must provide an assurance that it (or, in the case of an applicant for a State Entity Grant or CMO Grant, any charter school that it funds) will not use any implementation funds for a charter school until after the charter school has received a charter from an authorized public chartering agency and has a contract, lease, mortgage, or other documentation indicating that it has a facility in which to operate. Consistent with sections 4303(b)(1), 4303(h)(1)(B), and 4310(6) of the ESEA, an eligible applicant may use CSP planning funds for post-award planning and design of the educational program of a proposed new or replicated high-quality charter school that has not yet opened, which may include hiring and compensating teachers, school leaders, and specialized instructional support personnel; providing training and professional development to staff; and other critical planning activities that need to occur prior to the charter school opening when such costs cannot be met from other sources.

Assurance Applicable to State Entity Grants and CMO Grants:

Each applicant must provide an assurance that, within 120 days of the date of the grant award notification (GAN), or the date of any subgrant award notifications for State Entity Grants, the grantee will post on its website:

(a) A list of the charter schools slated to receive CSP funds, including the following for each school:

(1) The name, address, and grades served.

(2) A description of the educational model.

(3) If the charter school has contracted with a for-profit management organization, the name of the management organization, the amount

of CSP funding the management organization will receive from the school, and a description of the services to be provided.

(4) The award amount, including any funding that has been approved for the current year and any additional years of the CSP grant for which the school will receive support.

(5) The grant or subgrant application (redacted as necessary).

(6) For State entity grantees, the peer review materials, including reviewer comments and scores (redacted as necessary) from the subgrant competition.

(b) As applicable for CMO grants, such a list must be updated at least annually and provide the anticipated number of charter schools that will receive CSP planning funds before securing a facility.

Final Definitions

Definitions Applicable to State Entity Grants, CMO Grants, and Developer Grants:

Community assets means resources that can be identified and mobilized to improve conditions in the charter school and local community. These assets may include—

(1) Human assets, including capacities, skills, knowledge base, and abilities of individuals within a community; and

(2) Social assets, including networks, organizations, businesses, and institutions that exist among and within groups and communities.

Disconnected youth means an individual, between the ages of 14 and 24, who may be from a low-income background, experiences homelessness, is in foster care, is involved in the justice system, or is not working or not enrolled in (or at risk of dropping out of) an educational institution.

Educator means an individual who is an early learning educator, teacher, principal or other school or district leader, specialized instructional support personnel (*e.g.,* school psychologist, counselor, school social worker, early intervention service personnel), paraprofessional, or faculty.

Underserved student means a student in one or more of the following subgroups:

(1) A student who is living in poverty or is served by schools with high concentrations of students living in poverty.

(2) A student of color.

(3) A student who is a member of a federally recognized Indian Tribe.

(4) An English learner (as defined in section 8101 of the ESEA).

(5) A child or student with a disability (as defined in section 8101 of the ESEA).

(6) A disconnected youth.

(7) A migrant student.

(8) A student experiencing homelessness or housing insecurity.

(9) A student who is in foster care.

(10) A pregnant, parenting, or caregiving student.

(11) A student impacted by the justice system, including a formerly incarcerated student.

(12) A student performing significantly below grade level.

Definitions Applicable to State Entity Grants:

Educationally disadvantaged student means a student in one or more of the categories described in section 1115(c)(2) of the ESEA, which include children who are economically disadvantaged, children with disabilities, migrant students, English learners, neglected or delinquent students, homeless students, and students who are in foster care.

Final Selection Criteria

Selection Criteria Applicable to CMO Grants and Developer Grants:

(a) *Quality of the Needs Analysis.* The Secretary considers the quality of the needs analysis for the proposed project. In determining the quality of the needs analysis, the Secretary considers one or more of the following factors:

(1) The extent to which the needs analysis demonstrates that the proposed charter school will address the needs of all students served by the charter school, including underserved students; will ensure equitable access to high-quality learning opportunities; and demonstrates sufficient demand for the charter school.

(2) The extent to which the needs analysis demonstrates that the proposed charter school has considered and mitigated, whenever possible, potential barriers to application, enrollment, and retention of underserved students and their families.

(3) The extent to which the proposed charter school is supported by families and the community, including the extent to which parents and other members of the community were engaged in determining the need and vision for the school and will continue to be engaged on an ongoing basis, including in the academic, financial, organizational, and operational performance of the charter school.

(b) *Quality of the Charter School's Management Plan.* The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan, the Secretary considers one or more of the following factors:

(1) The adequacy of the applicant's plan to maintain control over all CSP grant funds.

(2) The adequacy of the applicant's plan to make all programmatic decisions.

(3) The adequacy of the applicant's plan to administer or supervise the administration of the grant, including maintaining management and oversight responsibilities over the grant.

Selection Criterion Applicable to State Entity Grants:

(a) *Quality of the Project Design.* The Secretary considers the quality of the project design for the proposed project. In determining the quality of the project design for the proposed project, the Secretary considers the quality of the State Entity's process for awarding subgrants, including—

(1) The extent to which the projected number of subgrant awards for each grant project year is supported by evidence of demand and need; and

(2) The extent to which the proposed average subgrant award amount is supported by evidence of the need of applicants.

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

Note: This notice does *not* solicit applications. In any year in which we choose to use one or more of these priorities, requirements, definitions and selection criteria, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

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

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

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

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

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

OMB has determined that this final regulatory action is a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

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

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

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

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

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

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

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

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

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

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities. We estimate funding for new awards in FY 2022 will be approximately $81,000,000 for State Entity Grants, $4,000,000 for Developer Grants, and $94,000,000 for CMO Grants. The total cost to the Department for this collection is estimated to be $179,000,000.

While this action would impose cost-bearing application requirements on participating State Entity Grant, Developer Grant, and CMO Grant applicants and on State Entity subgrant applicants, we expect that applicants would include requests for funds to cover such costs in their proposed project budgets. We believe this regulatory action will strengthen accountability for the use of Federal funds, and benefit students, by helping to ensure that CSP grants and subgrants are awarded to the entities that are most capable of expanding the number of high-quality charter schools available to our Nation's students.

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

The small entities that this regulatory action would affect are charter school developers. We believe that the costs imposed on an applicant by the priorities, requirements, definitions and selection criteria would be limited to paperwork burden related to preparing an application and that the benefits of these priorities, requirements, definitions and selection criteria would outweigh any costs incurred by the applicant. For these reasons these priorities, requirements, definitions and selection criteria would not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act of 1995: The CSP, including these final priorities, requirements, definitions and selection criteria, contain information collection requirements. These are new requirements for applicants to conduct a needs analysis and to submit detailed information on their management contracts with for-profit entities, including non-profit charter management organizations operated by or on behalf of for-profit entities. Consistent with prior information collection requirements for the CSP, the new package also requires applicants to describe the project for which funding is requested, identify the objectives, activities, and timelines for the funding period requested; describe the qualifications of key personnel; and provide a detailed budget and description of resources.

The Department has developed the following burden estimates for the information collection requirements associated with this NFP. For the years that the Department holds State Entity Grant, CMO Grant, and Developer Grant competitions and that State entities hold subgrant competitions, we estimate that 365 applicants will apply and submit applications. We estimate that it will take each applicant 60 hours to complete and submit the application, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The total burden hour estimate for this collection is 21,900 hours.

The Department requested and obtained a six month emergency approval from OMB for a new information collection request, which includes the requirements associated with this NFP. A separate notice requesting public comment for this information collection is being published in this issue of the **Federal Register** for emergency processing. The Information Collection Request (ICR) notice also provides a 30-day public comment period to solicit feedback on the estimated paperwork burden and to obtain a standard three year approval for the ICR. An assigned control number notifies the public that OMB has

approved these information collection requirements under the Paperwork Reduction Act of 1995.

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

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

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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Ruth E. Ryder,

Deputy Assistant Secretary for Policy and Programs, Office of Elementary and Secondary Education.

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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

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