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Contents

Federal Register

Vol. 87, No. 148

Wednesday, August 3, 2022

Editorial Note: The National Institutes of Health notice, FR Document 2022-16468 at 87 FR 47222 published in the printed version of the **Federal Register** for Tuesday, August 2, 2022, was inadvertently omitted from the Table of Contents of the **Federal Register.**

Agriculture Department
See Commodity Credit Corporation
See Food and Nutrition Service
See Foreign Agricultural Service

Alcohol, Tobacco, Firearms, and Explosives Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Certification of Qualifying State Relief from Disabilities Program, 47465

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 47423–47425

Centers for Medicare & Medicaid Services
RULES
Medicare Program:
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2023; etc., 47502–47619

Coast Guard
RULES
Safety Zones:
Sausalito Scattering Fireworks Display, Sausalito, CA, 47350–47352
Security Zones:
Naval Submarine Base New London, Groton, CT, 47352–47354
Special Local Regulations:
Cumberland River, Nashville, TN, 47348–47350
PROPOSED RULES
Safety Zones:
Mystic River, Mystic, CT, 47381–47383
NOTICES
Use of Wing-in-Ground Craft in Logistical Support of Offshore Platform Operations, 47437–47439

Commerce Department
See National Oceanic and Atmospheric Administration

Commodity Credit Corporation
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 47384–47385

Council on Environmental Quality
NOTICES
Request for Information:
Environmental Justice Scorecard Feedback, 47397–47398

Drug Enforcement Administration
NOTICES
Decision and Order:
Endre Kovacs, MD, 47467–47468
Michael Simental, MD, 47465–47466
Rebecca L. Adams, 47466–47467

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Charter School Programs Application: State Entity Grants, Developer Grants, and Charter Management Organization Grants, 47398–47399

Energy Department
See Federal Energy Regulatory Commission
See Western Area Power Administration
NOTICES
Energy Employees Occupational Illness Compensation Program Act:
List of Covered Facilities, 47399–47400
Environmental Impact Statements; Availability, etc.:
Final Versatile Test Reactor; Record of Decision, 47400–47406

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
California; Northern Sierra Air Quality Management District; Reasonably Available Control Technology, 47354–47359

Federal Aviation Administration
RULES
Airspace Designations and Reporting Points:
Milford, PA, 47342–47343
Airworthiness Directives:
Gulfstream Aerospace Corporation Airplanes, 47337–47341
The Boeing Company Airplanes, 47334–47336
Special Conditions:
Dassault Aviation Falcon Model 6X Airplane; Design Speed Definition, 47332–47334
NOTICES
Land Release Request:
Malden Regional Airport and Industrial Park, Malden, MO; Intent to Rule, 47495
Minimum Seat Dimensions Necessary for Safety of Air Passengers (Emergency Evacuation), 47494–47495

Federal Emergency Management Agency
RULES
Public Assistance Program's Simplified Procedures Large Project Threshold, 47359–47380

Federal Energy Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 47414–47417
Application:
Energy Stream, LLC, 47410–47411

Moretown Hydroelectric, LLC, 47411
Rye Hildebrand Hydroelectric, LLC, 47414
Rye Sutton Hydroelectric, LLC, 47412
Combined Filings, 47413, 47418–47419
Environmental Impact Statements; Availability, etc.:
Northern Natural Gas Co., Northern Lights 2023 Expansion Project, 47406–47409
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
DLS—Jean Duluth Project Co, LLC, 47409
DLS—Laskin Project Co, LLC, 47413–47414
DLS—Sylvan Project Co, LLC, 47412
Institution of Section 206 Proceeding and Refund Effective Date:
California Independent System Operator Corp., ISO New England, Inc., New York Independent System Operator, Inc., et al., 47409
Request for Temporary Waiver:
Bayou Midstream Bakken, LLC, 47413

Federal Maritime Commission
NOTICES
Filing of Complaint and Assignment:
BAKERLY, LLC (Complainant) v. SEAFRIGO USA, Inc. (Respondent), 47422

Federal Railroad Administration
NOTICES
Positive Train Control Safety Plan and Positive Train Control System:
National Railroad Passenger Corp. (Amtrak), 47495–47496

Fish and Wildlife Service
NOTICES
Marine Mammal Protection Act:
Stock Assessment Reports for Two Stocks of West Indian Manatee, 47445–47446
Permits; Applications, Issuances, etc.:
Endangered and Threatened Species, 47446–47457

Food and Drug Administration
RULES
Food Additives Permitted in Feed and Drinking Water of Animals:
Fumonisin Esterase, 47343–47344
NOTICES
Charter Amendments, Establishments, Renewals and Terminations:
Blood Products Advisory Committee, 47427–47428
Guidance:
Electronic Submission of Expedited Safety Reports from Investigational New Drug-Exempt Bioavailability/Bioequivalence Studies, 47431–47432
Product-Specific Guidances, 47425–47427
International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs:
ADB-BUTINACA; Adinazolam; Bromazolam; Protonitazene (propoxynitazene); Etazene (etodesnitazene); etc., 47428–47431
Meetings:
Peripheral and Central Nervous System Drugs Advisory Committee, 47432–47433

Food and Nutrition Service
RULES
Child Nutrition Programs:
Transitional Standards for Milk, Whole Grains, and Sodium; Correction, 47331–47332

Foreign Agricultural Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 47384–47385
Assessment of Fees:
Dairy Import Licenses; 2023 Tariff-Rate Import Quota Year, 47384

Foreign Assets Control Office
RULES
Russian Harmful Foreign Activities Sanctions Regulations:
Web General Licenses 13 and 13A, 47348
Web General Licenses 39, 40, 41, 42, and 43, 47344–47347
Web General Licenses 45 and 46, 47347

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See Health Resources and Services Administration
See National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 47436

Health Resources and Services Administration
NOTICES
National Vaccine Injury Compensation Program:
List of Petitions Received, 47433–47435

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency
NOTICES
Privacy Act; Systems of Records, 47439–47443

Housing and Urban Development Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Inspector Candidate Assessment Questionnaire, 47444
Request for Termination of Multifamily Mortgage Insurance, 47443–47444

Institute of Museum and Library Services
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Grants to States Program State Reporting System, Including Site Visit Checklist, 47471–47472

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See National Park Service

International Trade Commission
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Ammonium Sulfate from China; Scheduling of Full Five-Year Reviews, 47463–47465
Wooden Bedroom Furniture from China; Scheduling of Expedited Five-Year Review, 47463

Justice Department
See Alcohol, Tobacco, Firearms, and Explosives Bureau

See Drug Enforcement Administration
NOTICES
Proposed Consent Decree:
Resource Conservation and Recovery Act, 47468–47469

Labor Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Pattern of Violations, 47469–47470
Surface Coal Mines Daily Inspection; Certified Person; Reports of Inspection, 47470–47471
The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act Grants Evaluation, 47470

Land Management Bureau
NOTICES
Alaska Native Claims Selection, 47457–47459

Maritime Administration
NOTICES
Environmental Impact Statements; Availability, etc.:
Port of Long Beach (POLB or Port) Pier B On-Dock Rail Support Facility Project; Record of Decision and Final Section 4(f) Evaluation, 47496–47497

National Foundation on the Arts and the Humanities
See Institute of Museum and Library Services

National Institutes of Health
NOTICES
Request for Information:
Strategic Plan for Research on the Health of Women, 47436–47437

National Oceanic and Atmospheric Administration
NOTICES
Final 2021 Marine Mammal Stock Assessment Reports, 47385–47397

National Park Service
NOTICES
Intent to Repatriate Cultural Items:
Longyear Museum of Anthropology, Colgate University, Hamilton, NY, 47459–47461
Valentine Museum, Richmond, VA, 47461
Inventory Completion:
State University of New York at New Paltz, Department of Anthropology, New Paltz, NY, 47462

National Science Foundation
NOTICES
Antarctic Conservation Act Permit Applications, 47473
Antarctic Conservation Act Permit Modifications, 47472–47473
Antarctic Conservation Act Permits Issued, 47473
Request for Information:
Federal Big Data Research and Development Strategic Plan Update, 47473–47474

Postal Regulatory Commission
NOTICES
New Postal Products, 47474–47475

Securities and Exchange Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 47481
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Cboe BZX Exchange, Inc., 47478–47481
Self-Regulatory Organizations; Proposed Rule Changes:
BOX Exchange LLC, 47475–47478
Cboe C2 Exchange, Inc., 47491–47493
Cboe EDGX Exchange, Inc., 47489–47491
Municipal Securities Rulemaking Board, 47485
NYSE American LLC, 47481–47485
NYSE Arca, Inc., 47485–47489

Transportation Department
See Federal Aviation Administration
See Federal Railroad Administration
See Maritime Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 47497–47498

Treasury Department
See Foreign Assets Control Office

Unified Carrier Registration Plan
NOTICES
Meetings; Sunshine Act, 47498–47499

Western Area Power Administration
NOTICES
Rate Order:
WAPA–201; Washoe Project, Stampede Division, 47419–47422

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 47502–47619

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

7 CFR
210.....47331
215.....47331
220.....47331
226.....47331

14 CFR
25.....47332
39 (2 documents) 47334, 47337
71.....47342

21 CFR
573.....47343

31 CFR
587 (3 documents) 47322, 47347, 47348

33 CFR
100.....47348
165 (2 documents) 47350, 47352

Proposed Rules:
165.....47381

40 CFR
52.....47354

42 CFR
413.....47502
483.....47502

44 CFR
206.....47359

Rules and Regulations

Federal Register
Vol. 87, No. 148
Wednesday, August 3, 2022

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

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

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 210, 215, 220, and 226

RIN 0584–AE81

Child Nutrition Programs: Transitional Standards for Milk, Whole Grains, and Sodium; Correction

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Final rule; technical corrections.

SUMMARY: The Food and Nutrition Service (FNS) is correcting a final rule with request for comments that appeared in the **Federal Register** on February 7, 2022 and published in the Code of Federal Regulations (CFR) on July 1, 2022. The rule established Child Nutrition Program transitional standards for milk, whole grains, and sodium for school years 2022–23 and 2023–24.

DATES: This correction is effective on July 1, 2022.

FOR FURTHER INFORMATION CONTACT: Tina Namian, Director, School Meals Policy Division—4th Floor, Food and Nutrition Service, 1320 Braddock Place, Alexandria, VA 22314; telephone: 703–305–2590.

SUPPLEMENTARY INFORMATION: In FR Doc. 2022–02327, starting on page 7005 in the **Federal Register** of Monday, February 7, 2022, the following corrections are made:

§ 210.10 [Corrected]

■ 1. At 7 CFR 210.10(c), the Table 1 To Paragraph (C) Introductory Text—Lunch Meal Pattern is corrected to read as follows:

	Lunch meal pattern		
	Grades K–5	Grades 6–8	Grades 9–12
Food components	Amount of Food[a] per Week (minimum per day)		
Fruits (cups)[b]	2½ (½)	2½ (½)	5 (1)
Vegetables (cups)[b]	3¾ (¾)	3¾ (¾)	5 (1)
Dark green[c]	½	½	½
Red/Orange[c]	¾	¾	1¼
Beans and peas (legumes)[c]	½	½	½
Starchy[c]	½	½	½
Other[c d]	½	½	¾
Additional Vegetables to Reach Total[e]	1	1	1½
Grains (oz eq)[f]	8–9 (1)	8–10 (1)	10–12 (2)
Meats/Meat Alternates (oz eq)	8–10 (1)	9–10 (1)	10–12 (2)
Fluid milk (cups)[g]	5 (1)	5 (1)	5 (1)
Other Specifications: Daily Amount Based on the Average for a 5-Day Week			
Min-max calories (kcal)[h]	550–650	600–700	750–850
Saturated fat (% of total calories)[h]	<10	<10	<10
Sodium Interim Target 1 (mg)[h]	≤1,230	≤1,360	≤1,420
Sodium Interim Target 1A (mg)[h i]	≤1,110	≤1,225	≤1,280
Trans fat[h]	Nutrition label or manufacturer specifications must indicate zero grams of *trans* fat per serving.		

[a] Food items included in each group and subgroup and amount equivalents. Minimum creditable serving is ⅛ cup.
[b] One quarter-cup of dried fruit counts as ½ cup of fruit; 1 cup of leafy greens counts as ½ cup of vegetables. No more than half of the fruit or vegetable offerings may be in the form of juice. All juice must be 100% full-strength.
[c] Larger amounts of these vegetables may be served.
[d] This category consists of "Other vegetables" as defined in paragraph (c)(2)(iii)(E) of this section. For the purposes of the NSLP, the "Other vegetables" requirement may be met with any additional amounts from the dark green, red/orange, and beans/peas (legumes) vegetable subgroups as defined in paragraph (c)(2)(iii) of this section.
[e] Any vegetable subgroup may be offered to meet the total weekly vegetable requirement.
[f] At least 80 percent of grains offered weekly (by ounce equivalents) must meet the whole grain-rich criteria specified in FNS guidance, and the remaining grain items offered must be enriched.
[g] All fluid milk must be fat-free (skim) or low-fat (1 percent fat or less). Milk may be unflavored or flavored, provided that unflavored milk is offered at each meal service.
[h] Discretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, *trans* fat, and sodium. Foods of minimal nutritional value and fluid milk with fat content greater than 1 percent are not allowed.
[i] Sodium Interim Target 1A must be met no later than July 1, 2023 (SY 2023–2024).

§ 220.8 [Corrected]

■ 2. On page 7007, in § 220.8(c), the Table 1 to Paragraph (c) Introductory Text—Breakfast Meal Pattern is corrected to read as follows:

Food components	Breakfast meal pattern		
	Grades K–5	Grades 6–8	Grades 9–12
	Amount of Food [a] per Week (minimum per day)		
Fruits (cups) [b c]	5 (1)	5 (1)	5 (1)
Vegetables (cups) [b c]	0	0	0
Dark green	0	0	0
Red/Orange	0	0	0
Beans and peas (legumes)	0	0	0
Starchy	0	0	0
Other	0	0	0
Grains (oz eq) [d]	7–10 (1)	8–10 (1)	9–10 (2)
Meats/Meat Alternates (oz eq) [e]	0	0	0
Fluid milk (cups) [f]	5 (1)	5 (1)	5 (1)
Other Specifications: Daily Amount Based on the Average for a 5-Day Week			
Min-max calories (kcal) [g h]	350–500	400–550	450–600
Saturated fat (% of total calories) [h]	<10	<10	<10
Sodium Target 1 (mg) [h]	≤540	≤600	≤640
Trans fat [h]	Nutrition label or manufacturer specifications must indicate zero grams of *trans* fat per serving.		

[a] Food items included in each group and subgroup and amount equivalents. Minimum creditable serving is ⅛ cup.
[b] One-quarter cup of dried fruit counts as ½ cup of fruit; 1 cup of leafy greens counts as ½ cup of vegetables. No more than half of the fruit or vegetable offerings may be in the form of juice. All juice must be 100% full-strength.
[c] Schools must offer 1 cup of fruit daily and 5 cups of fruit weekly. Vegetables may be substituted for fruits, but the first two cups per week of any such substitution must be from the dark green, red/orange, beans/peas (legumes), or "Other vegetables" subgroups, as defined in § 210.10(c)(2)(iii) of this chapter.
[d] At least 80 percent of grains offered weekly must meet the whole grain-rich criteria specified in FNS guidance, and the remaining grain items offered must be enriched. Schools may substitute 1 oz. eq. of meat/meat alternate for 1 oz. eq. of grains after the minimum daily grains requirement is met.
[e] There is no meat/meat alternate requirement.
[f] All fluid milk must be fat-free (skim) or low-fat (1 percent fat or less). Milk may be unflavored or flavored, provided that unflavored milk is offered at each meal service.
[g] The average daily calories for a 5-day school week must be within the range (at least the minimum and no more than the maximum values).
[h] Discretionary sources of calories (solid fats and added sugars) may be added to the meal pattern if within the specifications for calories, saturated fat, trans fat, and sodium. Foods of minimal nutritional value and fluid milk with fat content greater than 1 percent milk fat are not allowed.

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–16466 Filed 8–2–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2021–1193; Special Conditions No. 25–798–SC]

Special Conditions: Dassault Aviation Falcon Model 6X Airplane; Design Speed Definition

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Dassault Aviation (Dassault) Model Falcon 6X Airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is a high speed protection system that limits nose-down pilot authority at speeds above V_C/M_C. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Dassault on August 3, 2022. Send comments on or before September 19, 2022.

ADDRESSES: Send comments identified by Docket No. FAA–2021–1193 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in title 14, Code of Federal Regulations (14 CFR) 11.35, the FAA will post all comments received without change to *http://*

www.regulations.gov/, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about these special conditions.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, 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 the indicated comments will not be placed in the public docket of these special conditions. Send submissions containing CBI to Todd Martin, Materials and Structural Properties Section, AIR–621, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3210; email *Todd.Martin@faa.gov.* Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for these special conditions.

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Todd Martin, Materials and Structural Properties Section, AIR–621, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3210; email *Todd.Martin@faa.gov.*

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA finds, pursuant to § 11.38(b), that new comments are unlikely, and notice and comment prior to this publication are unnecessary.

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

The FAA will consider all comments received by the closing date for comments. The FAA may change these special conditions based on the comments received.

Background

On July 1, 2012, Dassault Aviation applied for a type certificate for its new Model Falcon 5X airplane. However, Dassault has decided not to release an airplane under the model designation Falcon 5X, instead choosing to change that model designation to Falcon 6X.

In February of 2018, due to engine supplier issues, Dassault extended the type certificate application date for its Model Falcon 5X airplane under new Model Falcon 6X. This airplane is a twin-engine business jet with seating for 19 passengers and a maximum takeoff weight of 77,460 pounds.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.17, Dassault must show that the Model Falcon 6X airplane meets the applicable provisions of part 25, as amended by amendments 25–1 through 25–146.

If the Administrator finds that the applicable airworthiness regulations (*e.g.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Dassault Model Falcon 6X airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

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

In addition to the applicable airworthiness regulations and special conditions, the Dassault Model Falcon 6X airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

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

Novel or Unusual Design Features

The Dassault Model Falcon 6X airplane will incorporate the following novel or unusual design feature:

The airplane is equipped with a high speed protection system that limits nose-down pilot authority at speeds above V_C/M_C, and prevents the airplane from actually performing the maneuver required under 14 CFR 25.335(b)(1).

Discussion

Section 25.335(b)(1) is an analytical envelope condition, adopted initially in part 4b of the Civil Air Regulations, to provide an acceptable speed margin between design cruise speed and design dive speed. The design dive speed impacts flutter clearance design speeds and airframe design loads. While the initial condition for the upset specified in the rule is 1g level flight, protection is afforded for other inadvertent overspeed conditions. Section 25.335(b)(1) is intended as a conservative enveloping condition for potential overspeed conditions, including non-symmetric ones.

To establish that potential overspeed conditions are enveloped, the applicant should demonstrate that any reduced speed margin, based on the high speed protection system on the Dassault Model Falcon 6X, will not be exceeded in inadvertent, or gust induced, upsets resulting in initiation of the dive from non-symmetric attitudes; or that the flight-control laws protect the airplane from getting into non-symmetric upset conditions. The proposed special conditions identify various symmetric and non-symmetric maneuvers to ensure that an appropriate design dive speed, V_D/M_D, is established.

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

Applicability

As discussed above, these special conditions are applicable to the Dassault Model Falcon 6X airplane. Should Dassault apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on one model of airplane. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Dassault Aviation Model Falcon 6X Airplane.

Design Speed Definition

(a) In lieu of compliance with 14 CFR 25.335(b)(1), if the flight-control system includes functions that act automatically to initiate recovery before the end of the 20 second period specified in § 25.335(b)(1), V_D/M_D must be determined from the greater of the speeds resulting from conditions (a) and (b) below. The speed increase occurring in these maneuvers may be calculated, if reliable or conservative aerodynamic data are used.

(1) From an initial condition of stabilized flight at V_C/M_C, the airplane is upset so as to take up a new flight path 7.5 degrees below the initial path. The pilot implements a control application to try to maintain this new flight path up to full authority. Twenty seconds after initiating the upset, manual recovery is made at a load factor of 1.5 g (0.5 acceleration increment), or such greater load factor the system automatically applies with the pilot's pitch control neutral. Power, as specified in § 25.175(b)(1)(iv), is assumed until the pilot initiates a recovery, at which time power reduction and the use of pilot-controlled drag devices may be used.

(2) From a speed below V_C/M_C, with power to maintain stabilized level flight at this speed, the airplane is upset so as to accelerate through V_C/M_C at a flight path 15 degrees below the initial path (or at the steepest nose-down attitude that the system will permit with full control authority if less than 15 degrees). The pilot's controls may be in the neutral position after reaching V_C/M_C and before recovery is initiated. Three seconds after a high-speed warning system annunciation, the pilot may initiate recovery by applying a load of 1.5g (0.5 acceleration increment), or such greater load factor that is automatically applied by the system with the pilot's pitch control neutral. Power may be reduced simultaneously. All other means of decelerating the airplane, the use of which is authorized up to the highest speed reached in the maneuver, may be used. The interval between successive pilot actions must not be less than one second.

(b) The applicant must also demonstrate that the speed margin, established as above, will not be exceeded in inadvertent, or gust induced, upsets resulting in initiation of the dive from non-symmetric attitudes, unless the flight-control laws protect the airplane from getting into non-symmetric upset conditions. The upset maneuvers described in Advisory Circular 25–7D, ''Flight Test Guide For Certification of Transport Category Airplanes,'' paragraphs 10.2.3.3.1 and 10.2.3.3.3, paragraphs c.(3)(a) and (c) may be used to comply with this requirement.

(c) Any failure of the high-speed protection system that would result in an airspeed exceeding those determined by conditions (a) and (b), above, must have a probability of occurrence of less than 1E–5 per flight hour.

(d) Failures of the system must be annunciated to the pilots. Flight manual instructions must be provided that reduce the maximum operating speeds, V_{MO}/M_{MO}. The operating speed must be reduced to a value that maintains a speed margin between V_{MO}/M_{MO} and V_D/M_D that is consistent with showing compliance with § 25.335(b) without the benefit of the high-speed protection system.

(e) Dispatch of the airplane with the high-speed protection system inoperative could be allowed under an approved minimum equipment listing that would require flight manual instructions to indicate reduced maximum operating speeds, as described in condition (d), above. In addition, the cockpit display of the reduced operating speeds, and the overspeed warning for exceeding those speeds, must be equivalent to that of the normal airplane with the high-speed protection system operative. It must also be shown that no additional hazards are introduced with the high-speed protection system inoperative.

Issued in Kansas City, Missouri, on July 20, 2022.

Patrick R. Mullen,

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

[FR Doc. 2022–16558 Filed 8–2–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0880; Project Identifier AD–2022–00620–T; Amendment 39–22126; AD 2022–15–06]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model 777 airplanes. This AD was prompted by high electrical resistance within the gust suppression sensor (GSS) transorb modules due to corrosion on the transorb module threads. This AD requires disconnecting the connectors and capping and stowing the wires that had been attached to the affected transorb modules. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 18, 2022.

The FAA must receive comments on this AD by September 19, 2022.

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

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

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No.

FAA–2022–0880; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Joe Salameh, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3536; email: *Joe.Salameh@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

During scheduled maintenance inspection, high electrical resistance was found across the GSS transorb modules. The most likely cause of the high resistance is corrosion over time of the transorb threads. High electrical resistance in both transorb modules, if not addressed, can result in two actuator control electronics (ACEs), which are part of the flight control system, being exposed to damaging lightning transient voltages in excess of the qualification levels, potentially inducing erroneous or oscillatory outputs to flight control surfaces, which could result in loss of control of the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

The gust suppression function on the Boeing Model 777 airplanes is a non-essential feature of the essential flight control system. The gust suppression function provides a minor improvement to ride quality during lateral wind gusts at low airspeeds. The actions required by this AD disable the non-essential gust suppression function, which does not affect the safety of flight.

FAA's Determination

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

AD Requirements

This AD requires disconnecting the connectors from the affected transorbs and capping and stowing those wires.

Interim Action

The FAA considers this AD to be an interim action. The manufacturer is currently developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, the FAA might consider additional rulemaking.

Justification for Immediate Adoption and Determination of the Effective Date

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

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because failed electrical bonds in both transorb module lightning protection devices can cause two ACEs to be exposed to damaging lightning transient voltages. The failure mode of the transorb module is latent, and therefore is not annunciated to the operator. Damaging lightning transient voltages in excess of the qualification levels could induce erroneous or oscillatory outputs to control surfaces and result in loss of control of the airplane. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

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

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include Docket No. FAA–2022–0880 and Project Identifier AD–2022–00620–T at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Joe Salameh, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3536; email: *Joe.Salameh@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 279 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Disconnecting connectors, capping and stowing wires.	3 work-hours × $85 per hour = $255	$0	$255	$71,145

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–15–06 The Boeing Company: Amendment 39–22126; Docket No. FAA–2022–0880; Project Identifier AD–2022–00620–T.

(a) Effective Date

This airworthiness directive (AD) is effective August 18, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 777–200, 777–200LR, 777–300, 777–300ER, and 777F series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by high electrical resistance within the gust suppression sensor (GSS) transorb modules due to corrosion on the transorb threads. The FAA is issuing this AD to address high electrical resistance in both transorb modules, which can result in two actuator control electronics (ACEs) being exposed to damaging lightning transient voltages in excess of the qualification levels, potentially inducing erroneous or oscillatory outputs to flight control surfaces, and result in loss of control of the airplane.

(f) Compliance

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

(g) Disconnect, Cap, and Stow Transorb Module Connectors

At the later of the times specified in paragraphs (g)(1) and (2) of this AD: Disconnect the connectors and cap and stow the wires to bundles/connectors W7314/D02006P and W7579/D02005P from the transorb module part numbers CLPT–12SP–06, –07, and –67.

Note 1 to the introductory text of paragraph (g): Guidance on locating wire bundles/connectors W7314/D02006P and W7579/D02005P can be found in Section 05–55–43 of the Boeing 777 airplane maintenance manual.

Note 2 to the introductory text of paragraph (g): Guidance on capping and stowing the wires once they are disconnected can be found in Section 20–10–11 of the Boeing Standard Wiring Practices Manual.

(1) Before the accumulation of 75,000 total flight hours or 23,000 total flight cycles, whichever occurs first.

(2) Within 3 months after the effective date of this AD.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(i) Related Information

For more information about this AD, contact Joe Salameh, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3536; email: *Joe.Salameh@faa.gov.*

(j) Material Incorporated by Reference

None.

Issued on July 11, 2022.

Gaetano A. Sciortino,

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

[FR Doc. 2022–16606 Filed 8–1–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0958; Project Identifier 2019–CE–010–AD; Amendment 39–22133; AD 2022–16–04]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Gulfstream Aerospace Corporation (Gulfstream) Model GV and GV–SP airplanes. This AD was prompted by corrosion of the horizontal stabilizer lower bonded skin assemblies. This AD requires inspecting the horizontal stabilizer lower skin and associated bonded doublers and bonded stringers, repairing any area with corrosion beyond allowable damage limits, and incorporating revisions to the airworthiness limitations section (ALS) in the existing aircraft maintenance manual (AMM) or progressive maintenance program. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 7, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of September 7, 2022.

ADDRESSES: For service information identified in this final rule, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402; phone: (800) 810–4853; fax: (912) 965–3520; email: *pubs@gulfstream.com*; website: *www.gulfstream.com/en/customer-support/*. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *www.regulations.gov* by searching for and locating Docket No. FAA–2021–0958.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2021–0958; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this 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: Ronald Wissing, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5552; email: *9-ASO-ATLACO-ADs@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Gulfstream Model GV and GV–SP airplanes. The NPRM published in the **Federal Register** on November 5, 2021 (86 FR 61088). The NPRM was prompted by bond line corrosion on Model GV and GV–SP airplanes, which causes disbonding between the horizontal stabilizer lower skin and associated bonded doublers and bonded stringers. Gulfstream determined that the existing visual inspection in the AMM did not reliably detect bond line corrosion and added a repetitive non-destructive testing (NDT) inspection to detect the damage. In the NPRM, the FAA proposed to require inspecting the horizontal stabilizer lower skin and associated bonded doublers and bonded stringers, repairing any area with corrosion beyond allowable damage limits, and incorporating revisions to the ALS in the existing AMM. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from one commenter, Gulfstream. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Clarify Information in the Preamble

Gulfstream requested that the FAA revise a phrase describing part of the proposed corrective action under **SUMMARY** and under the ''Proposed AD Requirements in This NPRM'' section of **SUPPLEMENTARY INFORMATION**. Gulfstream requested the FAA change ''repairing the area susceptible to corrosion'' to ''identify if a repair is required.'' Gulfstream stated that the bonded structure is ''susceptible'' to corrosion but does not necessarily require ''repair'' because the need for repair is based on the inspection results.

The FAA agrees that all areas susceptible to corrosion do not necessarily require repair. The FAA has revised the **SUMMARY** of this final rule to clarify that only areas with corrosion that exceeds allowable damage limits need to be repaired. The ''Proposed AD Requirements in This NPRM'' section is not restated in this final rule, so a change is unnecessary.

Request To Revise the Description of a Service Document

Gulfstream requested the FAA change the description of Gulfstream Service Letter Document No. GSL505510019, Revision E, dated September 3, 2021, in the ''Other Related Service Information'' section of the preamble. In the NPRM, the FAA stated that the service letter contains procedures for applying on-wing corrosion inhibiting compound (CIC) to the horizontal stabilizer. Gulfstream advised that this description is inaccurate because although the service letter specifies applying CIC, it references another service letter for the application instructions. Gulfstream requested that the preamble state instead that this service letter ''contains allowable damage limits for the horizontal stabilizer assembly.''

The FAA agrees and has revised this final rule accordingly.

Request Regarding the Airplane Effectivity Range

Gulfstream requested that the FAA remove language in the preamble explaining that the proposed AD would apply to all Model GV and GV–SP airplanes, while the service bulletins exclude certain serial-numbered airplanes. Gulfstream also requested that the inspection proposed in paragraph (i) of the proposed AD not be required for these same serial-numbered airplanes. Gulfstream stated that four airplanes were excluded from the effectivity of the customer bulletin because the airplanes had not yet reached the baseline compliance time for doing the initial ''Part II'' inspection of the horizontal stabilizer lower skin. Gulfstream explained that removing those four airplanes from the inspection portion of the proposed AD would not have an impact on safety, because those airplanes will be inspected in accordance with the 144-month entry into service inspection specified in Chapter 5 of the AMM.

The FAA disagrees. Gulfstream's request appears to be based on the compliance time for those four airplanes and not whether they are subject to the unsafe condition identified in this AD.

The inspection required by paragraph (i) of this AD is necessary to correct the unsafe condition on all Model GV–SP airplanes with a serial number in the range of 5001 through 5158. The FAA did not change this AD based on this comment.

Request To Include Terminating Action

Gulfstream requested that the FAA add terminating actions for the ALS revision proposed in paragraph (g) and for the inspection proposed in paragraph (i) of the proposed AD. Gulfstream stated that otherwise owners will have to comply for an indefinite period.

The FAA does not agree because paragraphs (g) and (i) of this AD require one-time actions and not repetitive actions; therefore, terminating action is not necessary. Once an operator has revised the maintenance or inspection program for its airplane by incorporating the applicable ALS revision, the operator has complied with paragraph (g) of this AD. As explained in the NPRM, although the service bulletins allow the inspection to be repeated indefinitely every 48 months, this AD does not. Instead, paragraph (i) of this AD requires the inspection once, and any necessary repairs within 48 months after the inspection. The FAA did not change this AD based on this comment.

Request To Remove Entry Into Service Criteria

Gulfstream requested that the FAA revise paragraph (i) of the proposed AD to remove the criteria that the inspection be required for airplanes ''where more than 132 months have elapsed since the original certificate of airworthiness issue date (often referred to as entry into service date).'' In support, Gulfstream explained that this language is no longer applicable because all affected airplanes have accumulated 132 months since entry into service. In addition, Gulfstream noted that the entry into service date and the original certificate of airworthiness issue date are two different dates and are not interchangeable.

The FAA agrees and has revised paragraph (i) of this AD accordingly.

Request To Remove Note Regarding ALS Inspections

Gulfstream requested that the FAA remove Note 2 to the introductory text of paragraph (i) of the proposed AD, which advised that the inspections listed in the ALS revision (required by paragraph (g) of the proposed AD) must be done at the same time as the Part II inspection. Gulfstream stated it is not necessary to mandate the ALS maintenance inspections at the same time as the Part II inspection of the horizontal stabilizer lower skin for bond line corrosion. Gulfstream explained there is no reason to accomplish these actions together and doing so could result in duplication of efforts.

The FAA agrees that, to correct the unsafe condition, the ALS maintenance inspections are not required at the same time as the airworthiness inspection of the horizontal stabilizer lower skin for bond line corrosion. However, operators may align these inspections to establish a baseline for the required repetitive inspection intervals. The FAA has revised Note 2 to the introductory text of paragraph (i) of this AD accordingly.

Request To Clarify Note 2 of the Proposed AD

Gulfstream requested the FAA clarify the intent and placement of Note 2, which was located after the introductory text of paragraph (i) of the proposed AD and before paragraphs (i)(1) and (2) of the proposed AD. Gulfstream explained that due to the placement of the note, it is unclear whether paragraphs (i)(1) and (2) of the proposed AD are part of the note or whether they are lower level paragraphs of paragraph (i) of the proposed AD. Gulfstream also stated that this note does not follow FAA policy and guidance, which states that notes are for informational purposes, because it introduces a requirement not otherwise stated in the AD.

Paragraphs (i)(1) and (2) of this AD are lower level paragraphs of paragraph (i) of this AD. Paragraph (i) of this AD requires inspecting the horizontal stabilizer lower skin for bond line corrosion and applying CIC. Paragraphs (i)(1) and (2) of this AD provide the compliance time for repairing any corrosion found as a result of the inspection: either within 48 months after applying CIC if the corrosion is within allowable damage limits, or before further flight if any corrosion exceeds allowable damage limits. The placement of the note after the introductory text of paragraph (i) of this AD follows the formatting requirements for regulatory documents in the Office of the Federal Register's Document Drafting Handbook. The FAA did not change this AD based on this comment.

Request To Remove Paragraphs (i)(1) and (2) of the Proposed AD

Gulfstream requested that the FAA remove paragraphs (i)(1) and (2) of the proposed AD, which proposed to require, after performing the Part II inspection, repairing the area using a method approved by Gulfstream's Organization Designation Authorization (ODA). Gulfstream stated that these paragraphs are unnecessary and redundant with normal operating and repair station procedures. Gulfstream further noted that the FAA's regulations in 14 CFR part 43 already require that aircraft with corrosion exceeding allowable damage limits be repaired and in an airworthy state before approval for return to service.

The FAA disagrees with removing paragraph (i)(2) of this AD. For corrosion that exceeds allowable damage limits, the FAA finds that the repair mandated by paragraph (i)(2) of this AD is required to address the identified unsafe condition. Aircraft found with corrosion that exceeds allowable damage limits will require corrective action that may appreciably affect the structural strength of the airframe. FAA-approved (or ODA-approved) engineering data will likely be required to return the aircraft to service. In addition, the FAA is unaware of a repair procedure or specification that could be used to approve all affected aircraft for return to service. Rather, unique, airplane-specific repairs will be necessary.

However, the FAA agrees that standard maintenance practices are sufficient to repair corrosion within allowable limits and has revised paragraph (i)(1) of this AD accordingly. The FAA has also clarified the scope of the repair required after the CIC application by revising paragraph (i)(1) of this AD. Instead of the broader requirement to repair ''the area,'' that paragraph now specifies repairing ''all bond line corrosion.'' This change will decrease the burden of this requirement on operators while appropriately addressing bond line corrosion.

Request To Address Airplanes Repaired Prior to AD Issuance

Gulfstream requested that, for airplanes that have been ''permanently'' repaired prior to AD issuance, the FAA give operators the full benefit of the repair. Alternatively, Gulfstream suggested the FAA allow a 48-month compliance time, the same as for an airplane with allowable bond line corrosion, to avoid immediately grounding airplanes.

The FAA agrees operators should have the benefit of repairs accomplished by Gulfstream before the effective date of the AD, provided Gulfstream's ODA approves those repairs as restoring the airplane to its type certification basis. The FAA infers that by ''permanent'' repair, Gulfstream is referring to repairs to airplanes found with corrosion exceeding allowable damage limits.

Gulfstream has accomplished these repairs on many of the affected airplanes prior to the effective date of the AD under its ODA procedures. In the NPRM, the FAA proposed that these repairs must be made using a method approved by Gulfstream's ODA under the procedures for alternative methods of compliance (AMOCs). In order to more efficiently give operators the benefit of these repairs, the FAA has revised paragraph (i)(2) of this AD to require an FAA-approved or ODA-approved repair method without using AMOC procedures. The document approving the repair method must still specifically reference this AD.

The FAA finds that the additional compliance time requested by Gulfstream is unnecessary. Operators have 12 months after the effective date of this AD to perform the resonance C-Scan (Part II) inspection required by the introductory text of paragraph (i) of this AD, apply CIC, and repair any corrosion that exceeds allowable limits using an FAA-approved or ODA-approved method. Operators have this same 12-month compliance time to take credit for any actions ''already done'' under paragraph (f) of this AD, including ''permanent'' repairs that Gulfstream's ODA may need to approve by specifically referring to this AD.

Request To Clarify Allowable Damage Limit

Gulfstream requested that the FAA revise paragraph (i)(2) of the proposed AD to clarify that the term ''allowable damage limit'' means the allowable damage limits provided by Gulfstream as the original equipment manufacturer. Gulfstream explained that these limits are defined in various Gulfstream documents.

The FAA agrees to clarify the term ''allowable damage limit'' and has revised paragraph (i)(2) of this AD to specify that the limits are those in the applicable service information or those approved by Gulfstream's ODA.

Request To Clarify Required for Compliance (RC) Steps

Gulfstream requested that the FAA revise paragraph (j)(4)(i) of the proposed AD (paragraph (k)(4)(i) of this AD) to clarify that operators only need to comply with the RC steps required by paragraph (i) of the proposed AD. Gulfstream noted that paragraph (j)(4)(i), as proposed, implies that operators would have to do all of the actions labeled ''RC'' in the customer bulletin, even though the proposed AD does not specify all of those steps.

The FAA agrees and has revised paragraph (k)(4)(i) of this AD accordingly.

Additional Changes Made to This AD

After the NPRM was issued, Gulfstream revised the portions of the ALS that are relevant to the proposed AD: Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G500–5000 Aircraft Maintenance Manual, Revision 36, dated March 15, 2022; Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G550 Aircraft Maintenance Manual, Revision 36, dated March 15, 2022; and Section F and Table 12: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream V Aircraft Maintenance Manual, Revision 55, dated March 15, 2022. The FAA reviewed these revisions and determined they do not require additional work or impose any substantive changes to those proposed in the NPRM. Therefore, the FAA has revised paragraph (g) of this AD to require incorporating these later-issued revisions of the applicable section and table of Section 05–10–10 of the ALS. The FAA has also added paragraph (j) of this AD to provide credit for operators who have revised their ALS before the effective date of this AD using the ALS revisions specified in the NPRM. Subsequent paragraphs have been re-designated accordingly.

The FAA has also updated the ALS table number reference in paragraphs (g)(2) and (3) of this AD. This reference changed from Table 12 to Table 11 when Gulfstream revised Section 05–10–10 of the applicable AMMs.

Conclusion

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Gulfstream G500–5000 Customer Bulletin No. 190, Revision B; Gulfstream G550 Customer Bulletin No. 190, Revision B; and Gulfstream GV Customer Bulletin No. 228, Revision B; all dated October 31, 2019. For the applicable marketing designation specified on each document, the customer bulletins specify procedures for inspecting the horizontal stabilizer lower bonded skin.

The FAA also reviewed Section F and Table 12: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream V Aircraft Maintenance Manual, Revision 55, dated March 15, 2022; Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G500–5000 Aircraft Maintenance Manual, Revision 36, dated March 15, 2022; and Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G550 Aircraft Maintenance Manual, Revision 36, dated March 15, 2022. For the applicable marketing designation specified on each document, the service information contains inspection intervals for nondestructive testing of the lower horizontal stabilizer skins and provides the specific reference for the inspection procedures.

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

Other Related Service Information

The FAA also reviewed the following service documents related to this final rule.

- Gulfstream Service Letter Document No. GSL505510019, Revision E, dated September 3, 2021, which contains allowable damage limits for the horizontal stabilizer assembly.
- Gulfstream Service Letter Document No. GSL505510020, Revision C, dated March 12, 2020, which contains procedures for applying CIC to the horizontal stabilizer.
- Gulfstream V Nondestructive Testing Procedures Manual Chapter 05–00–00, 1. Horizontal Stabilizer Lower Skin Resonance C-Scan—NDT Procedure.

Differences Between This AD and the Service Information

The differences between Gulfstream G500–5000 Customer Bulletin No. 190, Revision B; Gulfstream G550 Customer Bulletin No. 190, Revision B; and Gulfstream V Customer Bulletin No.

228, Revision B; all dated October 31, 2019; and this AD are listed below.

- The customer bulletins exclude certain serial-numbered airplanes inspected by Gulfstream, but this AD applies to all Model GV and GV–SP airplanes.
- The customer bulletins include an optional horizontal stabilizer lower skin resonance A-Scan NDT inspection (referred to in the customer bulletins as ''Part I Inspection'') for critical areas of the horizontal stabilizer bonded lower skin assemblies, but this AD does not require the Part I Inspection.
- The customer bulletins allow the horizontal stabilizer lower skin resonance C-Scan NDT inspection (referred to in the customer bulletins as a ''Part II Inspection'') and application of CIC to be repeated indefinitely every 48 months. This AD only allows the Part II inspection to be performed one time and, within 48 months after the inspection, requires approved repairs.
- The customer bulletins contain actions labeled RC, and the language in the customer bulletins and in paragraph (k)(4) of this AD indicate that operators must comply with all actions labeled RC for compliance with this AD. However, this AD does not require all of the steps in the customer bulletins that are labeled as RC. Operators only need to comply with the RC steps required by paragraph (i) of this AD.

Costs of Compliance

The FAA estimates that this AD affects up to 694 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per airplane	Cost on U.S. operators
Resonance C-Scan NDT (Part II) inspection and CIC application.	80 work-hours × $85 per hour = $6,800	Not applicable	$6,800	$2,196,400 (for 323 airplanes).
AMM revision	1 work-hour × $85 per hour = $85	Not applicable	85	$58,990 (for 694 airplanes).

The extent of corrosion found during the inspection may vary significantly from airplane to airplane. The FAA has no way of determining the number of airplanes that might need repair or the cost to repair each airplane.

Authority for This Rulemaking

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

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

Regulatory Findings

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:

2022–16–04 Gulfstream Aerospace Corporation: Amendment 39–22133; Docket No. FAA–2021–0958; Project Identifier 2019–CE–010–AD.

(a) Effective Date

This airworthiness directive (AD) is effective September 7, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace Corporation Model GV and GV–SP airplanes, all serial numbers, certificated in any category.

Note 1 to paragraph (c): Model GV–SP airplanes are also referred to by the marketing designations G500, G550, and G500–5000.

(d) Subject

Joint Aircraft System Component (JASC) Code 5510, Horizontal Stabilizer Structure.

(e) Unsafe Condition

This AD results from corrosion of the horizontal stabilizer lower bonded skin assemblies. The FAA is issuing this AD to detect and correct bond line corrosion, which if not addressed, could result in compromise of the structural integrity of the horizontal stabilizer and lead to loss of control of the airplane.

(f) Compliance

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

(g) Incorporation of Airworthiness Limitations (ALS) Revisions

Within 30 days after the effective date of this AD, incorporate into your existing maintenance or inspection program the ALS revision specified in paragraph (g)(1), (2), or (3) of this AD for your applicable airplane designation.

(1) For Model GV airplanes: Section F and Table 12: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream V Aircraft Maintenance Manual, Revision 55, dated March 15, 2022.

(2) For Model GV–SP (G500 and G500–5000) airplanes: Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G500–5000 Aircraft Maintenance Manual, Revision 36, dated March 15, 2022.

(3) For Model GV–SP (G550) airplanes: Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G550 Aircraft Maintenance Manual, Revision 36, dated March 15, 2022.

(h) Applicable Customer Bulletins

The customer bulletins specified in paragraphs (h)(1) through (3) of this AD contain procedures for compliance with the actions required by paragraph (i) of this AD for your applicable airplane designation:

(1) Gulfstream GV Customer Bulletin No. 228, Revision B, dated October 31, 2019;

(2) Gulfstream G500–5000 Customer Bulletin No. 190, Revision B, dated October 31, 2019; or

(3) Gulfstream G550 Customer Bulletin No. 190, Revision B, dated October 31, 2019.

(i) Inspection

For Model GV airplanes, all serial numbers, and Model GV–SP airplanes, serial numbers 5001 through 5158: Within 12 months after the effective date of this AD, perform the horizontal stabilizer lower skin resonance C-Scan inspection (Part II inspection) for bond line corrosion and apply corrosion inhibiting compound (CIC) by following steps 6.2.a. through 6.2.e. and 6.3.a. of appendix A of the applicable customer bulletin listed in paragraph (h) of this AD.

Note 2 to the introductory text of paragraph (i): Operators may align the inspections listed in the applicable ALS revision in paragraph (g) of this AD with the Part II inspection.

(1) Within 48 months after applying CIC, repair all bond line corrosion.

(2) If there is bond line corrosion that exceeds the allowable damage limits in Table 2 of appendix A of the applicable customer bulletin listed in paragraph (h) of this AD, or other allowable damage limits established by an appropriately authorized Gulfstream Organization Designation Authorization (ODA) unit member, repair all bond line corrosion before further flight using a repair approved by the FAA or an appropriately authorized Gulfstream ODA unit member.

(i) For a repair method to be approved by the FAA, the FAA's approval of the repair must specifically refer to this AD.

(ii) For a repair method to be approved by a Gulfstream ODA unit member, the unit member must be authorized in writing by the Manager of the Atlanta ACO Branch to approve repairs for this AD, and the unit member's approval of the repair must specifically refer to this AD.

(j) Credit for Previous Actions

You may take credit for the ALS revision required by paragraph (g) of this AD if you revised the ALS before the effective date of this AD using the service information specified in paragraph (j)(1), (2), or (3) of this AD, as applicable to your airplane designation.

(1) For Model GV airplanes: Section F and Table 12: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream V Aircraft Maintenance Manual, Revision 53, dated February 28, 2020.

(2) For Model GV–SP (G500 and G500–5000) airplanes: Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G500–5000 Aircraft Maintenance Manual, Revision 34, dated March 15, 2021.

(3) For Model GV–SP (G550) airplanes: Section F and Table 12: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G550 Aircraft Maintenance Manual, Revision 34, dated March 15, 2021.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by a Gulfstream Engineering Authorized Representative (EAR) of the Gulfstream ODA that has been authorized by the Manager, Atlanta ACO Branch, to make those findings. To be approved, the repair, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the following provisions apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, that are required by paragraph (i) of this AD must be done to comply with this AD. An AMOC is required for any deviations to RC steps required by paragraph (i) of this AD, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

(1) For more information about this AD, contact Ronald Wissing, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5552; email: *9-ASO-ATLACO-ADs@faa.gov.*

(2) 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 of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

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

(i) Gulfstream G500–5000 Customer Bulletin No. 190, Revision B, dated October 31, 2019.

(ii) Gulfstream G550 Customer Bulletin No. 190, Revision B, dated October 31, 2019.

(iii) Gulfstream GV Customer Bulletin No. 228, Revision B, dated October 31, 2019.

(iv) Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G500–5000 Aircraft Maintenance Manual, Revision 36, dated March 15, 2022.

(v) Section F and Table 11: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream G550 Aircraft Maintenance Manual, Revision 36, dated March 15, 2022.

(vi) Section F and Table 12: Horizontal Stabilizer Inspection Table in Section 05–10–10, Airworthiness Limitations, of Chapter 05, Time Limits/Maintenance Checks, of the Gulfstream V Aircraft Maintenance Manual, Revision 55, dated March 15, 2022.

(3) For service information identified in this AD, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402; phone: (800) 810–4853; fax: (912) 965–3520; email: *pubs@gulfstream.com*; website: *www.gulfstream.com/en/customer-support/.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(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: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on July 26, 2022.

Christina Underwood,

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

[FR Doc. 2022–16535 Filed 8–2–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0523; Airspace Docket No. 22–AEA–7]

RIN 2120–AA66

Revocation of Class E Airspace; Milford, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes Class E airspace in Milford, PA, as Myer Airport has been abandoned, and controlled airspace is no longer required. This action enhances the safety and management of controlled airspace within the national airspace system.

DATES: Effective 0901 UTC, November 3, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations, and Reporting Points, and subsequent amendments can be viewed online *www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it removes Class E airspace extending upward from 700 feet above the surface at Myer Airport, Milford, PA, due to the closing of the airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 29243, May 13, 2022) for Docket No. FAA–2022–0523 to remove Class E airspace extending upward from 700 feet above the surface at Myer Airport, Milford, PA.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations, and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by removing Class E airspace extending upward from 700 feet above the surface at Myer Airport, Milford, PA, as the airport has closed. Therefore, the airspace is no longer necessary. This action enhances the safety and management of controlled airspace within the national airspace system.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11F, Airspace Designations, and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA PA E5 Milford, PA [Removed]

Issued in College Park, Georgia, on July 27, 2022.

Lisa Burrows,

Manager, Airspace & Procedures Team North, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–16422 Filed 8–2–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2020–F–1275]

Food Additives Permitted in Feed and Drinking Water of Animals; Fumonisin Esterase

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of fumonisin esterase to degrade fumonisins present in swine feed. This action is in response to a food additive petition filed by Biomin GmbH.

DATES: This rule is effective August 3, 2022. See section V of this document for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final rule must be submitted by September 2, 2022.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2022. Objections 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 objections in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, 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–F–1275 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Fumonisin Esterase.'' Received objections, 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.

• Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in 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 objections. 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 objections 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 objections 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: Wasima Wahid, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–221), Rockville, MD 20855, 240–402–5857, *wasima.wahid@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of May 6, 2020 (85 FR 26902), FDA announced that we had filed a food additive petition (animal use) (FAP 2311) submitted by Biomin GmbH, Erber Campus 1, 3131 Getzersdorf, Austria. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of fumonisin esterase to degrade fumonisins present in swine feed.

II. Conclusion

FDA concludes that the data establish the safety and utility of fumonisin esterase to degrade fumonisins in swine feed, and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in

§ 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Add § 573.485 to subpart B to read as follows:

§ 573.485 Fumonisin esterase.

The food additive fumonisin esterase may be safely used to degrade fumonisins in swine feed in accordance with the following prescribed conditions:

(a) Fumonisin esterase, a carboxylesterase, is produced by a nontoxigenic and nonpathogenic yeast, *Komagataella phaffii,* genetically engineered to express the fumonisin esterase gene from the bacterium *Sphingopyxis* sp. Hydrolyzed fumonisin and two tricarballylic acid molecules are the reaction products of fumonisin hydrolysis by this 493 amino acid fumonisin esterase enzyme.

(b) The additive shall meet the following specifications:

(1) The fermentation media for the *Komagataella phaffii* shall not contain methanol.

(2) Viable genetically engineered *Komagataella phaffii* shall not be present.

(3) One unit of fumonisin esterase activity is defined as the amount of enzymatic activity required to release one micromole of tricarballylic acid (CAS 99–14–9) per minute from 100 micromolar fumonisin B1 in 20 millimolar Tris-hydrochloride buffer (pH 8.0) containing 0.1 milligram per milliliter of bovine serum albumin at 30 °C.

(c) The additive is incorporated at a minimum of 15 units of fumonisin esterase activity per kilogram of complete swine feed that cannot contain more than 10 parts per million of total fumonisins.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the common or usual name of the additive's source, dried *Komagataella phaffii* fermentation product.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) Adequate directions for use including a statement that the additive must be uniformly applied and thoroughly mixed into complete feeds;

(ii) A guarantee for the minimum amount of fumonisin esterase activity, expressed in accordance with paragraph (b)(3) of this section, and the unit of weight being consistent with the inclusion rate stated in the directions for use;

(iii) Appropriate warning and safety precaution statements concerning the additive as a respiratory sensitizer;

(iv) A cautionary statement concerning the maximum fumonisin content as established in paragraph (c) of this section.

Dated: July 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16566 Filed 8–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 39, 40, 41, 42, and 43

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing five general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GL 39, GL 40, GL 41, GL 42, and GL 43, each of which was previously issued on OFAC's website.

DATES: GL 39, GL 40, GL 41, GL 42, and GL 43 were each issued on June 28, 2022. See **SUPPLEMENTARY INFORMATION** of this document for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On June 28, 2022, OFAC issued GL 39, GL 40, GL 41, GL 42, and GL 43 on its website to authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587. GL 39 expires at 12:01 a.m. eastern daylight time, August 11, 2022. GL 41 expires at 12:01 a.m. eastern standard time, December 22, 2022. GL 43 expires at 12:01 a.m. eastern daylight time, August 31, 2022. GL 40 and GL 42 do not contain expiration dates. The texts of GLs 39, 40, 41, 42, and 43 are provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 39

Authorizing the Wind Down of Transactions Involving State Corporation Rostec

(a) Except as provided in paragraph (b) of this general license, all transactions ordinarily incident and necessary to the wind down of any transaction involving State Corporation Rostec, or any entity blocked not earlier than June 28, 2022 in which State Corporation Rostec owns, directly or indirectly, a 50 percent or greater interest, that are prohibited by Executive Order (E.O.) 14024 are authorized through 12:01 a.m. eastern daylight time, August 11, 2022, provided that any payment to a blocked person must be made into a blocked account in accordance with the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR).

(b) This general license does not authorize:

(1) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any transactions prohibited by Directive 4 under E.O. 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation;* or

(3) Any transactions otherwise prohibited by the RuHSR, including transactions involving any person blocked pursuant to the RuHSR other than the blocked persons described in paragraph (a) of this general license, unless separately authorized.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

Dated: June 28, 2022.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 40

Civil Aviation Safety

(a) Except as provided in paragraph (b), all transactions ordinarily incident and necessary to the provision, exportation, or reexportation of goods, technology, or services to ensure the safety of civil aviation involving one or more of the blocked entities listed in the Annex to this general license and that are prohibited by Executive Order (E.O.) 14024 are authorized, provided that:

(1) The aircraft is registered in a jurisdiction solely outside of the Russian Federation; and

(2) The goods, technology, or services that are provided, exported, or reexported are for use on aircraft operated solely for civil aviation purposes.

(b) This general license does not authorize:

(1) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any transactions prohibited by Directive 4 under E.O. 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation;* or

(3) Any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR other than the blocked entities listed in the Annex to this general license, unless separately authorized.

Note to General License 40. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies, including export, reexport, and transfer (in-country) licensing requirements maintained by the Department of Commerce's Bureau of Industry and Security under the Export Administration Regulations, 15 CFR parts 730–774.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

Dated: June 28, 2022.

Annex—Blocked Entities Described in Paragraph (a) of General License 40

List of blocked entities described in paragraph (a) of General License 40:

(a) Public Joint Stock Company United Aircraft Corporation;

(b) Irkut Corporation Joint Stock Company;

(c) Energotsentr Irkut;

(d) Irkut-Avtotrans;

(e) Irkut-Remstroi;

(f) Irkut-Stanko Service;

(g) Rapart Servisez;

(h) Sportivno-Ozdorovitelnyi Tsentr Irkut-Zenit;

(i) Tipografiya Irkut;

(j) Joint Stock Company Ilyushin Finance Company;

(k) Open Joint Stock Company Ilyushin Aviation Complex;

(l) Public Joint Stock Company Taganrog Aviation Scientific-Technical Complex N.A. G.M. Beriev;

(m) Joint Stock Company Flight Research Institute N.A. M.M. Gromov;

(n) Tupolev Public Joint Stock Company;

(o) Limited Liability Company Kapo-Avtotrans;

(p) Limited Liability Company Kapo-Zhilbitservis;

(q) Limited Liability Company Networking Company Irkut; or

(r) Any entity in which one or more of the above persons own, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 41

Authorizing Certain Transactions Related to Agricultural Equipment

(a) Except as provided in paragraph (b) of this general license, all transactions ordinarily incident and necessary to the manufacture, sale, and maintenance, including the provision and receipt of warranty and maintenance services, of agricultural equipment, components, and spare parts produced by Nefaz Publicly Traded Company (''Nefaz'') or Public Joint Stock Company Tutaev Motor Plant (''Tutaev Motor Plant''), or any entity in which Nefaz or Tutaev Motor Plant owns, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest, that are prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), are authorized through 12:01 a.m. eastern standard time, December 22, 2022, provided that any payment to a blocked person must be made into a blocked account in accordance with the RuHSR.

(b) This general license does not authorize:

(1) The opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity subject to Directive 2 under Executive Order (E.O.) 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation; or

(3) Any transaction prohibited by E.O. 14066, E.O. 14068, or E.O. 14071.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

Dated: June 28, 2022.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 42

Authorizing Certain Transactions With the Federal Security Service

(a) Except as provided in paragraph (b) of this general license, all transactions involving the Federal Security Service (a.k.a. Federalnaya Sluzhba Bezopasnosti) (a.k.a. FSB) prohibited by Executive Order (E.O.) 14024 are authorized, provided that such transactions and activities are ordinarily incident and necessary to:

(1) Requesting, receiving, utilizing, paying for, or dealing in licenses, permits, certifications, or notifications issued or registered by the Federal Security Service for the importation, distribution, or use of information technology products in the Russian Federation, provided that (i) the exportation, reexportation, or provision of any goods or technology that are subject to the Export Administration Regulations, 15 CFR parts 730 through 774, is licensed or otherwise authorized by the Department of Commerce; and (ii) the payment of any fees to the Federal Security Service for such licenses, permits, certifications, or notifications does not exceed $5,000 in any calendar year;

Note to paragraph (a)(1). Except for the limited purposes described in paragraph (a)(1), this paragraph does not authorize the exportation, reexportation, or provision of goods or technology to or on behalf of the Federal Security Service.

(2) Complying with law enforcement or administrative actions or investigations involving the Federal Security Service; and

(3) Complying with rules and regulations administered by the Federal Security Service.

(b) This general license does not authorize:

(1) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any transactions prohibited by Directive 4 under E.O. 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation;* or

(3) Any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR other than the blocked person described in paragraph (a) of this general license, unless separately authorized.

Note 1 to General License No. 42. See Cyber General License 1B for an authorization for certain transactions with the Federal Security Service prohibited by E.O. 13694, as amended by E.O. 13757, the Cyber-Related Sanctions Regulations, 31 CFR part 578, the Weapons of Mass Destruction Proliferators Sanctions Regulations, 31 CFR part 544, and Section 224 of the Countering America's Adversaries Through Sanctions Act (22 U.S.C. 9524).

Note 2 to General License No. 42. The exportation, reexportation, sale, or supply, directly or indirectly, from the United States, or by a United States person, wherever located, of any goods, services, or technology to the so-called ''Donetsk People's Republic'' or ''Luhansk People's Republic'' (DNR/LNR) regions of Ukraine, or such other regions of Ukraine as may be determined by the Secretary of the Treasury, in consultation with the Secretary of State, pursuant to E.O. 14065, or to the Crimea region of Ukraine remain prohibited pursuant to authorities implemented by the Ukraine-/Russia-Related Sanctions Regulations, 31 CFR part 589.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

Dated: June 28, 2022.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 43

Divestment or Transfer of Debt or Equity of, and Wind Down of Derivative Contracts Involving, Public Joint Stock Company Severstal or Nord Gold PLC

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions prohibited by Executive Order (E.O.) 14024 that are ordinarily incident and necessary to the divestment or transfer of debt or equity of Public Joint Stock Company Severstal (''Severstal'') or Nord Gold PLC (''Nord Gold''), or any entity in which Severstal or Nord Gold owns, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest, purchased prior to June 2, 2022 (''covered debt or equity'') are authorized through 12:01 a.m. eastern daylight time, August 31, 2022, provided that any divestment or transfer, or facilitation of divestment or transfer, of covered debt or equity must be to a non-U.S. person.

(b) Except as provided in paragraph (d) of this general license, all transactions prohibited by E.O. 14024 that are ordinarily incident and necessary to the wind down of derivative contracts entered into prior to June 2, 2022 that (i) include a blocked person described in paragraph (a) of this general license as a counterparty or (ii) are linked to covered debt or equity are authorized through 12:01 a.m. eastern daylight time, August 31, 2022, provided that any payments to a blocked person are made into a blocked account in accordance with the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR).

(c) Paragraph (a) of this general license does not authorize:

(1) U.S. persons to sell, or to facilitate the sale of, covered debt or equity to, directly or indirectly, any person whose property and interests in property are blocked; or

(2) U.S. persons to purchase or invest in, or to facilitate the purchase of or investment in, directly or indirectly, covered debt or equity, other than purchases of or investments in covered debt or equity that are ordinarily incident and necessary to the divestment or transfer of covered debt or equity, as described in paragraph (a) of this general license.

(d) This general license does not authorize:

(1) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any transactions prohibited by Directive 4 under E.O. 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation;* or

(3) Any transactions otherwise prohibited by the RuHSR, including transactions involving any person blocked pursuant to the RuHSR other than the persons described in paragraph (a) of this general license, unless separately authorized.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

Dated: June 28, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–16538 Filed 8–2–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 45 and 46

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of Web General Licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing two general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GL 45 and GL 46, each of which was previously issued on OFAC's website.

DATES: GL 45 and GL 46 were each issued on July 22, 2022. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On July 22, 2022, OFAC issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (the ''Regulations''), GL 45 and GL 46, each of which authorize certain transactions prohibited by the Regulations. GL 45 expires at 12:01 a.m. eastern daylight time, October 20, 2022. GL 46 does not contain an expiration date.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 45

Authorizing Transactions Related to the Wind Down of Certain Financial Contracts Prohibited by Executive Order 14071

(a) Except as provided in paragraph (b) of this general license, all transactions prohibited by section (1)(a)(i) of Executive Order (E.O.) 14071 that are ordinarily incident and necessary to the wind down of financial contracts or other agreements that were entered into on or before June 6, 2022 and involve, or are linked to, debt or equity issued by an entity in the Russian Federation (''covered contracts''), are authorized through 12:01 a.m. eastern daylight time, October 20, 2022.

Note to paragraph (a). The transactions authorized in paragraph (a) of this general license include: (1) the purchase by U.S. persons of debt or equity issued by an entity in the Russian Federation where that purchase is ordinarily incident and necessary to the wind down of covered contracts; and (2) the facilitating, clearing, and settling of a purchase by U.S. persons of debt or equity issued by an entity in the Russian Federation, where that purchase is ordinarily incident and necessary to the wind down of covered contracts.

(b) This general license does not authorize any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR, unless separately authorized.

Note to General License No. 45. See RuHSR General License No. 46 for an authorization for certain transactions in support of an auction process to settle credit derivatives transactions prohibited by E.O. 14071.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control.

Dated: July 22, 2022.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 46

Authorizing Transactions in Support of an Auction Process To Settle Certain Credit Derivative Transactions Prohibited by Executive Order 14071

(a) Except as provided in paragraph (d) of this general license, all transactions related to the establishment, administration, participation in, and execution of an auction process as announced by the EMEA Credit Derivatives Determination Committee (''the auction'') to settle credit derivative transactions with a reference entity of ''the Russian Federation'' and prohibited by section 1(a)(i) of Executive Order (E.O.) 14071 are authorized.

(b) Except as provided in paragraph (d) of this general license, the purchase or receipt of debt obligations of the Russian Federation by U.S. persons prohibited by section 1(a)(i) of E.O. 14071 is authorized for the period beginning two business days prior to the announced date of the auction and ending eight business days after the conclusion of the auction.

(c) Except as provided in paragraph (d) of this general license, all transactions ordinarily incident and necessary to facilitating, clearing, and settling transactions authorized by paragraph (a) or (b) of this general license that are prohibited by section 1(a)(i) of E.O. 14071 are authorized.

(d) This general license does not authorize any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR, unless separately authorized.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control.

Dated: July 22, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–16537 Filed 8–2–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 13 and 13A

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing two general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GL 13 and GL 13A, each of which was previously issued on OFAC's website.

DATES: GL 13 was issued on March 2, 2022, and GL 13A was issued on May 25, 2022. See **SUPPLEMENTARY INFORMATION** of this document for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On March 2, 2022, OFAC issued GL 13 on its website to authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (the ''Regulations''). GL 13 was issued with an expiration date of 12:01 a.m. eastern daylight time, June 24, 2022. On May 25, 2022, OFAC issued GL 13A on its website to authorize certain transactions otherwise prohibited by the Regulations. GL 13 was replaced and superseded in its entirety by GL 13A. GL 13A expires at 12:01 a.m. eastern daylight time, September 30, 2022. The texts of GL 13 and 13A are provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 13

Authorizing Certain Administrative Transactions Prohibited by Directive 4 Under Executive Order 14024

(a) Except as provided in paragraph (b) of this general license, U.S. persons are authorized to pay taxes, fees, or import duties, and purchase or receive permits, licenses, registrations, or certifications, to the extent such transactions are prohibited by Directive 4 under Executive Order (E.O.) 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation,* provided such transactions are ordinarily incident and necessary to such persons' day-to-day operations in the Russian Federation, through 12:01 a.m. eastern daylight time, June 24, 2022.

(b) This general license does not authorize any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

Dated: March 2, 2022.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

GENERAL LICENSE NO. 13A

Authorizing Certain Administrative Transactions Prohibited by Directive 4 Under Executive Order 14024

(a) Except as provided in paragraph (b) of this general license, U.S. persons, or entities owned or controlled, directly or indirectly, by a U.S. person, are authorized to pay taxes, fees, or import duties, and purchase or receive permits, licenses, registrations, or certifications, to the extent such transactions are prohibited by Directive 4 under Executive Order (E.O.) 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation,* provided such transactions are ordinarily incident and necessary to the day-to-day operations in the Russian Federation of such U.S. persons or entities, through 12:01 a.m. eastern daylight time, September 30, 2022.

(b) This general license does not authorize:

(1) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation; or

(2) Any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR, unless separately authorized.

(c) Effective May 25, 2022, General License No. 13, dated March 2, 2022, is replaced and superseded in its entirety by this General License No. 13A.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

Dated: May 25, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–16536 Filed 8–2–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2022–0512]

RIN 1625–AA08

Special Local Regulation; Cumberland River, Nashville, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for the Cumberland River from mile marker 190 to mile marker 192 on August 4, 2022 until August 6, 2022. The special local regulation is needed to protect personnel, vessels, and the marine environment from potential hazards created by the high powered jet skis associated with the event. Entry of vessels or persons into the special local regulation is prohibited unless specifically authorized by the Captain of the Port Sector Ohio Valley.

DATES: This rule is effective from 7 a.m. on August 4, 2022 through 6 p.m. on August 6, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0512 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Third Class Benjamin Gardner, U.S. Coast Guard; telephone 615–736–5421, email *Benjamin.t.gardner@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard was notified of the event without ample time to allow for a reasonable comment period because we must establish this special local regulation by August 4, 2022.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because action is needed on August 4, 2022 to ensure the safety of the participants in the Pro Watercross Music City Grand Prix Invitational marine event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with the boat races, will be a safety concern for anyone within mile markers 190 to 192 on the Cumberland River. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the special local regulation during the duration of the event.

IV. Discussion of the Rule

This rule establishes a temporary special local regulation on the Cumberland River from mile marker 190 to 192, from 7:00 a.m. until 6:00 p.m. each day from August 4, 2022 through August 6, 2022. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while high speed jet ski races are taking place. No non-participant vessels or persons will be permitted to enter the special local regulation without obtaining permission from the COTP or a designated representative. Vessels and persons transiting the area must comply with all orders or directions given to them by the COTP or their designated representative. The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners and by on-scene designated representatives.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based the event will be outside of the navigable channel and in a cove. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation lasting only 11 hours that will occur for 3 days in downtown Nashville from mile marker 190 to 192 on the Cumberland River. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

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

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T08–0512 to read as follows:

§ 100.T08–0512 Special Local Regulation; Cumberland River, Mile Marker 190–192, Nashville, TN.

(a) *Regulated area:* This section applies to the following area: Cumberland River Mile Marker (MM) 190 to 192, extending the entire width of the river.

(b) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Ohio Valley or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by phone at 502–779–5422. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners and local notice to mariners.

(c) *Enforcement period.* This section will be enforced from 7 a.m. to 6 p.m. each day from August 4, 2022 until August 6, 2022.

Dated: July 25, 2022.

H.R. Mattern,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2022–16633 Filed 8–2–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0615]

RIN 1625–AA00

Safety Zone; Sausalito Scattering Fireworks Display, Sausalito, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the San Francisco Bay, near Sausalito, CA, in support of the Sausalito Scattering Fireworks display on August 8, 2022. This safety zone is necessary to protect personnel, vessels, and the marine environment from the dangers associated with pyrotechnics. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port San Francisco or a designated representative.

DATES: This rule is effective from 6:30 p.m. to 9:30 p.m. on August 8, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0615 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant William K. Harris Coast Guard Sector San Francisco; telephone 415–399–7443, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard did not receive final details for this event until July 20, 2022. It is impracticable to go through the full notice and comment rule making process because the Coast Guard must establish this safety zone by August 8, 2022 and lacks sufficient time to provide a reasonable comment period and to consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for

making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is necessary to protect personnel, vessels, and the marine environment from the potential safety hazards associated with the fireworks display in the San Francisco Bay near Sausalito, CA on August 8, 2022.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco has determined that potential hazards associated with the Sausalito Scattering Fireworks Display on August 8, 2022, will be a safety concern for anyone within a 100-foot radius of the fireworks display dock during loading and staging and anyone within a 600-foot radius of the fireworks starting 30 minutes before the fireworks display is scheduled to commence and ending 30 minutes after the conclusion of the fireworks display. For this reason, this temporary safety zone is needed to protect personnel, vessels, and the marine environment in the navigable waters around the fireworks display location and during the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 6:30 p.m. until 9:30 p.m. on August 8, 2022. During the loading and staging of the fireworks display until 30 minutes prior to the start of the fireworks display, the safety zone will encompass the navigable waters around and under the fireworks display location, from surface to bottom, within a circle formed by connecting all points 100 feet out from the fireworks display. The pyrotechnics will be loaded and staged on the dock from 6:30 p.m. to 8:00 p.m. on August 8, 2022, at Clipper Yacht Harbor in Sausalito, CA. The display vessel will transit from the dock to the display location from 8:00 p.m. to 8:30 p.m., where it will remain until the conclusion of the fireworks display.

At 8:30 p.m. on August 8, 2022, 15 minutes prior to the commencement of the 15 minute display, the safety zone will increase in size and encompass the navigable waters around and under the fireworks display vessel, from surface to bottom, within a circle formed by connecting all points 600 feet from the circle center at approximate position 37°50′12″ N, 122°28′01″ W (NAD 83). The safety zone will terminate at 9:30 p.m. on August 8, 2022 or as announced via Broadcast Notice to Mariners.

This regulation is necessary to keep persons and vessels away from the immediate vicinity of the fireworks loading, staging, and display location. Except for persons and vessels authorized by the Captain of the Port San Francisco (COTP) or the COTP's designated representative, no person or vessel may enter or remain in the restricted area. A ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone. This regulation is necessary to ensure the safety of personnel, vessels, and the marine environment.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterways users will be notified to ensure the safety zone will result in minimum impact. The vessels desiring to transit through or around the temporary safety zone may do so upon express permission from the COTP or the COTP's designated representative.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial

direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone in the navigable waters around the loading, staging, and display locations located in Sausalito, CA and on the San Francisco Bay. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70054; 3 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. § 165.T11–109 to read as follows:

§ 165.T11–109 Safety Zone; Sausalito Scattering Fireworks Display, San Francisco Bay, Sausalito, CA

(a) *Location.* The following area is a safety zone: all navigable waters of the San Francisco Bay, from surface to bottom, within a circle connecting all points 100 feet out from the fireworks display vessel during the loading and staging of the display in Sausalito, CA. Between 8:30 p.m. and 9:30 p.m. on August 8, 2022, the safety zone will expand to all navigable waters, from surface to bottom, within a circle formed by connecting all points 600 feet out from the display vessel in approximate position 37°50′12″ N, 122°28′01″ W (NAD 83) or as announced via Broadcast Notice to Mariners.

(b) *Definitions.* As used in this section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

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

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced from 6:30 p.m. until 9:30 p.m. on August 8, 2022.

(e) *Information broadcasts.* The COTP or the COTP's designated representative will notify the maritime community of periods during which this zone will be enforced, in accordance with 33 CFR 165.7.

Dated: July 28, 2022.

Jordan M. Baldueza,

Captain, U.S. Coast Guard, Alternate Captain of the Port, San Francisco.

[FR Doc. 2022–16531 Filed 8–2–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0082]

RIN 1625–AA87

Security Zone; Naval Submarine Base New London, Groton, CT

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the security zone boundaries surrounding Naval Submarine Base New London in Groton, CT. This rule will amend the previous security zone to encompass the entire operational area of the Naval Submarine Base.

DATES: This rule is effective September 2, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0082 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email If you have questions about this proposed rulemaking, call or email MST2 Mark Paget, Waterways Management Division, Sector Long Island Sound; telephone: (203) 468–4583; email: *Mark.A.Paget@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Long Island Sound
DHS Department of Homeland Security
FR Federal Register
NOAA National Oceanic and Atmospheric Administration
NPRM Notice of proposed rulemaking

§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Naval Submarine Base New London, Groton, CT, is the home to a portion of the U.S. Navy's Fast Attack Nuclear Submarines. During a recent security assessment of the base, it was determined that the existing security zone does not adequately cover the entirety of naval assets, piers, or planned pier extension projects. Therefore, Naval Submarine Base New London requested to expand the existing security zone to safeguard its waterfront facility and its naval vessels while moored to prevent destruction, loss, or injury from sabotage or other subversive acts, or other causes of a similar nature.

In response, on April 27, 2022, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Security Zone, Naval Submarine Base New London, Groton, CT (87 FR 24927). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this limited access area. During the comment period that ended May 27, 2022, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Long Island Sound (COTP) has determined that a security zone is necessary to mitigate any moored naval vessels from destruction, loss, or injury from sabotage or other subversive acts, or other causes of a similar nature.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published April 27, 2022.

We were informed though by the National Oceanic and Atmospheric Administration (NOAA) Marine Chart Division that the third coordinate on the proposed security zone, 41°22′50.3″ N, 072°05′30.8″ W, does not appear to be consistent with the rest of the security zone. The Coast Guard reviewed NOAA's suggestion with Naval Submarine Base New London and revised the third coordinate to 41°23′26.42″ N, 72°5′30.771″ W. This is the only change to the regulatory text of this rule from the proposed rule in the NPRM.

This rule modifies and expands the existing security zone cited in 33 CFR 165.154(a)(3) Safety and Security Zones: Captain of the Port Long Island Sound Zone, that would allow the zone to completely encompass the security barriers and allow room to expand piers as required.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, and duration of the security zone. This rule will amend the previous security zone to encompass the entire operational area of the Naval Submarine Base. Vessel traffic will be able to safely transit around or through the security zone with COTP or their designated representative's permission which would impact a small designated area of the Thames River.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received 0 comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a

State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a security zone to limit access near Naval Submarine Base New London, Groton, CT. It is categorically excluded from further review under paragraph L60a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Security Measures, Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Revise § 165.154(a)(3) to read as follows:

§ 165.154 Safety and Security Zones; Captain of the Port Long Island Sound Zone Safety and Security Zones.

* * * * *

(a) * * *

(3) Naval Submarine Base New London, Groton, CT. All navigable waters of the Thames River, from surface to bottom, West of Naval Submarine Base New London, Groton, CT, enclosed by a line beginning at a point on the shoreline at 41°23′7.9″ N, 072°05′13.7″ W; then to 41°23′7.9″ N, 072°05′16.9″ W; then to 41°23′26.42″ N, 72°5′30.771″ W; then to 41°23′42.9″ N, 072°05′40.1″ W; then to 41°23′46.7″ N, 072°05′42.3″ W; then to 41°23′53.9″ N, 072°05′44.5″ W; then to 41°24′8.7″ N, 072°05′44.5″ W; then to 41°24′16.2″ N, 072°05′43.4″ W; then to a point on the shoreline 41°24′16.2″ N, 072°05′36.4″ W; then along the shoreline to the point of beginning (NAD 83).

* * * * *

Dated: July 21, 2022.

E.J. Van Camp,

Captain, U.S. Coast Guard, Captain of the Port Long Island Sound.

[FR Doc. 2022–16622 Filed 8–2–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0818; FRL–9264–02–R9]

Air Plan Approval; California; Northern Sierra Air Quality Management District; Reasonably Available Control Technology

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the Northern Sierra Air Quality Management District (NSAQMD or ''District'') portion of the California State Implementation Plan (SIP). This revision concerns NSAQMD's demonstration regarding reasonably available control technology (RACT) requirements and negative declarations for the 2015 8-hour ozone national ambient air quality standards (NAAQS or ''standards'') in the Western Nevada County ozone nonattainment area, which is under the jurisdiction of the District.

DATES: This rule is effective September 2, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2021–0818. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Elijah Gordon, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3158 or by email at *gordon.elijah@epa.gov.*

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

Table of Contents

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

I. Proposed Action

On February 10, 2022 (87 FR 7779), the EPA proposed to approve the California Air Resources Board's (CARB) March 23, 2021 submittal of the Northern Sierra Air Quality Management District (NSAQMD or ''District'') Reasonable Available Control Technology (RACT) State Implementation Plan (SIP) for the 2015 Ozone National Ambient Air Quality Standards (NAAQS) (''2015 ozone RACT SIP'').

TABLE 1—SUBMITTED DOCUMENT

Local agency	Document	Adopted	Submitted
NSAQMD	Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Revision for Western Nevada County 8-Hour Ozone Nonattainment Area.	01/25/21	03/23/21

We proposed to approve this submittal because we determined that it complies with the relevant Clean Air Act (CAA or ''Act'') requirements. Our proposed action contains more information on the submittal and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving the 2015 ozone RACT SIP into the California SIP.

IV. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 3, 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 oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 20, 2022.

Kerry Drake,

Acting Regional Administrator, Region IX.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(585) to read as follows:

§ 52.220 Identification of plan—in part.

(c) * * *

(585) The following plan was submitted on March 23, 2021, by the Governor's designee as an attachment to a letter dated March 22, 2021.

(i) [Reserved]

(ii) *Additional materials.* (A) Northern Sierra Air Quality Management District.

(*1*) Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Revision for Western Nevada County 8-Hour Ozone Nonattainment Area, adopted on January 25, 2021.

(*2*) [Reserved]

(B) [Reserved]

■ 3. Revise § 52.222(a)(9) to read as follows:

§ 52.222 Negative declarations.

(a) * * *

(9) Northern Sierra Air Quality Management District.

(i) The following negative declarations for the 1997 ozone NAAQS were adopted by the Northern Sierra Air Quality Management District.

TABLE 1 TO PARAGRAPH (a)(9)(i)—NEGATIVE DECLARATIONS FOR THE 1997 OZONE NAAQS

CTG document No.	Title	Adopted: 05/19/2008 Submitted: 08/14/2008 SIP Approved: 04/18/2012	Adopted: 04/25/2011 Submitted: 05/17/2011 SIP Approved: 04/18/2012	Adopted: 06/25/2007 Submitted: 02/07/2008 SIP Approved: 04/13/2015
EPA–450/2–77–008.	Surface Coating of Cans			X
EPA–450/2–77–008.	Surface Coating of Coils			X
EPA–450/2–77–008.	Surface Coating of Paper			X
EPA–450/2–77–008.	Surface Coating of Fabric			X
EPA–450/2–77–008.	Surface Coating of Automobiles and Light-Duty Trucks.			X
EPA–450/2–77–022.	Solvent Metal Cleaning			X
EPA–450/2–77–025.	Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.			X
EPA–450/2–77–026.	Tank Truck Gasoline Loading Terminals.			X
EPA–450/2–77–032.	Surface Coating of Metal Furniture			X
EPA–450/2–77–033.	Surface Coating of Insulation of Magnet Wire.			X
EPA–450/2–77–034.	Surface Coating of Large Appliances			X
EPA–450/2–78–029.	Manufacture of Synthesized Pharmaceutical Products.			X
EPA–450/2–78–030.	Manufacture of Pneumatic Rubber Tires.			X
EPA–450/2–78–032.	Factory Surface Coating of Flat Wood Paneling.			X
EPA–450/2–78–033.	Graphic Arts—Rotogravure and Flexography.			X
EPA–450/2–78–036.	Leaks from Petroleum Refinery Equipment.			X
EPA–450/2–78–047.	Petroleum Liquid Storage in External Floating Roof Tanks.			X
EPA–450/3–82–009.	Large Petroleum Dry Cleaners			X
EPA–450/3–83–006.	Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.			X
EPA–450/3–83–007.	Leaks from Natural Gas/Gasoline Processing Plants.			X
EPA–450/3–83–008.	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.			X
EPA–450/3–84–015.	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.			X
EPA–450/4–91–031.	Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.			X
EPA–453/R–96–007.	Wood Furniture Manufacturing Operations.			X
EPA–453/R–94–032.	ACT Surface Coating Operations at Shipbuilding and Ship Repair Facilities.			X
	Shipbuilding and Ship Repair Operations (Surface Coating), *see the* ***Federal Register*** *of 08/27/96*.			
EPA–453/R–97–004.	Coating Operations at Aerospace Manufacturing and Rework Operations.			X
	NESHAPS Aerospace Manufacturing and Rework, *see the* ***Federal Register*** *of 06/06/94*.			

TABLE 1 TO PARAGRAPH (a)(9)(i)—NEGATIVE DECLARATIONS FOR THE 1997 OZONE NAAQS—Continued

CTG document No.	Title	Adopted: 05/19/2008 Submitted: 08/14/2008 SIP Approved: 04/18/2012	Adopted: 04/25/2011 Submitted: 05/17/2011 SIP Approved: 04/18/2012	Adopted: 06/25/2007 Submitted: 02/07/2008 SIP Approved: 04/13/2015
EPA–453/R–06–001.	Industrial Cleaning Solvents	X		
EPA–453/R–06–002.	Offset Lithographic Printing and Letterpress Printing.	X		
EPA–453/R–06–003.	Flexible Package Printing	X		
EPA–453/R–06–004.	Flat Wood Paneling Coatings	X		
EPA 453/R–07–003.	Paper, Film, and Foil Coatings	X		
EPA 453/R–07–004.	Large Appliance Coatings	X		
EPA 453/R–07–005.	Metal Furniture Coatings	X		
EPA 453/R–08–004.	Fiberglass Boat Manufacturing Materials.		X	
EPA 453/R–08–005.	Miscellaneous Industrial Adhesives		X	
EPA 453/R–08–006.	Automobile and Light-Duty Truck Assembly Coatings.		X	
—N/A—	Major non-CTG VOC sources			X
—N/A—	Major non-CTG NO_X sources			X

(ii) [Reserved]

(iii) [Reserved]

(iv) The following negative declarations for the 2008 ozone NAAQS were adopted by the Northern Sierra Air Quality Management District.

TABLE 1 TO PARAGRAPH (a)(9)(iv)—NEGATIVE DECLARATIONS FOR THE 2008 OZONE NAAQS

CTG document No.	Title	Adopted: 03/26/2018 Submitted: 06/07/2018 SIP Approved: 01/15/2020
EPA–450/2–77–008	Surface Coating of Cans	X
EPA–450/2–77–008	Surface Coating of Coils	X
EPA–450/2–77–008	Surface Coating of Paper	X
EPA–450/2–77–008	Surface Coating of Fabric	X
EPA–450/2–77–008	Surface Coating of Automobiles and Light-Duty Trucks	X
EPA–450/2–77–022	Solvent Metal Cleaning	X
EPA–450/2–77–025	Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.	X
EPA–450/2–77–026	Tank Truck Gasoline Loading Terminals	X
EPA–450/2–77–032	Surface Coating of Metal Furniture	X
EPA–450/2–77–033	Surface Coating of Insulation of Magnet Wire	X
EPA–450/2–77–034	Surface Coating of Large Appliances	X
EPA–450/2–77–035	Bulk Gasoline Plants	X
EPA–450/2–77–036	Storage of Petroleum Liquids in Fixed-Roof Tanks	X
EPA–450/2–78–029	Manufacture of Synthesized Pharmaceutical Products	X
EPA–450/2–78–030	Manufacture of Pneumatic Rubber Tires	X
EPA–450/2–78–032	Factory Surface Coating of Flat Wood Paneling	X
EPA–450/2–78–033	Graphic Arts-Rotogravure and Flexography	X
EPA–450/2–78–036	Leaks from Petroleum Refinery Equipment	X
EPA–450/2–78–047	Petroleum Liquid Storage in External Floating Roof Tanks	X
EPA–450/3–82–009	Large Petroleum Dry Cleaners	X
EPA–450/3–83–006	Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.	X
EPA–450/3–83–007	Leaks from Natural Gas/Gasoline Processing Plants	X
EPA–450/3–83–008	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins	X
EPA–450/3–84–015	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry	X
EPA–450/4–91–031	Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.	X
EPA–453/R–96–007	Wood Furniture Manufacturing Operations	X
EPA–453/R–94–032	ACT Surface Coating Operations at Shipbuilding and Ship Repair Facilities	X
	Shipbuilding and Ship Repair Operations (Surface Coating), *see the* ***Federal Register*** *of 08/27/96.*	
EPA–453/R–97–004	Coating Operations at Aerospace Manufacturing and Rework Operations	X
	NESHAPS Aerospace Manufacturing and Rework, *see the* ***Federal Register*** *of 06/06/94.*	
EPA–453/R–06–001	Industrial Cleaning Solvents	X

TABLE 1 TO PARAGRAPH (a)(9)(iv)—NEGATIVE DECLARATIONS FOR THE 2008 OZONE NAAQS—Continued

CTG document No.	Title	Adopted: 03/26/2018 Submitted: 06/07/2018 SIP Approved: 01/15/2020
EPA–453/R–06–002	Offset Lithographic Printing and Letterpress Printing	X
EPA–453/R–06–003	Flexible Package Printing	X
EPA–453/R–06–004	Flat Wood Paneling Coatings	X
EPA 453/R–07–003	Paper, Film, and Foil Coatings	X
EPA 453/R–07–004	Large Appliance Coatings	X
EPA 453/R–07–005	Metal Furniture Coatings	X
EPA 453/R–08–003	Miscellaneous Metal Parts and Plastic Parts Coatings Tables 3–6	X
EPA 453/R–08–004	Fiberglass Boat Manufacturing Materials	X
EPA 453/R–08–005	Miscellaneous Industrial Adhesives	X
EPA 453/R–08–006	Automobile and Light-Duty Truck Assembly Coatings	X
EPA 453/B–16–001	Oil and Natural Gas Industry	X
—N/A—	Major non-CTG VOC sources	X
—N/A—	Major non-CTG NO_X sources	X

(v) The following negative declarations for the 2015 ozone NAAQS were adopted by the Northern Sierra Air Quality Management District.

TABLE 1 TO PARAGRAPH (a)(9)(v)—NEGATIVE DECLARATIONS FOR THE 2015 OZONE NAAQS

CTG document No.	Title	Adopted: 01/25/2021 Submitted: 03/23/2021 SIP Approved: 08/03/2022
EPA–450/2–77–008	Surface Coating of Cans	X
EPA–450/2–77–008	Surface Coating of Coils	X
EPA–450/2–77–008	Surface Coating of Paper	X
EPA–450/2–77–008	Surface Coating of Fabric	X
EPA–450/2–77–008	Surface Coating of Automobiles and Light-Duty Trucks	X
EPA–450/2–77–022	Solvent Metal Cleaning	X
EPA–450/2–77–025	Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.	X
EPA–450/2–77–026	Tank Truck Gasoline Loading Terminals	X
EPA–450/2–77–032	Surface Coating of Metal Furniture	X
EPA–450/2–77–033	Surface Coating for Insulation of Magnet Wire	X
EPA–450/2–77–034	Surface Coating of Large Appliances	X
EPA–450/2–77–035	Bulk Gasoline Plants	X
EPA–450/2–77–036	Storage of Petroleum Liquids in Fixed-Roof Tanks	X
EPA–450/2–78–015	Surface Coating of Miscellaneous Metal Parts and Products	X
EPA–450/2–78–029	Manufacture of Synthesized Pharmaceutical Products	X
EPA–450/2–78–030	Manufacture of Pneumatic Rubber Tires	X
EPA–450/2–78–032	Factory Surface Coating of Flat Wood Paneling	X
EPA–450/2–78–033	Graphic Arts—Rotogravure and Flexography	X
EPA–450/2–78–036	Leaks from Petroleum Refinery Equipment	X
EPA–450/2–78–047	Petroleum Liquid Storage in External Floating Roof Tanks	X
EPA–450/3–82–009	Large Petroleum Dry Cleaners	X
EPA–450/3–83–006	Leaks from Synthetic Organic Chemical and Polymer Manufacturing Equipment	X
EPA–450/3–83–007	Equipment Leaks from Natural Gas/Gasoline Processing Plants	X
EPA–450/3–83–008	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins	X
EPA–450/3–84–015	Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry	X
EPA–450/4–91–031	Reactor Processes and Distillation Operations Processes in the Synthetic Organic Chemical Manufacturing Industry.	X
EPA–453/R–96–007	Wood Furniture Manufacturing Operations	X
EPA–453/R–94–032	ACT Surface Coating Operations at Shipbuilding and Ship Repair Facilities Shipbuilding and Ship Repair Operations (Surface Coating), *see the* ***Federal Register*** *of 08/27/96.*	*X*
EPA–453/R–97–004	Coating Operations at Aerospace Manufacturing and Rework Operations NESHAPS Aerospace Manufacturing and Rework, *see the* ***Federal Register*** *of 06/06/94.*	X
EPA–453/R–06–001	Industrial Cleaning Solvents	X
EPA–453/R–06–002	Offset Lithographic Printing and Letterpress Printing	X
EPA–453/R–06–003	Flexible Package Printing	X
EPA–453/R–06–004	Flat Wood Paneling Coatings	X
EPA 453/R–07–003	Paper, Film, and Foil Coatings	X
EPA 453/R–07–004	Large Appliance Coatings	X
EPA 453/R–07–005	Metal Furniture Coatings	X
EPA 453/R–08–003	Miscellaneous Metal and Plastic Parts Coatings; Table 2—Metal Parts and Products.	X
EPA 453/R–08–003	Miscellaneous Metal and Plastic Parts Coatings; Table 3—Plastic Parts and Products.	X

TABLE 1 TO PARAGRAPH (a)(9)(v)—NEGATIVE DECLARATIONS FOR THE 2015 OZONE NAAQS—Continued

CTG document No.	Title	Adopted: 01/25/2021 Submitted: 03/23/2021 SIP Approved: 08/03/2022
EPA 453/R–08–003	Miscellaneous Metal and Plastic Parts Coatings; Table 4—Automotive/Transportation and Business Machine Plastic Parts.	X
EPA 453/R–08–003	Miscellaneous Metal and Plastic Parts Coatings; Table 5—Pleasure Craft Surface Coating.	X
EPA 453/R–08–003	Miscellaneous Metal and Plastic Parts Coatings; Table 6—Motor Vehicle Materials	X
EPA 453/R–08–004	Fiberglass Boat Manufacturing Materials	X
EPA 453/R–08–005	Miscellaneous Industrial Adhesives	X
EPA 453/R–08–006	Automobile and Light-Duty Truck Assembly Coatings	X
EPA 453/B–16–001	Oil and Natural Gas Industry	X
—N/A—	Major non-CTG sources of VOC	X
—N/A—	Major sources of NO_X	X

* * * * *

[FR Doc. 2022–16019 Filed 8–2–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 206

[Docket ID FEMA–2022–0020]

RIN 1660–AB10

Public Assistance Program's Simplified Procedures Large Project Threshold

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) is revising its regulations governing the Public Assistance program that provides grants to State, local, Tribal, and territorial governments, as well as eligible private nonprofit organizations, for debris removal, emergency protective measures, and the repair, replacement, or restoration of disaster-damaged facilities after a presidentially-declared major disaster to update the monetary threshold for when FEMA will process an application using ''simplified procedures.''

DATES: This rule is effective August 3, 2022. Comments must be received on or before October 3, 2022.

ADDRESSES: The docket for this rulemaking is available for inspection using the Federal eRulemaking Portal at *http://www.regulations.gov* and can be viewed by following that website's instructions.

FOR FURTHER INFORMATION CONTACT: Tod Wells, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, *Tod.Wells@fema.dhs.gov,* (202) 646–3834. Persons with speech or hearing difficulties may reach this number via teletype at 711.

SUPPLEMENTARY INFORMATION:

1. Public Participation

Interested persons are invited to participate in this rulemaking by submitting comments and related materials. We will consider all comments and material received during the comment period.

If you submit a comment, include the Docket ID FEMA–2022–0020, indicate the specific section of this document to which each comment applies, and give the reason for each comment. All submissions may be posted, without change, to the Federal e-Rulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. For more information about privacy and the docket, see 83 FR 48645.

Viewing comments and documents: For access to the docket to read background documents or comments received, go to the Federal e-Rulemaking Portal at *http://www.regulations.gov.*

2. Background and Discussion of Rule

FEMA's Public Assistance (PA) program provides grants to State, local, Tribal, and territorial governments, as well as eligible private nonprofit (PNP) organizations, for debris removal, emergency protective measures, and the repair, replacement, or restoration of disaster-damaged facilities after a Presidentially-declared major disaster.[1] FEMA categorizes each grant award as either a small or large project,[2] which is determined by a monetary threshold set each year by FEMA pursuant to statute. *See* section 422 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), codified at 42 U.S.C. 5189.[3] FEMA obligates money for a small project based on an estimate of the project costs, and FEMA obligates money for a large project based on actual project costs as the project progresses and cost documentation is provided to FEMA.[4]

In 2013, the Sandy Recovery Improvement Act (SRIA)[5] amended section 422(b) of the Stafford Act and required FEMA to complete an analysis to determine whether an increase in the large project threshold was appropriate and submit to Congress a report on its findings not later than one year after January 29, 2013.[6] On January 29, 2014, FEMA submitted its report to Congress, which recommended increasing the maximum threshold from $68,500[7] to $120,000.[8] Section 422(b)(2) of the Stafford Act required FEMA to implement the new threshold ''immediately'' following submission of the report to Congress, ''without regard

[1] The PA program is authorized by the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C. 5170b, 5172, 5173, 5192.

[2] A project is a logical grouping of work required as a result of the declared major disaster or emergency and may include eligible work at several sites. *See* 44 CFR 206.201(k); FEMA Policy 104–009–2, *Public Assistance Program and Policy Guide,* v.4 (PAPPG), pp. 60–63 (June 1, 2020), *available at https://www.fema.gov/sites/default/files/documents/fema_pappg-v4-updated-links_policy_6-1-2020.pdf.*

[3] *See also* 44 CFR 206.203(c), 206.205. FEMA obligates money for a small project based on an estimate of the project costs; FEMA obligates money for a large project based on actual project costs as the project progresses and cost documentation is provided to FEMA.

[4] *See* 44 CFR 206.203(c); PAPPG, pp. 199–202.

[5] Public Law 113–2, section 1107.

[6] 42 U.S.C. 5189(b)(1).

[7] The large project threshold for Fiscal Year (FY) 2014. 78 FR 64232 (Oct. 28, 2013). *See also https://www.fema.gov/assistance/public/applicants/per-capita-impact-indicator.*

[8] A copy of this report is on *regulations.gov* under docket ID FEMA–2014–0009.

to chapter 5 of title 5'' of the United States Code, on Administrative Procedure, which includes a section on Rule making,[9] (*see* Section 3.A below) and to adjust the threshold annually to reflect changes in the Department of Labor's Consumer Price Index for Urban Consumers (CPI–U).[10] Following submission of its report, FEMA published a final rule updating the maximum threshold to $120,000.[11]

In addition to the final rule, FEMA published a notice requesting comments from the public regarding the report that justified the increase.[12] FEMA received 19 public comments, 18 of which were from 16 States.[13] Of these, eight States [14] supported increasing the maximum threshold. Commenters noted benefits of the updated maximum threshold, such as increased State/local control over funding and decreased documentation burden, time, and expenses in administering PA grants, especially regarding reduced need for final reconciliation of actual costs, final inspections, funding increase requests, and monitoring. Commenters also noted that the ability to immediately disburse 75 percent of project costs after obligation will help expedite recovery in affected areas.

Five States [15] opposed increasing the maximum threshold. Indiana noted that its State Administrative Plan requires reconciliation of costs, and that it performs audits in accordance with the Single Audit Act.[16] Neither of these requirements should prevent adoption of an increase to the threshold. All non-Federal entities that expend $750,000 or more during the non-Federal entity's fiscal year in Federal awards are subject to the Single Audit Act and must have a single or program-specific audit conducted for that year in accordance with the provisions 2 CFR part 200.[17] The scope of the audits are to ensure that non-Federal entities have complied with Federal statutes, regulations, and the terms and conditions of Federal awards.[18] The State Administrative Plan each State is required to have for the PA program refers back to the audit procedures in 2 CFR part 200 and should be updated annually.[19] This rule will change FEMA's regulations and the terms and conditions of PA grants with respect to the large project threshold. That means there will be no impact to States with respect to any Federal auditing requirements. It appears that this has since been understood and adopted by the State of Indiana; FEMA reviewed Indiana's 2021 State Administrative Plan and determined that it only requires reconciliation of costs for large projects.

North Carolina expressed concern that an increase in the maximum threshold may increase the frequency of cost overruns and underruns, putting additional pressure on recipients to ensure that estimates are accurate. Since 2014, FEMA has taken concerns about the accuracy of its estimates into consideration, and has adopted changes within the PA program that have significantly improved, streamlined, and centralized its cost estimating process to establish more consistent estimating across all regions and disasters. This has resulted in continued improvements to the accuracy of all its estimates.[20]

Arizona stated that it has a statutory requirement to audit all projects, and also noted that fronting a larger Federal share based on estimates could increase its burden when the estimated costs of a subrecipient's project differ from actual costs. FEMA reviewed Arizona's 2021 State Administrative Plan and, similar to Indiana, it appears that Arizona no longer has the statutory requirement because its 2021 Plan only requires reconciliation of costs for large projects. Arizona also objected to FEMA's implementing the change in threshold without prior consultation with the States. However, Congress explicitly directed FEMA to ''immediately'' establish the threshold ''without regard to chapter 5 of title 5'' of the United States Code. 42 U.S.C. 5189(b)(2)(A). As a result, FEMA immediately implemented the updated threshold in 2014 without seeking prior public comment, but sought post-promulgation comments on the report. FEMA intends to reach out specifically to the five States who objected in 2014 to ensure that they understand how to implement the increase and issue clarifying guidance, if necessary.

Ohio and Pennsylvania both commented that because they pay for 25 percent of projects (through the cost share), they were unlikely to change their procedures in order to ensure reconciliation.[21] FEMA acknowledges that many States have their own requirements to reconcile all project costs, and may wish to ensure that local governments have a higher level of accuracy when completing PA projects based on the State's 25 percent contribution to their projects. While FEMA lacks control over what rules States may impose upon themselves, FEMA notes that the current threshold has failed to keep pace with the PA program's increased disaster spending, and increasing the threshold would greatly reduce the administrative burden and resources spent by FEMA and recipients without audit requirements. This reduction in administrative burden would result in expedited funding, facilitating quicker recovery in these areas. That some recipients impose upon themselves rules that may ultimately prevent their recovery in the most expedited manner does not mean that FEMA should deprive all recipients of the opportunity to expedite recovery.

Congress enacted section 422 of the Stafford Act to increase the administrative efficiency of the PA program. The simplified procedures authorized under section 422 allow FEMA to award funding for projects

[9] 5 U.S.C. 553.

[10] 42 U.S.C. 5189(b)(2).

[11] 79 FR 10686 (Feb. 26, 2014).

[12] 79 FR 68899 (Nov. 19, 2014).

[13] FEMA received 18 comments from the following States: Alaska, Arizona, Arkansas, Idaho, Indiana, Kansas, New Jersey, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Washington, and Wisconsin. (Alaska and Kansas each submitted two comments). FEMA received one comment from a private citizen from California.

[14] South Carolina (FEMA–2014–0009–0005); Idaho (FEMA–2014–0009–0007); New Jersey (FEMA–2014–0009–0009); Oregon (FEMA–2014–0009–0010); Wisconsin (FEMA–2014–0009–0011); Arkansas (FEMA–2014–0009–0012); Alaska (FEMA–2014–0009–0020 and FEMA–2014–0009–0022); and Washington (FEMA–2014–0009–0021).

[15] Indiana (FEMA–2014–0009–0013); Arizona (FEMA–2014–0009–0014); Ohio (FEMA–2014–0009–0015); North Carolina (FEMA–2014–0009–0017); and Pennsylvania (FEMA–2014–0009–0018).

[16] The Single Audit Act, passed by Congress in 1984, requires most governmental recipients of Federal assistance to have annual financial or compliance audits. *See* 31 U.S.C. 7501 *et seq.*

[17] 2 CFR 200.501(a).

[18] 2 CFR 200.514(d).

[19] 44 CFR 206.207(b)(1)(iii)(H); 44 CFR 206.207(b)(3).

[20] To ensure that the estimation process is accurate, FEMA also conducted an analysis on Net Small Project Overruns (NSPOs), the process by which a subrecipient requests additional funding through the PA appeals process if its total cost incurred for all of its small projects exceeds the total amount FEMA obligated for those projects. The analysis showed that out of 627,656 total obligated small projects since 1997, there were only 20 instances of second appeal NSPOs (0.003 percent). Additionally, out of 137,913 total obligated small projects since 2013, there were only 70 instances of first appeal NSPOs (0.05 percent). Small projects make up a significant majority of the PA project universe; for example, since the adoption of the National PA Delivery Model in 2017, 45,944 out of 59,178 total projects were small projects, making up 78 percent of the total number of PA projects in that time. The number of first and second NSPO appeals in relation to the total number of small projects is not statistically significant. This indicates that the funding FEMA provides for small projects is, by and large, sufficient for applicants to complete all of their small projects. A copy of this report is on regulations.gov under docket ID FEMA–2014–0009.

[21] Ohio also noted, however, that good quality Project Worksheets (PWs) and clear scopes of work would likely reduce its administrative costs.

under the threshold based on estimates, simplifying final accounting and project closeout procedures. This expedites FEMA's processing of PA grant funding by eliminating much of the administrative burden that FEMA experiences when awarding projects at or above the threshold (*i.e.,* large projects), ultimately reducing FEMA's cost of administering PA funding. PA projects beneath the established threshold represent the vast majority of individual projects, but a small portion of FEMA's overall funding under the PA program. These procedures, therefore, allow FEMA to expedite its provision of Federal disaster assistance, saving FEMA, and by extension, the American taxpayer, time and money on small projects, but still provide financial oversight for the majority of funding provided under the PA program. Moreover, States without statutory audit requirements [22] will also benefit from these efficiencies in their administration of PA grants.

In 1988, when Congress set the original threshold at $35,000, it noted that ''damage survey reports of less than $35,000 have constituted 95% of all damage survey reports but only 32% of all expended dollars.'' [23] Congress envisioned that these simplified procedures would allow ''. . . [applicants] [to] receive an amount estimated by the Federal Government . . . rather than the standard—and sometimes cumbersome—procedure of performing audits and inspections to verify the cost of an eligibility for payment of the costs of the work.'' [24] Congress believed that this more streamlined approach would ''result in substantial savings of time and money that . . . should have a significant and beneficial impact on FEMA's overall program.'' [25] Through the SRIA amendments to section 422(b), Congress again highlighted the importance of the administrative efficiency of the PA program when it directed FEMA to determine whether an increase in the threshold was appropriate and to review the threshold every three years.[26] FEMA is mindful both of Congress' efforts to improve administrative efficiency of the program and its responsibility to be fiscal stewards of public funding.

Following 2014, FEMA continued to adjust the threshold annually to reflect changes in the CPI–U, as required under section 422(b)(2).[27] Section 422(b)(3) requires FEMA to review the threshold every three years.[28] FEMA conducted an analysis in 2017 and recommended no change to the threshold at that time.[29] As a result, FEMA has only made annual CPI–U adjustments to the threshold since then.[30]

Since FEMA's analysis in 2017, the United States has seen increased disaster activity either due to, or amplified or aggravated by, the climate crisis. For example, in 2017, Hurricanes Harvey, Irma, and Maria caused a combined total of $294.2 billion in damages,[31] with FEMA providing over $49.9 billion in PA funding for these disasters.[32] Damages from wildfires in that year and the next totaled approximately $46.2 billion; [33] FEMA provided over $742 million in PA funding for the 2017 wildfires.[34] In 2020, FEMA responded to 22 events with losses exceeding $1 billion—the highest in its history—which included a record number of tropical storms in the Atlantic and the Nation's most active wildfire year recorded.[35] The estimated damages from these 22 events totaled approximately $95 billion, with over $6.5 billion comprising FEMA's share of non-COVID related PA funding.[36]

In addition to increased natural disasters, in 2020 FEMA also issued an unprecedented 57 major disaster declarations in response to COVID–19,[37] including every State, 5 territories, the Seminole Tribe of Florida, and the District of Columbia.[38] Defeating COVID–19 remains the Administration's top public health priority. As of January 24, 2022, the Nation has lost more than 869,000 lives to COVID–19, which has particularly affected vulnerable populations who are at the highest risk of infection and adverse outcomes. It is the policy of the United States to prioritize and invest in the Nation's public health system to address health disparities that have been exposed and worsened by COVID–19 and build a stronger public health system that allows us to be ready for the next virus.[39] In line with the goal of defeating the pandemic, the President directed FEMA to expand financial support of State, local, Tribal, and territorial partners by increasing the Federal cost share under PA to 100 percent to ensure safe re-opening.[40] FEMA also

[22] States without audit requirements that supported the increase were Oregon (FEMA–2014–0009–0010); Arkansas (FEMA–2014–0009–0011); and Alaska (FEMA–2014–0009–0020 and FEMA–2014–0009–0022). Idaho (FEMA–2014–0009–0007), which reconciles actual costs on all projects, also supported the increase, as did South Carolina (FEMA–2014–0009–0005), which reconciles actual costs on 20 percent of small projects (and all large projects).

[23] *See* H.R. REP. NO. 100–517 (1988), p. 11. ''Damage survey reports'' is the former name of PA project worksheets.

[24] *Id.*

[25] *Id.*

[26] In 2013, the number of projects beneath the threshold had decreased from 95 percent (1988) to 88 percent.

[27] 42 U.S.C. 5189(b)(2). FEMA publishes the annual adjustments to the large project threshold at *https://www.fema.gov/assistance/public/applicants/per-capita-impact-indicator.* For more information on the National PA Delivery Model, *see* the Public Assistance Delivery Model Fact Sheet (Aug. 17, 2018), *available at https://www.fema.gov/sites/default/files/2020-07/fema_pa_delivery-model_factsheet.pdf.*

[28] 42 U.S.C. 5189(b)(3).

[29] A copy of this analysis is on regulations.gov under docket ID FEMA–2022–0020. During the period of 2014–2017, FEMA saw fewer disasters and, as a result, decreased disaster spending. Compared to FY 2013, when FEMA spent a total of $18.4 billion on recovery, FEMA spent under $2 billion annually in FYs 2014 to 2017.

[30] The current threshold, for Fiscal Year 2022, is $139,800. 86 FR 63040 (Nov. 15, 2021); *see also* FEMA, Per Capita Impact Indicator and Project Thresholds, *https://www.fema.gov/assistance/public/applicants/per-capita-impact-indicator* (accessed Nov. 3, 2021). Note, however, that the analysis included in this rule was conducted based on the Fiscal Year 2021 threshold of $132,800. See 85 FR 69639 (Nov. 3, 2020).

[31] *See* National Oceanic & Atmospheric Administration (NOAA), National Centers for Environmental Information (NCEI), *Billion-Dollar Weather and Climate Disasters: Events, https://www.ncdc.noaa.gov/billions/events/US/1980-2021* (accessed Nov. 3, 2021); *see also https://www.washingtonpost.com/news/energy-environment/wp/2018/01/08/hurricanes-wildfires-made-2017-the-most-costly-u-s-disaster-year-on-record/.*

[32] This estimate of PA funding is based on data from FEMA's Emergency Management Mission Integrated Environment (EMMIE) Enterprise Data Warehouse, as of Dec. 10, 2021.

[33] *See* NOAA NCEI, *Billion-Dollar Weather and Climate Disasters: Events, https://www.ncdc.noaa.gov/billions/events/US/1980-2021* (accessed Nov. 3, 2021).

[34] This estimate of PA funding is based on data from FEMA's EMMIE Enterprise Data Warehouse, as of Dec. 10, 2021.

[35] *See* National Oceanic and Atmospheric Administration, ''Record Number of Billion-Dollar Disasters Struck U.S. in 2020, Jan. 8, 2021, *available at https://www.noaa.gov/stories/record-number-of-billion-dollar-disasters-struck-us-in-2020* (last accessed Nov. 3, 2021).

[36] *Id.* The estimate of PA funding is based on data from FEMA's EMMIE Enterprise Data Warehouse, as of Dec. 10, 2021.

[37] COVID–19 is a communicable disease caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2), that was first identified as the cause of an outbreak of respiratory illness that began in Wuhan, Hubei Province, People's Republic of China. On March 13, 2020, the President declared a nationwide emergency under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, authorizing FEMA to provide assistance for emergency protective measures to respond to the COVID–19 pandemic. COVID–19 Emergency Declaration *available at https://www.fema.gov/news-release/2020/03/13/covid-19-emergency-declaration* (accessed Dec. 15, 2020).

[38] *See https://www.fema.gov/disasters/* (accessed Dec. 15, 2020).

[39] Proclamation 10175 of April 5, 2021, ''National Public Health Week, 2021,'' 86 FR 18171 (Apr. 8, 2021).

[40] *See* Memorandum of February 2, 2021, ''Maximizing Assistance From the Federal

Continued

participates in the White House's COVID–19 Pandemic Testing Board, which coordinates the Federal Government's efforts to promote COVID–19 testing and identifies barriers to increase testing among priority populations and high-risk groups,[41] and has helped vaccinate more than 200 million Americans.[42]

In Fiscal Year 2020 declarations, FEMA's funding under the PA program is over $35.9 billion. Although costs for COVID–19 accounted for 93 percent of this funding,[43] as climate change continues to make natural disasters more frequent and more destructive, FEMA expects even greater spending on recovery will be required in the future.[44]

In 2020, FEMA conducted another analysis to ensure that FEMA is maximizing the benefits of simplified procedures in light of its more recent disaster spending, while also effectively managing risk associated with the provision of Federal disaster assistance and the responsible stewardship of public funds.[45] In particular, FEMA considered the extent to which increasing the threshold would reduce the administrative burden and resources spent by FEMA and recipients without statutory audit requirements, and how that reduction in administrative burden would result in expedited funding, facilitating quicker recovery. FEMA also considered past performance, specifically how the current threshold has failed to keep pace with the PA program's increased disaster spending. Regarding accountability measures, FEMA concluded that the reduced scrutiny accompanying an increased threshold would not pose a significant risk given FEMA's improvements to its cost estimating procedures.[46] Based on this analysis, FEMA determined that it should increase the threshold for simplified procedures to $1,000,000. FEMA determined that projects below the Fiscal Year (FY) 2021 CPI-adjusted threshold of $132,800 represented only 76.8 percent of the total number of projects and 2.4 percent of total funding. Raising the threshold to $1,000,000 achieves the same approximate percentage of total projects as Congress' original adoption of simplified procedures in 1988 at 95 percent.[47] Raising the threshold to $1,000,000 accounts for a larger amount of small projects (from 76.8 to 94.4 percent) and an increase in the percentage of total funding (from 2.4 to 8.4 percent). This comports with Congress' original goal of maximizing the number of total projects eligible for simplified procedures while minimizing the amount of funding subject to the risks inherent to simplified final accounting. FEMA will continue to adjust annually for inflation based on the CPI–U.

This rule also adds a new paragraph ''(c)(3)'' in section 206.203 providing that the new threshold will apply to all Project Worksheets (PWs) for major disasters and emergencies declared on or after March 13, 2020, that have not been obligated as of the effective date of this rule.[48] For PWs from major disasters and emergencies declared before March 13, 2020, or that have already been obligated, the threshold will continue to be the amount previously published in the **Federal Register** for the applicable fiscal year.[49] As a result, this rule's applicability to unobligated future PWs will ensure FEMA and recipients can more efficiently process unobligated PWs for (for instance) COVID–19 declarations, which continue to fund important pandemic-related work, while avoiding unnecessary confusion and administrative burden by not affecting previous project size determinations. FEMA notes that on March 1, 2022, the President directed FEMA to continue funding assistance for COVID–19 declarations at a 100 percent Federal share through July 1, 2022.

3. Regulatory Analysis

A. Administrative Procedure Act

The Administrative Procedure Act (APA) generally requires agencies to publish a notice of proposed rulemaking in the **Federal Register** and provide interested persons the opportunity to submit comments. *See* 5 U.S.C. 553(b) and (c). The APA provides an exception to this prior notice and comment requirement for matters relating to public property, loans, grants, benefits, or contracts. 5 U.S.C. 553(a)(2). FEMA's PA program is a grant program through which FEMA obligates funding to State, local, Tribal, and territorial governments, as well as eligible PNP organizations, for debris removal, emergency protective measures, and the repair, replacement, or restoration of disaster-damaged facilities after a presidentially-declared major disaster. Because this rule relates to FEMA's obligation of grant funding under the PA program, it is exempt from notice and comment rulemaking under the APA.

FEMA acknowledges its general policy to provide for public participation in rulemaking unless it determines that circumstances warrant a departure from that general policy.[50] The circumstances presented here warrant such a departure. First, FEMA is still receiving and processing COVID–19 PWs and will continue to fund them at 100 percent Federal funding through at least July 1, 2022. Taking pre-promulgation comment on the rule would delay application of the new threshold and the more efficient processing of unobligated PWs for COVID–19 declarations, which continue to fund important pandemic-related work.

Second, the APA also provides an exception to prior notice and comment for rules of agency organization, procedure, or practice. 5 U.S.C. 553(b)(A). In addition to falling under the APA's exception to notice and comment for rules relating to grants, this final rule is also a procedural rule, promulgated for agency efficiency purposes, because it is limited to updating FEMA's internal procedures regarding the dollar figure at or below which FEMA will obligate funding based on an estimate of project costs, and above which FEMA will obligate

Emergency Management Agency To Respond to COVID–19,'' 86 FR 8281 (Feb. 5, 2021).

[41] Executive Order 13996, ''Establishing the COVID–19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID–19 and Other Biological Threats,'' 86 FR 7197 (Jan. 26, 2021).

[42] *https://www.fema.gov/blog/100-days-fema-and-our-partners-action* (last accessed May 4, 2021).

[43] FEMA's COVID–19 PA Obligations are $33.5 billion as of November 8, 2021.

[44] Since 1980, for instance, the U.S. has sustained 291 climate-related disasters where damages reached or exceeded $1 billion, with the total cost of these events alone exceeding $1.900 trillion. National Oceanic and Atmospheric Administration, ''Billion-Dollar Weather and Climate Disasters: Overview,'' *available at https://www.ncdc.noaa.gov/billions/* (last accessed Apr. 12, 2021).

[45] A copy of this analysis is on *regulations.gov* under docket ID FEMA–2022–0020.

[46] *See infra,* note 20.

[47] In FEMA's 2014 report, it noted that projects under $400,000 made up 98 percent of projects. Projects under $1,000,000 now make up 95 percent of projects primarily due to extreme outlier projects. In 2014, FEMA had only had one $1 billion project ever, while it has had eight projects over $1 billion since 2017, two of which are in the ~$10 billion range. These projects heavily skew the curve. The reason for the very large projects may be related to both the increase in very large disasters since 2014, and FEMA's current method of consolidating projects. Stafford Act section 428, ''Public Assistance Program Alternative Procedures,'' was authorized by SRIA in 2013 and allows FEMA to combine multiple projects into one project. (The PA Program does not combine projects unless they are 428 projects; PA only combines sites when the project is not a 428 project). Following the introduction of section 428, FEMA has seen a notable uptick in project costs under the 428 consolidated designation.

[48] FEMA chose to limit the application of the new threshold based on the date of obligation, rather than the date of the disaster, because the date of obligation is the point at which FEMA and the recipient agree on the estimate.

[49] *See https://www.fema.gov/assistance/public/applicants/per-capita-impact-indicator.*

[50] 44 CFR 1.3(a) and (c).

funding based on actual project costs. When FEMA classifies a project as ''small,'' FEMA reviews the project to ensure the work is eligible, and FEMA forgoes the administrative burden of validating all costs with respect to the project. Not having to validate all costs would reduce documentation requirements for both FEMA and recipients. Additionally, small project classification allows recipients and FEMA to forgo quarterly report submission and review, respectively, as well as undergo an abbreviated closeout process that would not affect substantive rights. This action does not affect the substantive rights or obligations of PA recipients, including their eligibility to receive funding under the PA program. Instead, FEMA is updating the threshold in order to classify more projects as ''small'' to reduce burdens for both FEMA and the recipient.

Lastly, section 422(b) of the Stafford Act also contains a waiver of the APA, allowing FEMA to establish the threshold for eligibility ''without regard to [5 U.S.C. chapter 5].'' FEMA interprets 42 U.S.C. 5189(b)(2)'s APA waiver to apply to future updates to the threshold as a result of the three-year review that 5189(b)(3) requires. Specifically, subsection (b)(3) requires FEMA to ''review the threshold for eligibility under this section'' every three years. It is possible to read the phrase ''under this section'' as simply clarifying that the threshold to which the three-year review applies is the threshold authorized under 42 U.S.C. 5189 with no further meaning attributed to the words. However, this interpretation ignores the context and history of 42 U.S.C. 5189 and would mean that the direction from Congress is simply to review the threshold every three years with no indication of what Congress intended FEMA to do with the results of the three-year review.[51] Congress specifically directed FEMA in subsection (b)(2)(B) to adjust the threshold annually to reflect changes in the Consumer Price Index for all Urban Consumers published by the Department of Labor. It stands to reason that Congress would also provide direction to FEMA regarding adjustments to the base threshold as a result of the three-year review, and yet this interpretation would mean that Congress did not provide such direction.

Legislative history suggests that Congress intended that FEMA maintain administrative efficiency in the PA program with an adjustable threshold.[52] The three-year review cycle coupled with an APA waiver creates such administrative efficiency. The phrase ''threshold for eligibility'' refers generally to the simplified procedure threshold and ''under this section'' refers to the review process established under the section. Under that review process, as established in subsection (b)(2), FEMA completes an analysis of the threshold, submits a report to Congress regarding the analysis, and then immediately establishes the new threshold without regard to the APA.

In so interpreting the statute, FEMA also relies on the fact that 42 U.S.C. 5189(b) is silent as to the expiration of the APA waiver. Generally, if Congress knows how to say something but chooses not to, its silence is controlling.[53] 42 U.S.C. 5189(b) contains no restrictions typically found in other APA waivers. There is an instructive example of a time-limited APA waiver within another section of the Stafford Act. 42 U.S.C. 5174, which governs the Individual Assistance program, generally requires FEMA to promulgate regulations to implement the program.[54] However, as amended by the Disaster Recovery Reform Act,[55] it states that FEMA may ''waive notice and comment rulemaking'' to carry out new authority for a state-managed housing program as a pilot program if FEMA determined that doing so was necessary for expeditious implementation.[56] This APA waiver for the state-managed housing program, however, was limited to two years and since FEMA did not publish final regulations within that time frame, the waiver authority and authority to conduct a pilot expired.[57] As with other APA waivers, Congress in 42 U.S.C. 5174 provided a definitive temporal limitation to its APA waiver (and specified a consequence associated with that limitation), whereas in 42 U.S.C. 5189 Congress provided none. This further supports the conclusion that Congress did not intend to limit the APA waiver for establishing a simplified procedures threshold.

Further, the APA generally requires that substantive rules incorporate a 30-day delayed effective date. 5 U.S.C. 553(d). Because this rule is a procedural rule and is also otherwise exempt from the APA's notice and comment requirement, FEMA finds that a delayed effective date is unnecessary.

B. Executive Orders 12866, ''Regulatory Planning and Review'' and 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

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

i. Need for Regulation

In accordance with Executive Orders 12866, 13563, and Office of Management and Budget (OMB) Circular A–4, an agency must identify the problem that it intends to address through regulatory action. The action may be taken to address a statutory or judicial directive, significant market failure, or to meet some other compelling public need. This final rule responds to a statutory directive and will improve the functioning of government by changing the maximum threshold to a level that improves efficiency and reduces administrative costs. Because PA is a Federal program, regulation at the Federal level is appropriate.

Section 1107 of the Sandy Recovery Improvement Act of 2013 (SRIA)[58] amends section 422 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act[59] authorizing Simplified Procedures for the PA program under

[51] ''The words of the statute must be read in their context and with a view to their place in the overall statutory scheme . . . A court must therefore interpret the statute as a symmetrical and coherent regulatory scheme, . . . and fit, if possible, all parts into an harmonious whole.'' *FDA* v. *Brown & Williamson Tobacco,* 529 U.S. 120, 132–33 (2000).

[52] *See* H.R. REP. NO. 100–517 (1988), p. 11.

[53] *Animal Legal Defense Fund* v. *USDA,* 789 F.3d 1206 (11th Cir. 2015), citing *In re Haas,* 48 F.3d 1153, 1156 (11th Cir. 1995), abrogated on other grounds by *In re Griffith,* 206 F.3d 1389 (11th Cir. 2000).

[54] 42 U.S.C. 5174(j).

[55] Public Law 115–254, div. D, Oct. 5, 2018, 132 Stat. 3438.

[56] 42 U.S.C. 5174(f)(3)(J)(i).

[57] *See* 42 U.S.C. 5174(f)(3)(J)(ii)–(iii).

[58] Public Law 113–2, section 1107, 127 Stat. 46.

[59] 42 U.S.C. 5189.

sections 403, 406, 407, and 502.[60] The objective of Simplified Procedures is to allow FEMA to quickly provide grant funding for recovery while lowering the administrative burden in cases where the benefit of uncovering fraud or waste is low. Every three years, after the initial implementation of the thresholds, the President, acting through the FEMA Administrator, shall review the threshold for Simplified Procedures under the Stafford Act.[61] Since the authority and direction are present in statute, updating the thresholds in line with the statutory requirement is both appropriate and necessary. Without this update, moreover, both FEMA and recipients will continue to not be able to fully realize the benefits of Simplified Procedures.

Since the adoption of Simplified Procedures, the maximum threshold has gradually shifted away from the initial policy benchmarks. Congress set the threshold at $35,000 in 1988, which represented 95 percent of FEMA projects and 32 percent of PA disaster assistance funding.[62] Despite past adjustments to the maximum threshold and increases for inflation, small projects below the current threshold account for fewer than 76.8 percent of the total number of projects and 2.4 percent of funding due to the increasing frequency and magnitude of major weather and climate disasters.[63] [64] From 1990–1999, FEMA obligated on average about $2.7 billion in PA funding for disasters per year.[65] From 2000–2009, FEMA obligated on average about $5.8 billion in PA funding for disasters per year.[66] From 2010–2019, FEMA obligated on average about $8.1 billion in PA funding for disasters per year.[67] Prior adjustments include yearly adjustments to the maximum threshold every fiscal year based on the CPI–U and a thorough review by the program every three years. FEMA is updating its regulations, as required by section 422(b), based on the findings of the 2020 review.

ii. Affected Population

The final rule will affect all potential applicants for Federal assistance under the PA program. Eligible applicants for PA include 56 State and territorial governments, 573 Federally recognized Indian Tribal governments, local governments, and certain PNPs.

iii. Summary of Regulatory Changes

TABLE 1—SUMMARY OF CHANGES

Item	Current	Change	Impact
Maximum threshold for Simplified Procedures.	$132,800 in FY 2021, adjusted every fiscal year using CPI–U.	$1,000,000 for unobligated PWs processed on or after the effective date of the rule for major disasters and emergencies declared on or after March 13, 2020, adjusted every fiscal year using CPI–U.	—The annual average benefit will be $6,464,964. The total net 3-year benefit discounted at 3 percent and 7 percent, respectively, are 18,286,871 and $16,966,108. The annualized benefit is $6,464,964 and $6,464,964 at the 3 and 7 percent discount rates, respectively. —The annual cost will be $10,454 for just the first year. The total 3-year net cost discounted at 3 percent and 7 percent, respectively, are $10,150 and $9,770. The annualized cost is $3,588 and $3,723 at the 3 and 7 percent respective discount rates. —The total 3-year transfer payments from FEMA to the recipients discounted at 3 and 7 percent are $40,803,651 and $37,856,623, respectively. This estimated transfer is $14,425,330 annualized.

iv. Methodology

This economic analysis adheres to the guidelines in: Executive Order 12866, ''Regulatory Planning and Review'' and amendments; Executive Order 13563, ''Improving Regulation and Regulatory Review;'' and the Office of Management and Budget's (OMB) Circular A–4 on Regulatory Analysis.

The methodology discussed below pertains to the Regulatory Impact Analysis (RIA) assessing the costs, benefits, and transfers associated with an increase of the PA small project maximum threshold to $1,000,000 for major disasters and emergencies declared on or after March 13, 2020, for unobligated projects.[68] The maximum threshold will be implemented to capture projects necessitated by the COVID–19 pandemic.

The analysis to determine the maximum threshold was completed prior to this RIA and reported in the 2020 Review. The 2020 Review evaluated multiple alternative maximum thresholds and the benefits and costs of each with regards to the PA Program; a brief discussion of those alternatives is included in this document. This RIA aligns with the 2020 Review by evaluating the selected threshold by using data from the same databases to analyze the benefits, costs, and transfers in similar ways. The two analyses differ in their purposes, with this RIA focusing specifically on the $1,000,000 threshold and its impacts for recipients, subrecipients, and FEMA. The two analyses also look at different periods. As explained further below, this analysis focuses on declaration

[60] 42 U.S.C. 5170b, 5172, 5173, 5192.

[61] 42 U.S.C. 5189(b)(3).

[62] *See* H.R. REP. NO. 100–517 (1988).

[63] National Oceanic & Atmospheric Administration (NOAA). (2021). *2020 U.S. billion-dollar weather and climate disasters in historical context.* Adam B. Smith. *https://www.climate.gov/news-features/blogs/beyond-data/2020-us-billion-dollar-weather-and-climate-disasters-historical.*

[64] U.S. Global Change Research Program (USGCRP). (2018). *Fourth National Climate Assessment, Chapter 2: Our Changing Climate. https://nca2018.globalchange.gov/chapter/2/.*

[65] Estimate based on data from FEMA's EMMIE Enterprise Data Warehouse, as of Dec. 10, 2021.

[66] *Id.*

[67] *Id.* FEMA analyzed the data for obligated PA projects up to September 30, 2020. All amounts are shown in 2020 dollars. Obligation of disaster funding can occur after the disaster year.

[68] For FY 2021, the maximum threshold for PA is $132,800. While in 2020, it was $131,100. The final rule will be implemented for major disasters and emergencies declared on or after March 13, 2020, for unobligated projects.

dates between August 25, 2017, through September 30, 2020.[69]

The primary data sources used for this analysis were PA data from Grants Manager (GM) and the Emergency Management Mission Integrated Environment (EMMIE). Data from GM provided several characteristics about the grants, including the number of projects and each project's cost. Data from EMMIE provided additional characteristics, including the obligation and deobligation amounts associated with each large project. FEMA formally adopted the National PA Delivery Model on August 25, 2017, and this is also when FEMA started collecting data using the GM database. Prior to the implementation of GM, EMMIE was the primary system of record for PA data. The GM database tracks the PA processes with more detail than EMMIE, including dates for all application and project process steps and tasks, as well as other attributes of the damages. The data from GM allows FEMA to perform analysis on project timeliness and accuracy using more detail. FEMA continues to also use EMMIE, which captures some data that GM does not, including obligation amounts. For this analysis, both GM and EMMIE data were needed and used. Therefore, the date that GM was adopted was selected as the beginning of the project data analyzed.[70] This analysis includes obligated project data for major disasters declared on or after August 25, 2017, through September 30, 2020. There are 1,132 days during this period. FEMA took the total number of days during the time of the analysis (1,132 days) and divided it by the number of days per year (365 days) to get the time span of data, 3.1 years (1,132 days ÷ 365 days). This provides a more accurate analysis of project thresholds within the context of the processes and procedures implemented as part of the National PA Delivery Model. It provides a better understanding of how potential adjustments to the threshold impact stakeholders based on the way that PA is currently implemented.

FEMA typically uses 10 years of historical data, analyzes it, then calculates a 10-year forward looking estimate for benefit, cost, and transfers. However, due to the data limitations discussed above, FEMA was only able to obtain 3.1 years of historical data. For the purpose of this analysis, FEMA estimated the benefits, costs, and transfers for the next three years, since the Stafford Act requires FEMA to reevaluate the maximum threshold every three years.

FEMA obtained additional data to estimate wage rates from the Office of Personnel Management (OPM) and Bureau of Labor Statistics (BLS). All wage rate data is in year 2020 dollars. Burden hours associated with applying for and processing small and large projects were determined through FEMA internal assessments at the regional level where the average number of hours involved to close out small and large projects was calculated.

To estimate the impacts of this regulation, FEMA assessed the number of projects classified as small projects at the current threshold (no action baseline) and after the threshold is raised to $1,000,000.

v. Assumptions

Project cost data in GM and obligation/deobligation data in EMMIE is reported in nominal dollars for their respective year. Due to the projects spanning multiple years from 2017 through 2020, the project cost data for each project was adjusted to year 2020 dollars using the CPI–U. Their status as either small or large was then assessed using the thresholds in 2020 dollars ($132,800 and $1,000,000).

This analysis calculated the Present Value (PV) of cost and transfer flows. PV calculations permit comparisons of cost and benefit streams that involve different time paths. FEMA used the following formula to calculate these flows:

$$\frac{1}{(1+r)^t}$$

where ''r'' is the discount rate, and ''t'' is the number of years in the future that the benefits or costs are expected to occur. Per OMB Circular A–4, FEMA used real discount rates of three percent and seven percent to discount benefits and costs measured in constant dollars. Unlike typical market interest rates, real rates exclude the expected rate of future price inflation. These figures estimate the value of future benefits and costs adjusted for differences in their timing.

vi. Baseline

Following guidance in OMB Circular A–4, FEMA assessed each impact of this rule against a no action baseline. A no action baseline is an assessment of the way the world would look absent this rule. For this analysis, the no action baseline is a maximum threshold that remains at $132,800, in 2020 dollars.

vii. Number of Projects and Total Dollars

To search for potential alternative thresholds, FEMA first analyzed the current situation if no changes were made to the maximum threshold for FY 2021 beyond the annual CPI–U adjustment. FEMA looked at the number of projects and total dollars by project amount since the adoption of the PA delivery model. Small projects, which are projects with total project costs below the $132,800 threshold, made up 76.8 percent, or 47,376, of the total count of 61,710 projects. Large projects, which are projects with a total project cost at or above the threshold, accounted for 23.2 percent, or 14,334 of the total count of 61,710 projects. From August 25, 2017 through FY 2020 (3.1 years), the funding of small projects was $1.6 billion (2.4 percent) and $66.0 billion (97.6 percent) for large projects.

FEMA also looked at the number of projects and total dollars over the same time period had $1,000,000 been the threshold. Small projects would have accounted for 94.4 percent, or 58,234, of the total count of 61,710 projects. Large projects would have accounted for 5.6 percent, or 3,476, of the total count of 61,710 projects. The funding of small projects would have been $5.7 billion (8.4 percent) and $62.0 billion (91.6 percent) for large projects. This would account for a difference of 10,858 projects classified as small under the $1,000,000 threshold that were classified as large under the $132,800 threshold (14,334 − 3,476).

viii. Cost

FEMA estimates that there will be a one-time familiarization cost of $10,454 associated from changing the maximum threshold from $132,800 to $1,000,000 for unobligated future projects for major disasters and emergencies declared on or after March 13, 2020, as discussed later in this analysis. The total 3-year net cost rate discounted at 3 percent and 7 percent, respectively, are $10,150 and $9,770. The annualized cost is $3,588 and $3,723 at the 3 and 7 percent respective discount rates.

Small projects are subject to less scrutiny than large projects and by increasing the maximum threshold to $1,000,000, a total of 10,858 more projects would have been classified as small projects that were classified as large projects under the current threshold of $132,800.

Under the $1,000,000 threshold, the small projects will be subject to less scrutiny compared to the no action

[69] The 2020 Review includes data with declaration dates from August 25, 2017 through November 8, 2021.

[70] For more information on the National PA Delivery Model, *see* the Public Assistance Delivery Model Fact Sheet published on August 17, 2018, *available at https://www.fema.gov/sites/default/files/2020-07/fema_pa_delivery-model_factsheet.pdf* (last accessed Feb. 1, 2022).

baseline. This could potentially increase the risk of inaccurate reporting and decrease the ability for FEMA to identify and remedy noncompliance for these projects. This risk already exists for small projects, as recipients and subrecipients are only required to certify that they spent the money appropriately according to FEMA's policy. Conversely, recipients and subrecipients of large projects are required to fill out additional paperwork and provide proof to verify their spending.

When a recipient or subrecipient applies for PA funding, they would complete the phases of the Public Assistance delivery model.[71] These phases are 1. Operational planning, 2. Impacts and eligibility, 3. Scoping and costing, 4. Final review, 5. Obligation and recovery transition, 6. Post-award monitoring and amendments, and 7. Final reconciliation and closeout. FEMA does not perform a final inspection of completed small projects; however, the applicants must certify that the subapplicants completed the work in compliance with all applicable laws, regulations, and policies.[72] Noncompliance would occur if the recipient or subrecipient did not complete the work for a project that has been obligated by FEMA based on the Statement of Work (SOW). FEMA assumes that it is rare for noncompliance to occur since the applicants must certify the work and would be subject to penalties if they certify the completion of work when that information is inaccurate. For this reason, FEMA assumes that the cost to FEMA for noncompliance is minimal. Data is not available to estimate how common noncompliance occurs in small projects. FEMA acknowledges this risk exists, but is following the lead of Congress that believes that having a large dollar threshold for small projects creates a more streamlined approach that would ''result in substantial savings of time and money that . . . should have a significant and beneficial impact on FEMA's overall program.'' [73]

A subrecipient may request additional funding through the PA appeals process, also known as the Net Small Project Overrun (NSPO) process, if the cost incurred for all of its small projects exceeds the total amount requested by the subrecipient for which FEMA has already obligated for those projects. Subrecipients do not have this option for large projects. Increasing the maximum threshold to $1,000,000 would result in more small projects, which would mean that subrecipients would have more opportunities to apply for additional funds. Historically, only 0.05 percent of small projects have had first appeal NSPOs and 0.003 percent have had second appeal NSPOs.[74] Raising the maximum threshold to $1,000,000 would lead to 10,858 more small projects over the 3.1 year period, and approximately 5.8 additional NSPOs (10,858 × (.05 percent in first appeal NSPOs + 0.003 percent in second appeal NSPOs)) over the time period, or fewer than 2 annually (5.8 additional NSPOs ÷ 3.1 years). These additional NSPOs would require time from subrecipients to apply and FEMA to process. FEMA cannot estimate the number of hours due to a lack of data available on time estimates for NSPOs.

Familiarization Costs for Recipients

The increase of the maximum threshold to $1,000,000 for unobligated future project worksheets for major disasters and emergencies declared on or after March 13, 2020, will require time for the recipients to familiarize themselves with the changes made in this final rule. The total cost for familiarization would be $10,454 for the first year. FEMA estimates recipients would spend one hour to familiarize themselves with this change. FEMA assumes a State Government Chief Executive, a senior level government official, or equivalent occupation, would read the existing and updated regulations to understand the changes.[75] FEMA obtained the wage rate of $58.34 for a State Government Chief Executive from BLS Occupational Employment Statistics (OES) data.[76] To account for employee benefits, the fully-loaded hourly mean wage rate for Chief Executives is $93.34 ($58.34 hourly mean wage for Chief Executives × 1.6 wage rate multiplier for State and local government workers).[77] FEMA used 56 States and territories in the estimate as this is the level from which a PA disaster declaration request is made. FEMA assumes there would be at least 112 (56 States and territories × 2) Chief Executives that review the changes, two from each State and territories. FEMA estimates it would cost $10,454 for recipients to familiarize themselves with the changes ($93.34 fully-loaded hourly mean wage rate × 1 hour × 112 Chief Executives). This will be a one-time cost for the recipients in the first year.

FEMA assumes the States and territories regularly update their emergency response networks and local emergency management divisions on changes in the field and the States and territories will disseminate the regulatory changes through each State's and territory's respective process. FEMA expects there to be no additional implementation costs.

Summary of Costs

There is an unquantifiable risk of an increase in noncompliance due to a lower level of oversight on small projects that are classified as large projects under the no action baseline.

FEMA estimates that the cost associated from changing the maximum threshold from $132,800 to $1,000,000 for unobligated projectss for major disasters and emergencies declared on or after March 13, 2020, would be $10,454. This cost is for familiarization of the $1,000,000 maximum threshold for these unobligated projects.

[71] FEMA. How to Apply for Public Assistance. *https://www.fema.gov/assistance/public/apply#phases.* Last accessed on Dec. 1, 2021.

[72] *See* Stafford Act § 422 (42 U.S.C. 5189).

[73] *See* H.R. REP. NO. 100–517 (1988), p. 11; *see also, e.g.,* OFFICE OF INSPECTOR GEN., ASSESSMENT OF FEMA'S PUBLIC ASSISTANCE PROGRAM POLICIES AND PROCEDURES (2009), available at *http://www.oig.dhs.gov/assets/Mgmt/OIG_10-26_Dec09.pdf* (recommended increasing the maximum threshold because of the administrative efficiency and streamlined process for all parties); U.S. GEN. ACCOUNTING OFFICE, DISASTER ASSISTANCE: IMPROVEMENTS NEEDED IN DETERMINING ELIGIBILITY FOR PUBLIC ASSISTANCE (1996), available at *http://www.gao.gov/assets/160/155459.pdf* (recommended increasing the minimum threshold to increase administrative efficiency); HOMELAND SEC. STUDIES AND ANALYSIS INST., ANALYSIS OF THE FEMA PUBLIC ASSISTANCE (PA) PROGRAM (2011), *available at http://assets.fiercemarkets.net/public/sites/govit/fema_foia_perera_bottomupreview.pdf* (recommended increasing the minimum threshold to increase administrative efficiency).

[74] Out of 137,913 total obligated small projects since 2013, there were only 70 instances of first appeal NSPOs (0.05 percent). Out of 627,656 total obligated small projects since 1997, there were only 20 instances of second appeal NSPOs (0.003 percent).

[75] Estimates for time and wage rates were taken from the *Factors Considered When Evaluating a Governor's Request for Individual Assistance for a Major Disaster* Final Rule, 84 FR 10632, 10649 (Mar. 21, 2019).

[76] BLS OES, May 2020, State Government, Standard Occupational Code 11–1011 for Chief Executives, mean wage. *https://www.bls.gov/oes/2020/may/oes111011.htm.* Last accessed on July 16, 2021.

[77] Bureau of Labor Statistics. Employer Costs for Employee Compensation, Table 1. ''Employer costs per employee compensation March 2020. Retrieved from *https://www.bls.gov/news.release/archives/ecec_06182020.pdf.* Accessed on October 19, 2021. The wage multiplier is calculated by dividing total compensation for State and local government workers of $52.45 by Wages and salaries for State and local government workers of $32.62 per hour yielding a benefits multiplier of approximately 1.6.

The following calculations are estimates of costs for three years in the future. The annual cost will be $10,454 for only the first year. The average cost will be $3,485 ($10,454 ÷ 3) each year. The discounted total net 3-year cost rate at 3 percent and 7 percent, respectively, are $10,150 and $9,770. The annualized cost is $3,588 and $3,723 at the 3 and 7 percent discount rates. (*See* Table 2).

TABLE 2—ESTIMATED COST OVER A 3-YEAR PERIOD

[2020$]

Year	Total cost	Annual cost discounted at 3%	Annual cost discounted at 7%
1	$10,454	$10,150	$9,770
2	0	0	0
3	0	0	0
Total	10,454	10,150	9,770
Annualized		3,588	3,723

ix. Benefits

FEMA identifies both qualitative and quantitative benefits to support increasing the maximum threshold. Raising the maximum threshold to $1,000,000 will reduce the administrative burden and improve program efficiency for recipients, subrecipients, and FEMA. FEMA considers these cost savings to be benefits.

FEMA requires subrecipients to restrict each PW to a conceptual and logical grouping of eligible work at one or more sites to minimize the number of PWs necessary to provide assistance for each subrecipient.[78] Some subrecipients currently try to avoid including too many sites on a single PW in order to stay below the maximum threshold. Increasing the maximum threshold will remove the need to adjust PWs in this way for projects near the current threshold, and lead to a higher total dollar amount per PW and a smaller number of PWs with more logically grouped work. Since small projects are generally less administratively burdensome for FEMA, recipients, and subrecipients, this rule will increase administrative efficiencies because it decreases the time it takes for staff to manage and review grants.

Cost Savings to FEMA

Processing a small project takes less time for FEMA to process than a large project. If the maximum threshold was $1,000,000, it would have resulted in a $13,246,760 administrative cost savings for FEMA, over a 3.1-year period.

The amount of time that FEMA spends to close out a project varies depending on whether it is classified as a large or small project. Based on State and FEMA regional offices' input to a National Emergency Management Association (NEMA) report, on average, each large project takes 24.8 hours and each small project takes 4.9 hours to close out, a difference of 19.9 hours (24.8 hours − 4.9 hours) per project.[79] The average amount of time FEMA spends to close out a large project is not dependent upon the dollar amount associated with the project. FEMA used the average hourly wage of $41.99 (($34.76 GS 11 Step 5 + $41.66 GS 12 Step 5 + $49.54 GS 13 Step 5) ÷ 3) based on OPM's locality pay area of rest of U.S. for 2020.[80] FEMA calculated the fully loaded hourly wage by multiplying the average hourly wage by 1.46 for civilian workers, resulting in $61.31 ($41.99 × 1.46) per hour.[81] FEMA multiplied the time for large and small projects by the fully loaded hourly wage, resulting in $1,520.49 ($61.31 × 24.8 hours) for the closing cost for large projects and $300.42 ($61.31 × 4.9 hours) for the closing cost for small projects. This results in the administrative efficiencies between large and small projects, with a difference of −$1,220.07 ($300.42 − $1,520.49). FEMA estimates that, on average, it saves the agency $1,220 per PW to process a small project over a large project. (*See* Table 3).

TABLE 3—ESTIMATED TOTAL ADMINISTRATIVE COST TO FEMA

	Large project	Small project
Average amount of time it takes FEMA to close out each project	24.8 hours	4.8 hours.
FEMA employee fully-loaded wage rate	$61.31	$61.31.
Total Admin Cost for FEMA for each project	$1,520	$300.

Small projects have fewer requirements for final reconciliation and close out time compared to large projects. By increasing the maximum threshold, FEMA expects more projects to be classified as small, therefore reducing the time spent on completing supplemental forms. If the maximum threshold would have been $1,000,000,

[78] *See* 44 CFR 206.201(k); FEMA Policy 104–009–2, *Public Assistance Program and Policy Guide,* v.4, pp. 60–63 (June 1, 2020), *available at https://www.fema.gov/sites/default/files/documents/fema_pappg-v4-updated-links_policy_6-1-2020.pdf.*

[79] ''Determination on the Public Assistance Simplified Procedures Thresholds: Fiscal Year 2014 Report to Congress, Analysis Report for Sandy Recovery Improvement Act of 2013'' (Jan. 29, 2014), page 26. Available at *https://www.regulations.gov/document/FEMA-2014-0009-0002.*

[80] Pay & Leave: Salaries & Wages for locality pay area of rest of U.S. OPM. Available at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/RUS_h.aspx.* Last accessed: May 6, 2021.

[81] Bureau of Labor Statistics, Employer Costs for Employee Compensation, Table 1. ''Employer costs for employee compensation: March 2020.'' Available at *https://www.bls.gov/news.release/archives/ecec_06182020.pdf.* Accessed November 2, 2021. The wage multiplier is calculated by dividing total compensation for civilian workers of $37.73 by Wages and salaries for civilian workers of $25.91 per hour yielding a benefits multiplier of approximately 1.46.

there would have been 10,858 projects classified as small that are currently classified as large.[82] Increasing the maximum threshold to $1,000,000 will increase the number of small projects so that it accounts for 94.4 percent of FEMA PA projects. This will align with the original threshold Congress set in 1988, where the number of small projects represented 95 percent of FEMA PA projects. The estimated cost savings to FEMA is $13,246,760 ($1,220 × 10,858) for 3.1 years. (*See* Table 4).

TABLE 4—ESTIMATED TOTAL COST SAVINGS TO FEMA OVER 3.1 YEARS

[2020$]

	$132,800 Threshold	$1M Threshold
Number of Small Projects at Each Threshold	47,376	58,234
Difference in the Number of Small Projects from the Current Threshold		10,858
Cost savings from Processing Each Small Project instead of a Large Project		$1,220
Estimated Total Cost Savings to FEMA[83]	$0	$13,246,760

Cost Savings to Recipients and Subrecipients

Processing a small project takes less time for recipients and subrecipients compared to a large project because small projects require fewer forms. If the maximum threshold were $1,000,000, it would have resulted in a $1,285,474 cost savings for recipients and subrecipients over the 3.1-year period.

To estimate cost savings, FEMA used BLS data for average hourly wage rates for Emergency Management Directors for State Governments, $34.97.[84] To account for benefits, FEMA multiplied the wage rate by 1.6 for State and local government workers to obtain a fully loaded hourly wage of $55.95 ($34.97 × 1.6). FEMA requires six supplemental forms for large projects that are not required for small projects.[85] [86] Based on FEMA regional input, recipients with projects over the maximum threshold must fill out (1) FEMA Form 009–0–123: Force Account Labor Summary Record, (2) FEMA Form 009–0–124: Materials Summary Record, (3) FEMA Form 009–0–125: Rented Equipment Summary Record, (4) FEMA Form 009–0–126: Contract Work Summary Record, (5) FEMA Form 009–0–127: Force Account Equipment Summary Record, and (6) FEMA Form 009–0–111: Quarterly Progress Report.

The recipient or subrecipient must submit FEMA Forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127 for each large project undertaken. These five forms take a combined total of 2 hours for each recipient or subrecipient to complete.[87] Additionally, each recipient must submit FEMA Form 009–0–111 once quarterly when it has at least one large ongoing project. This form would include all large projects for that recipient. The form takes 100 hours to fill out.

To estimate the cost savings for FEMA Forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127, FEMA multiplied the total time required to complete these forms by the fully-loaded wage rate for State and local government Emergency Management Directors. Recipients and subrecipients would have a cost savings of $111.90 (2 hours × $55.95) per project for recipients and subrecipients to process a small project over a large project. FEMA then multiplied the $112 cost savings per project by the 10,858 large projects that would have been a small projects if the maximum threshold were $1,000,000. FEMA estimated a total cost savings of $1,216,096 ($112 × 10,858) for recipients and subrecipients over the 3.1-year period for forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127. (*See* Table 5). Annually, FEMA estimated the cost savings to be $392,289 ($1,216,096 ÷ 3.1 years).

To estimate the cost savings for recipients for FEMA Form 009–0–111, FEMA multiplied the time required to complete this quarterly form by the fully-loaded wage rate for State and Local government Emergency Management Directors. Recipients would have a cost savings of $5,595 ($55.95 × 100 hours) per quarter. FEMA then analyzed the data to determine then number of recipients who would not have at least one ongoing large project if the maximum threshold were $1,000,000 compared to those who would at the $132,800 threshold. FEMA assumed all recipients with at least one ongoing project submitted FEMA Form 009–0–111 each quarter for the duration of the 3.1-year period and the recipient without an ongoing large project did not submit this form. Over the 3.1-year period, the number of recipients with at least 1 ongoing project would reduce by 1, from 56 to 55.[88] Annually, this cost savings for recipients equates to $22,380 ($5,595 × 4 quarters) and $69,378 over the 3.1-year period ($22,380 × 3.1 year).

Annually, increasing the maximum threshold from $132,800 to $1,000,000 would have a total cost savings for recipients and subrecipients of $414,669 ($392,289 + $22,380).

[82] 58,234 small projects would exist at the $1,000,000 threshold and 47,376 small projects at the actual threshold. The difference in the number of small projects is 58,234 − 47,376 = 10,858.

[83] Estimated savings is calculated by taking the number of small projects at each threshold and then multiplying it by the increase in small projects from the current threshold. $1,220 × 10,858 = $13,246,760.

[84] According to the U.S. Department of Labor, Bureau of Labor Statistics, the May 2020 Occupational Employment and Wage Estimates hourly mean wage rate for Emergency Management Directors (Standard Occupational Classification 11–9161) for State Government employees is $34.97. *https://www.bls.gov/oes/2020/may/oes119161.htm,* accessed November 23, 2021.

[85] Public Assistance Program, Paperwork Reduction Act Information Collection Supporting Statement, OMB Control Number: 1660–0017, available at: *www.reginfo.gov/public/do/PRAView Document?ref_nbr=201304-1660-001,* see Supporting Statement A.

[86] Recipients or subrecipients with small projects may fill out some of these five forms after the work is complete if they are submitting paperwork to request for funds for the actual cost(s).

[87] Public Assistance Program, Paperwork Reduction Act Information Collection Supporting Statement, OMB Control Number: 1660–0017, available at: *www.reginfo.gov/public/do/PRAView Document?ref_nbr=201304-1660-001,* see Supporting Statement A. According to the Paperwork Reduction Act Information Collection Supporting Statement, FEMA Form 009–0–123 takes 0.5 hours, 009–0–124 takes 0.25 hours, 009–0–125 takes 0.5 hours, 009–0–126 takes 0.5 hours, and 009–0–127 takes 0.25 hours to complete.

[88] The recipient was the State of Wyoming and the project cost was $142,489.

TABLE 5—ESTIMATED TOTAL COST SAVINGS TO RECIPIENTS AND SUBRECIPIENTS OVER 3.1 YEARS

[2020$]

	$132,800 Threshold	$1M Threshold
FEMA Forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127		
Number of Large Projects at Each Threshold	14,334	3,476
Decrease in the Number of Large Projects from the Current Threshold	0	10,858
Cost of Processing Each Large Project [89]		$112
Estimated Cost Savings for the Five Forms [90]	$0	$1,216,096
FEMA Form 009–0–111		
Number of Recipients with Ongoing Large Projects	56	55
Decrease in the Number of Recipients from the Current Threshold	0	1
Cost savings from Submitting Fewer Forms	$0	$69,378
Estimated Cost Savings for FEMA Form 009–0–111 [91]	$0	$69,378
Estimated Total Cost Savings to Recipients and Subrecipients over 3.1 Years [92]	$0	$1,285,474

Total Benefits at the $1M Threshold

TABLE 6—TOTAL BENEFITS AT THE $1M THRESHOLD OVER 3.1 YEARS

[2020$]

Administrative cost savings to FEMA	$1M Threshold
Decrease in the number of large projects PWs	10,858
Cost Savings from Processing Each Small Project over a Large Project	$1,220
Estimated Total Cost savings to FEMA [93]	$13,246,760
Administrative Cost Savings to Recipient and Subrecipient	
FEMA Forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127	
Decrease in the number of large projects from the Current Threshold	10,858
Dollars per PW to recipients/subrecipients (reduction in forms)	$112
Estimated Cost Savings for the Five Forms	$1,216,096
FEMA Form 009–0–111	
Decrease in the Number of Recipients from the Current Threshold	1
Cost savings from Submitting Fewer Forms	$69,378
Estimated Cost Savings for FEMA Form 009–0–111	$69,378
Estimated Total Cost Savings to Recipients and Subrecipients	$1,285,474
Total Administrative Cost Savings [94]	$14,532,234

Project Consolidations

A recipient may decide to consolidate its grant requests by combining eligible work at one or more sites on a single PW. Subrecipients have some discretion in how they group eligible work across PWs, and some currently try to avoid including too much on a single PW in order to stay below the maximum threshold. They instead spread the work across multiple PWs below the threshold. With a $1,000,000 threshold, projects under this threshold will be considered small, giving recipients and subrecipients greater flexibility in how they use the funds they receive. With small projects, recipients and subrecipients can retain any excess funds (as opposed to FEMA deobligating these funds) and can use them to reduce risk and improve future disaster operations. If a recipient or subrecipient were to exceed the threshold, it would potentially serve as a deterrent to fully consolidating eligible work on PWs, as the benefits of Simplified Procedures would then be lost. Raising the maximum threshold to $1,000,000 removes the disincentive for consolidating eligible work on PWs with a total cost under that amount. This reduces the total number of PWs to be processed, thereby increasing the administrative efficiency for recipients, subrecipients, and FEMA. Since there is no accurate way for FEMA to determine how much eligible work could potentially be consolidated on fewer

[89] For forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127.

[90] Estimated cost savings for the five forms = Decrease in the number of large projects from the current threshold × cost of processing each large project. 10,858 × $112 = $1,216,096.

[91] Estimated cost savings for FEMA Form 009–0–111 = Decrease in the number of recipients from the current threshold × cost savings from submitting fewer forms. 1 × $69,378 = $69,378.

[92] Estimated total cost savings to recipeients and subrecipients = Estimated cost savings for the five forms + estimated total cost savings for FEMA Form 009–0–111. $1,216,096 + $ 69,378 = $1,285,474.

[93] Estimated total cost savings to FEMA = Decrease in the number of large projects PWs × Cost Savings from processing each small project over a large project. 10,858 × $1,220 = $13,246,760.

[94] $13,246,760 + $1,285,474 = $14,532,234.

PWs, FEMA is not able to determine the exact number of small project PWs that will now no longer be submitted under the increased threshold. However, with a current average of 15,283 small projects annually and up to an additional 10,858 projects that will now be small projects, FEMA assumes additional consolidation will occur.[95]

Implementation Cost Savings for Applicable Unobligated PWs

FEMA will implement the $1,000,000 maximum threshold for major disasters and emergencies declared on or after March 13, 2020, for projects that have not been obligated as of the effective date of this rule. FEMA conducted the same analysis as above in the cost savings to FEMA and cost savings to recipients and subrecipients, but looked only at the projects that were unobligated at the time that FEMA pulled the data from data management systems.[96] FEMA adjusted the project cost data for these projects to year 2020 dollars using the CPI–U and their status as either small or large assessed using the thresholds in 2020 dollars ($132,800 and $1,000,000). This implementation will be applicable for current unobligated projects with a declaration date between March 13, 2020 to September 30, 2020.[97] FEMA identified projects in the database with a declaration date between March 13, 2020 to September 30, 2020 then focused on those projects that were currently unobligated. Then FEMA conducted two analyses: one looking at the number of unobligated small projects at $132,800 threshold, and the other looking at the number of unobligated small projects at the $1,000,000 threshold. FEMA then compared the differences in these numbers at the two thresholds. At the $132,800 threshold, there were 5,579 unobligated small projects. At the $1,000,000 threshold, there would be 9,715 unobligated small projects. FEMA estimates 4,136 (9,715 − 5,579) out of the 10,877 total unobligated projects will be classified as small that were formerly classified as large when the maximum threshold is adjusted to $1,000,000 for unobligated projects going back to March 13, 2020.

This will result in cost savings to FEMA of $5,045,920 ($1,220 × 4,136) and cost savings to recipients and subrecipients of $463,232 ($112 × 4,136) from FEMA Forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127. (*See* Table 7). The number of recipients filling out FEMA Form 009–0–111 will not be impacted because the number of recipients with large projects is not impacted when including the unobligated projects. This implementation will have a total cost savings of $5,509,152 ($5,045,920 + $463,232).

TABLE 7—ESTIMATED TOTAL COST SAVINGS FOR UNOBLIGATED PROJECTS WITH A DECLARATION DATE ON OR AFTER MARCH 13, 2020

	$132,800 Threshold	$1M Threshold
Number of Unobligated Small Projects at Each Threshold	5,579	9,715
Difference in the Number of Unobligated Small Projects from FY 2020 Threshold		4,136
Cost savings from Processing Each Unobligated Small Project instead of a Large Project for FEMA		$1,220
Estimated Total Cost Savings to FEMA[98]	$0	$5,045,920
Cost savings from Processing Each Unobligated Small Project instead of a Large Project for Recipients and Subrecipients for FEMA Forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127	0	$112
Estimated Total Cost Savings to Recipients and Subrecipients[99]	$0	$463,232
Total Cost Savings	$0	$5,509,152

Summary of Benefits Over a 3-Year Period

Based on historical data, FEMA estimates that the total benefit from changing the maximum threshold from $132,800 to $1,000,000 will be $20,041,386 ($14,532,234 + $5,509,152) over the period analyzed. These benefits are calculated from the 3.1 years of historical data from GM.[100]

The following calculations are estimates of benefits for three years in the future based on the previous section's benefits estimates. These figures include three-year total and discounted annualized figures. FEMA adjusts the 3.1-year period to 3 years to arrive at a the total undiscounted estimated benefit for three years of $19,394,890.[101]

The average annual benefit will be $6,464,964. The discounted total net 3-year benefit rate at 3 percent and 7 percent, respectively, are $18,286,871 and $16,966,108. The annualized benefit is $6,464,964 at both the 3 and 7 percent discount rates. (*See* Table 8).

[95] The data include 47,376 small projects between August 25, 2017 through September 30, 2020, or 3.1 years. 47,376 ÷ 3.1 = 15,283.

[96] FEMA pulled the data on April 6, 2021, from EMMIE and GM.

[97] September 30, 2020 is the last date of FY 2020 and the last date used for this RIA analysis. Obligation of disaster funding can occur after the disaster year.

[98] Estimated savings is calculated by taking the number of small projects at each threshold and then multiplying it by the increase in small projects from the FY 2020 threshold. $1,220 × 4,136 = $5,045,920.

[99] Estimated savings is calculated by taking the number of small projects at each threshold and then multiplying it by the increase in small projects from the FY 2020 threshold. $112 × 4,136 = $463,232.

[100] GM began on August 25, 2017. FEMA used data from August 25, 2017 to September 30, 2020 for this analysis. There are 1,132 days during this period. FEMA took the total number of days during the time of the analysis and divided it by the average of number of days per year. 1,132 ÷ 365 = 3.1.

[101] The total benefit amount over 3.1 years was $20,041,386. To adjust this figure for only 3 years, it was divided by 3.1 and then multiplied by 3. (($20,041,386 ÷ 3.1) × 3) = $19,394,890.

TABLE 8—ESTIMATED BENEFIT OVER A 3-YEAR PERIOD

[2020$]

Year	Total benefits	Annual benefits discounted at 3%	Annual benefits discounted at 7%
1	$6,464,964	$6,276,664	$6,042,022
2	6,464,964	6,093,849	5,646,750
3	6,464,964	5,916,358	5,277,336
Total		18,286,871	16,966,108
Annualized		6,464,964	6,464,964

x. Transfers

Transfer payments are monetary payments from one group to another that do not affect total resources available to society. Transfers such as Federal grants, insurance payments, direct subsidies, and indirect subsidies (*e.g.,* cross-subsidies) can have significant efficiency effects in addition to distributional effects and are not included in the estimates of the benefits or costs of a regulation. The transfers associated with this final rule are the amount that is from a reduction in deobligations of excess project funds.

Deobligation

When the cost estimates exceed actual costs for small projects, FEMA does not deobligate those funds from the recipients or subrecipients; it is only for large projects where excess funds are deobligated. For projects which become categorized as small under the increased threshold, FEMA will no longer deobligate those excess funds and the funds will remain with the recipients and subrecipients. By allowing recipients and subrecipients to keep these excess funds, the funds are still providing a benefit to the public since the funds are available given to recipients (State, local, Tribal, and territorial governments). FEMA does not place any requirements on how the excess funds are spent. FEMA cannot quantify the exact benefit to the public for these specific funds and recognizes that either efficiency gains or losses could occur once acquired by the recipients and subrecipients. These excess funds are a considered a transfer payment from FEMA to recipients and therefore would not affect the total resources available to society.

FEMA analyzed the deobligation amounts for large projects, adjusted to year 2020 dollars, and compared them using the current threshold of $132,800 and the increased threshold of $1,000,000.[102] Projects where the total obligated amount was deobligated were excluded from the analysis, as total deobligation indicates that the project was not conducted at all and the funds would not have been awarded regardless of project size. For large projects, those above the current threshold of $132,800, a total of $543,871,441 has been deobligated in the 3.1 years of projects analyzed. Using a threshold of $1,000,000, $499,152,919 would still have been deobligated over the same period, or a difference of $44,718,521 (8.2 percent) less. This difference accounts for 0.07 percent ($44,718,521 ÷ $67,659,994,342) of all PA costs during the same period. When the maximum threshold is changed from $132,800 to $1,000,000, the amount of deobligations decreases by $14,425,329 ($44,718,521 ÷ 3.1 years) per year amongst all 56 states and territories, or $257,595 ($14,425,329 ÷ 56) in average deobligations per State or territory per year.

Table 10 below shows the deobligated values and the amount that was deobligated for large projects at the $132,800 threshold compared to the amount that would have been deobligated for large projects using a $1,000,000 threshold. The resulting difference is the amount of deobligations that would not have been recouped by FEMA for projects considered large at the $132,800 threshold but small at a $1,000,000 threshold over the period analyzed.

TABLE 9—DEOBLIGATIONS AT EACH THRESHOLD OVER 3.1 YEARS

[2020$]

	$132,800 Threshold	$1M Threshold
Deobligation Amount	$543,871,441	$499,152,919
Difference From $132,800 Threshold	0	−$44,718,521

[102] Obligation and deobligation amounts for projects are available in the Emmie database. The dollar amounts were adjusted for inflation to year 2020 dollars to be accurately compared against the $132,800 and $1M thresholds, which are year 2020 dollars.

Estimated Transfers Over a 3-Year Period

The figures in the previous section are estimates of 3.1 years of historical deobligations compared at the two thresholds.[103] The following calculations are estimates of transfers for three years in the future based on the deobligation estimates found in the previous section. These figures include three-year total and discounted annualized figures. The total undiscounted estimated transfers for three years is $43,275,988.[104] The average annual undiscounted transfers from FEMA to recipients and subrecipients is $14,425,329.[105] The discounted total net 3-year transfer rate at 3 and 7 percent, respectively, are $40,803,651 and $37,856,623. Annualized transfers are $14,425,330 and $14,425,329, respectively.

TABLE 10—ESTIMATED TRANSFERS OVER A 3-YEAR PERIOD

[2020$]

Year	Transfers from FEMA to recipient	Total transfers	Annual transfers discounted at 3%	Annual transfers discounted at 7%
1	$14,425,329	$14,425,329	$14,005,174	$13,481,616
2	14,425,329	14,425,329	13,597,257	12,599,641
3	14,425,329	14,425,329	13,201,220	11,775,366
Total [106]	43,275,988	43,275,988	40,803,651	37,856,623
Annualized	.....	.....	14,425,330	14,425,329

xi. Impacts

FEMA will increase the large project maximum threshold pursuant to the SRIA. The subject of this RIA is an increase from the current maximum threshold for Simplified Procedures to $1,000,000 for major disasters and emergencies declared on or after March 13, 2020, for unobligated projects. This will impact current unobligated projects. It will then continue to be adjusted each fiscal year for inflation using the CPI–U and reevaluated again three years after implementation.[107]

Despite past adjustments to the maximum threshold, it has gradually shifted away from the initial policy benchmarks. Congress set the threshold at $35,000 in 1988, which represented 95 percent of FEMA projects and 32 percent of PA disaster assistance funding. Prior adjustments include yearly adjustments to the maximum threshold every fiscal year based on the CPI–U and a thorough review by the program every three years. With the $132,800 threshold in place, small projects account for 77 percent of all projects and 2.4 percent of funding due to the increasing frequency and magnitude of major disasters due to the increase in the number of weather and climate disasters. Those involved with the PA process are impacted by this rule, including State, local, Tribal, and territorial governments, and certain private non-profit organizations.

Raising the maximum threshold for Simplified Procedures to $1,000,000, thereby increasing the number of small projects, will help speed closure of both projects and funding for disaster recovery, which will decrease the administrative burden of a disaster, help speed disaster recovery, and reduce the associated length of ongoing government oversight and associated costs. FEMA estimates the average annual benefit of this rule will be $6,464,964. The discounted total 3-year benefit at 3 percent and 7 percent discount rates, respectively, are $18,286,871 and $16,966,108. The annualized benefit is $6,464,964 and $6,464,964 at both the 3 and 7 percent discount rates.

There will be a cost of $10,454 for the first year for recipients to familiarize themselves with the changes. The total 3-year total cost discounted at 3 percent and 7 percent, respectively, are $10,150 and $9,770. The annualized cost is $3,588 and $3,723 at the 3 and 7 percent respective discount rates.

Increasing the maximum threshold leads to FEMA failing to recoup some over-obligated funds. These funds instead remain with grant recipients, which are State, local, Tribal or territorial governments, and certain private non-profit organizations. This estimated transfer from FEMA to the recipients and subrecipients is $14,425,330 annualized.

Category	3% Discount rate	7% Discount rate	Source citation (RIA, preamble, etc.)
Benefits:			
Annualized Monetized benefits	$6,464,964	$6,464,964	RIA.
Annualized quantified, but unmonetized benefits	N/A	N/A	N/A.
Qualitative (unquantified) benefits	.....	.....	N/A.
Costs:			
Annualized monetized costs	$3,588	$3,723	RIA.
Annualized quantified, but unmonetized, costs	N/A	N/A	N/A.

[103] GM began on August 25, 2017. FEMA used data from August 25, 2017 to September 30, 2020 for this analysis. There are 1,132 days during this time period. FEMA took the total number of days during the time of the analysis and divided it by the average of number of days per year. 1,132 ÷ 365 = 3.1.

[104] The total deobligation amount over 3.1 years was $44,718,521. To adjust this figure for only 3 years, it was first divided by 3.1 and then multiplied by 3. (($44,718,521 ÷ 3.1) × 3) = $43,275,988.

[105] $43,275,988 ÷ 3 = $14,425,329.

[106] Figures may not total due to rounding.

[107] FEMA publishes the annual adjustments to the maximum threshold on its website. See *https://www.fema.gov/assistance/public/applicants/per-capita-impact-indicator.*

Category	3% Discount rate	7% Discount rate	Source citation (RIA, preamble, etc.)
Qualitative (unquantified) costs	Projects which would fall below the maximum threshold once the regulation goes into effect would be subjected to less scrutiny, which could potentially increase the risk of inaccurate reporting and decrease the ability for FEMA to identify and remedy noncompliance. While this risk exists, it is unclear how common noncompliance would be among these projects		RIA.
Transfers:			
Annualized monetized transfers: ''on-budget''	$14,425,330	$14,425,329	RIA.
from whom to whom?	From FEMA to grant recipients		
Annualized monetized transfers: ''off-budget''	N/A	N/A	N/A.
from whom to whom?	N/A		N/A.
Category	Effects		Source Citation (RIA, preamble, etc.)
Effects on State, local, and/or tribal governments	Eligible applicants for PA include 56 State and territorial governments and 573 Federally recognized Indian Tribal governments, as well as local governments, and certain private nonprofits (PNPs). Eligible applicants with projects below the $1M threshold would not incur the costs associated with large projects		RIA.
Effects on small businesses	Small PNPs that are eligible for PA funds, will be able to access funding at a lower administrative cost if it is under the maximum threshold		N/A.
Effects on wages	None		None.
Effects on growth	None		None.

xii. Uncertainty Analysis

The findings, results, and conclusions of this analysis could change if the assumptions used in the primary analysis were to change. FEMA cannot accurately forecast disasters due to their unpredictability, including how many disasters will occur or the magnitude of future disasters. Therefore, the estimates of this analysis are sensitive to future disaster declarations, which are uncertain.

High-cost climate disasters have been growing in frequency over the last few decades. From 1980–1989, there were 29 disasters and the average annual cost of damages was $17.8B. From 1990–1999, there were 53 disasters and the average annual cost of damages was $27.4B, with FEMA obligating on average about $2.7 billion in PA funding for these disasters per year. From 2000–2009, there were 62 disasters and the average annual cost of damages was $51.9B, with FEMA obligating on average about $5.8 billion in PA funding for these disasters per year. From 2010–2019, there were 119 disasters and the average annual cost of damages was $81.10B, with FEMA obligating on average about $8.1 billion in PA funding for these disasters per year.[108] [109] The number and cost of weather and climate disasters are increasing in the United States due to a combination of an increase in assets being exposed to risk, the level of damage a hazard of given intensity causes at a location, and the fact that climate change is increasing the frequency of some types of extreme weather events that lead to high-cost disasters.[110]

xiii. Alternatives Considered

FEMA has evaluated several alternative regulatory approaches within FEMA's statutory discretion for implementing the final rule in accordance with Section 6(a)(3)(c) of Executive Order 12866, ''Regulatory Planning and Review,'' and the formal principles of OMB's Circular A–4. Alternative approaches include different implementation methods for the final rule.

The alternatives for this final rule would be to leave the maximum threshold unchanged or increase it to a different maximum.

FEMA considered four alternatives for this final rule. FEMA considered:

[108] National Oceanic & Atmospheric Administration (NOAA). (2021). *2020 U.S. billion-dollar weather and climate disasters in historical context.* Adam B. Smith. *https://www.climate.gov/news-features/blogs/beyond-data/2020-us-billion-dollar-weather-and-climate-disasters-historical.*

[109] FEMA analyzed the data for obligated PA projects up to September 30, 2020. Obligation of disaster funding can occur after the disaster year.

[110] U.S. Global Change Research Program (USGCRP). (2018). *Fourth National Climate Assessment, Chapter 2: Our Changing Climate. https://nca2018.globalchange.gov/chapter/2/.*

- Leaving the maximum threshold unchanged at $132,800 for FY 2021;
- Increasing the maximum threshold to $250,000 for FY 2021;
- Increasing the maximum threshold to $500,000 for FY 2021; and
- Increasing the maximum threshold to $750,000 for FY 2021.

Annual inflation adjustments will continue each fiscal year pursuant to SRIA.

Current Threshold

If FEMA did not increase the maximum threshold, no regulatory or other program changes would be required. The current threshold would still achieve the goal of capturing a majority of the small PA projects at 76.8 percent; however, it would be a smaller percentage than the original goal in 1988 of 95 percent.[111] The funding for small projects accounts for 2.4 percent of the total funding of PA projects at the current threshold. There would be 14,334 large projects and 47,376 small projects.

$250,000 Threshold

If FEMA were to increase the maximum threshold to $250,000 for FY 2021, it would require regulatory changes. This would increase the percentage of small PA projects to 83.9 percent; however, it would be a smaller percentage than the original goal in 1988 of 95 percent. The funding for small projects would account for 3.6 percent of the total funding of PA projects. The number of large projects over the 3.1-year period of analysis would decrease from a current 14,334 to 9,960, or a decrease of 4,374 (14,334 − 9,960), which is approximately a 30.5 ((14,334 − 9,960) ÷ 14,334) percent decrease from the current threshold. The number of recipients with at least 1 ongoing large project would reduce by 1, from 56 to 55. The 4,374 decrease in the number of large projects would have an estimated cost savings of $5,336,280 (4,374 × $1,220) for FEMA. The decrease in number of projects and 1 fewer recipient would have an estimated cost savings of $559,266 ((4,374 × $112) + ($5,595 × 4 quarters × 3.1 years)) for recipients and subrecipients.

$500,000 Threshold

If FEMA were to increase the maximum threshold to $500,000 for FY 2021, it would require regulatory changes. This would increase the percentage of small PA projects to 90.0 percent; however, it would be a smaller percentage than the original goal in 1988 of 95 percent. The funding for small projects would account for 5.6 percent of the total funding of PA projects. The number of large projects over the 3.1-year period of analysis would decrease from 14,334 to 6,156, or a decrease of 8,178 (14,334 − 6,156), which is approximately a 57.1 ((14,334 − 6,156) ÷ 14,334) percent decrease from the current threshold. The number of recipients with at least 1 ongoing large project would reduce by 1, from 56 to 55. The 8,178 decrease in the number of large projects would have an estimated cost savings of $9,977,160 (8,178 × $1,220) for FEMA. The decrease in number of projects and 1 fewer recipient would and an estimated cost savings of $985,314 ((8,178 × $112) + ($5,595 × 4 quarters × 3.1 years)) for recipients and subrecipients.

$750,000 Threshold

If FEMA were to increase the maximum threshold to $750,000 for FY 2021, it would require regulatory changes. This would increase the percentage of small PA projects to 92.8 percent; however, it would be a smaller percentage than the original goal in 1988 of 95 percent. The funding for small projects would account for 7.1 percent of the total funding of PA projects. The number of large projects over the 3.1-period of analysis would decrease from 14,334 to 4,469, or a decrease of 9,865 (14,334 − 4,469), which is approximately a 68.8 ((14,334 − 4,469) ÷ 14,334) percent decrease from the current threshold. The number of recipients with at least 1 ongoing large project would reduce by 1, from 56 to 55. The 9,865 decrease in the number of large projects would have an estimated cost savings of $12,035,300 (9,865 × $1,220) for FEMA. The decrease in number of projects and 1 fewer recipient would have an estimated cost savings of $1,174,258 ((9,865 × $112) + ($5,595 × 4 quarters × 3.1 years)) for recipients and subrecipients.

TABLE 11—PA PROJECTS AND AGGREGATE PROJECT AMOUNTS SINCE THE ADOPTION OF THE PA DELIVERY MODEL (3.1-YEAR PERIOD). ADJUSTED FOR EACH ALTERNATIVE THRESHOLDS

	$250K Threshold	$500K Threshold	$750K Threshold	$1M Threshold
Number of Small Projects	51,750	55,554	57,241	58,234
Percentage of Small Projects to Total Projects	83.9%	90.0%	92.8%	94.4%
Number of Large Projects	9,960	6,156	4,469	3,476
Percentage of Large Projects to Total Projects	16.1%	10.0%	7.2%	5.6%
Total Small Project Funding	$2,432,028,984	$3,777,518,663	$4,812,471,896	$5,670,643,149
Percentage of Small Project Funding to Total Project Funding	3.6%	5.6%	7.1%	8.4%
Total Large Project Funding	$65,227,965,358	$63,882,475,679	$62,847,522,446	$61,989,351,193
Percentage of Large Project Funding to Total Project Funding	96.4%	94.4%	92.9%	91.6%

TABLE 12—COST SAVINGS FOR MAXIMUM THRESHOLDS ALTERNATIVES

Admin cost savings to FEMA	$250K Threshold	$500K Threshold	$750K Threshold	$1M Threshold
Increases in the number of small projects PWs	4,374	8,178	9,865	10,858
Cost Savings from Processing Each Small Project over a Large Project	$1,220	$1,220	$1,220	$1,220
Estimated Total Cost savings to FEMA	$5,336,280	$9,977,160	$12,035,300	$13,246,760

[111] The Disaster Relief and Emergency Assistance Amendment of 1988 introduced the Simplified Procedures maximum threshold to reduce administrative expenses and time associated with a Federal disaster grant. Congress initially selected $35,000 as the threshold because ''damage survey reports of less than $35,000 have constituted 95 percent of all damage survey reports but only 32 percent of all expended dollars.''

TABLE 12—COST SAVINGS FOR MAXIMUM THRESHOLDS ALTERNATIVES—Continued

Admin cost savings to FEMA	$250K Threshold	$500K Threshold	$750K Threshold	$1M Threshold
Admin Cost Savings to Recipient and Subrecipient	.....	.....	.....	.....
FEMA Forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127				
Decrease in the number of large projects PWs	4,374	8,178	9,865	10,858
Dollars per PW to recipients/subrecipients (reduction in forms)	$112	$112	$112	$112
Estimated Cost Savings for the Five Forms	$489,888	$915,936	$1,104,880	$1,216,096
FEMA Form 009–0–111				
Decrease in the Number of Recipients from the Current Threshold	1	1	1	1
Cost savings from Submitting Fewer Forms	$69,378	$69,378	$69,378	$69,378
Estimated Cost Savings for FEMA Form 009–0–111	$69,378	$69,378	$69,378	$69,378
Estimated Total Cost Savings to Recipients and Subrecipients	$559,266	$985,314	$1,174,258	$1,285,474
Total Administrative Cost Savings	$5,895,546	$10,962,474	$13,209,558	$14,532,234

After analyzing the five potential thresholds, FEMA selected a threshold of $1,000,000 because it would bring Simplified Procedures closest to the initial policy benchmarks, raising the percentage of small projects from 77 percent back to 94.4 percent and raising the percentage of PA disaster funding for small projects from 2.4 percent to 8.4 percent.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), and section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, 110 Stat. 847, 858–59 (Mar. 29, 1996) (5 U.S.C. 601 note) require that special consideration be given to the effects of regulations on small entities. The RFA applies only when an agency is ''required by section 553 . . . to publish general notice of proposed rulemaking for any proposed rule.'' 5 U.S.C. 603(a). An RFA analysis is not required for this rulemaking because FEMA is not required to publish a notice of proposed rulemaking.

D. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 658, 1501–1504, 1531–1536, 1571, pertains to any rulemaking which is likely to result in the promulgation of any rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) or more in any one year. If the rulemaking includes such a Federal mandate, the Act requires an agency to prepare an assessment of the anticipated costs and benefits of the Federal mandate. The Act also pertains to any regulatory requirements that might significantly or uniquely affect small governments. Before establishing any such requirements, an agency must develop a plan allowing for input from the affected governments regarding the requirements.

FEMA has determined that this rulemaking will not result in the expenditure by State, local, and Tribal governments, in the aggregate, nor by the private sector, of $100,000,000 or more in any one year as a result of a Federal mandate, and it will not significantly or uniquely affect small governments. In addition, this rulemaking falls under an exclusion to this Act for rules that provide for emergency assistance or relief at the request of any State, local, or Tribal government. *See* 2 U.S.C. 1503(4). Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

E. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA), as amended, 44 U.S.C. 3501–3520, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency obtains approval from the Office of Management and Budget (OMB) for the collection and the collection displays a valid OMB control number. *See* 44 U.S.C. 3506, 3507.

In this rule, FEMA is seeking a revision to the already existing collection of information, OMB Control Number 1660–0017. This rule revises FEMA's regulations governing the Public Assistance program at 44 CFR 206.203(c) to increase the monetary threshold for when FEMA will process an application using ''simplified procedures'' to $1,000,000. For this information collection, the number of annual responses is decreasing from 449,084 to 431,720, the annual burden hours are decreasing from 491,533 to 484,189, and the annual cost to respondents is decreasing from $27,845,344 to $27,090,374. These changes are due to a decrease in the number of responses for FEMA Forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127 and for the number of respondents for FEMA Form 009–0–111. FEMA requires that recipients of large projects fill out these supplemental forms to account for the actual costs for reconciliation purposes. These forms are not required for small projects. The decrease in the number of large projects as a result of the increase in the large project threshold means fewer applicants submitting these forms.

Collection of Information

Title: PA Program.

Type of information collection: Revision of a currently approved collection.

OMB Number: 1660–0017.

Forms: FEMA Form 009–0–49 Request for Public Assistance; FEMA Form 009–0–91 Project Worksheet (PW); FEMA Form 009–0–91A Project Worksheet (PW)—Damage Description and Scope of Work Continuation Sheet; FEMA Form 009–0–91B Project Worksheet (PW)—Cost Estimate Continuation Sheet; FEMA Form 009–0–91C Project Worksheet (PW)—Maps and Sketches Sheet; FEMA Form 009–0–91D Project Worksheet (PW)—Photo Sheet; FEMA Form 009–0–120 Special Considerations Questions; FEMA Form 009–0–121 PNP Facility Questionnaire; FEMA Form 009–0–123 Force Account Labor Summary Record; FEMA Form 009–0–124 Materials Summary Record;

FEMA Form 009–0–125 Rented Equipment Summary Record; FEMA Form 009–0–126 Contract Work Summary Record; FEMA Form 009–0–127 Force Account Equipment Summary Record; FEMA Form 009–0–128 Applicant's Benefits Calculation Worksheet; FEMA Form 009–0–111, Quarterly Progress Report; FEMA Form 009–0–141, FAC–TRAX System.

Abstract: The information collected is utilized by FEMA to make determinations for PA grants based on the information supplied by the respondents.

Affected Public: State, local, or Tribal Government.

Estimated Number of Respondents: 1,067.

Estimated Number of Responses: 431,720.

Estimated Total Annual Burden Hours: 484,189.

The table below provides estimates of annualized cost to respondents for the hour burdens for the collection of information.

TABLE 13—ESTIMATED ANNUALIZED BURDEN HOURS AND COSTS

Type of respondent	Form name/form No.	Number of respondents	Number of responses per respondent	Total number of responses	Avg. burden per response (in hours)	Total annual burden (in hours)	Avg. hourly wage rate	Total annual respondent cost
State, Local or Tribal Government.	FEMA Form 009–0–49, Request for PA	56	129	7,224	0.25	1,806	$55.95	$101,046
State, Local or Tribal Government.	FEMA Form 009–0–91, Project Worksheet (PW) and a Request for Time Extension.	56	840	47,040	1.5	70,560	55.95	3,947,832
State, Local or Tribal Government.	FEMA Form 009–0–91A Project Work Sheet (PW) Damage Description and Scope of Work.	56	784	43,904	1.5	65,856	55.95	3,684,643
State, Local or Tribal Government.	FEMA Form 009–0–91B, Project Worksheet (PW) Cost Estimate Continuation Sheet and Request for additional funding for Cost Overruns.	56	784	43,904	1.3333	58,537	55.95	3,275,145
State, Local or Tribal Government.	FEMA Form 009–0–91C Project Worksheet (PW) Maps and Sketches Sheet.	56	728	40,768	1.5	61,152	55.95	3,421,454
State, Local or Tribal Government.	FEMA Form 009–0–91D Project Worksheet (PW) Photo Sheet.	56	728	40,768	1.5	61,152	55.95	3,421,454
State, Local or Tribal Government.	FEMA Form 009–0–120, Special Considerations Questions/.	56	840	47,040	0.5	23,520	55.95	1,315,944
State, Local or Tribal Government.	FEMA Form 009–0–128, Applicant's Benefits Calculation Worksheet/.	56	784	43,904	0.5	21,952	55.95	1,228,214
State, Local or Tribal Government.	FEMA Form 009–0–121, PNP Facility Questionnaire.	56	94	5,264	0.5	2,632	55.95	147,260
State, Local or Tribal Government.	FEMA Form 009–0–123, Force Account Labor Summary Record [112].	56	32	1,792	0.5	896	55.95	50,131
State, Local or Tribal Government.	FEMA Form 009–0–124, Materials Summary Record/.	56	32	1,792	0.25	448	55.95	25,066
State, Local or Tribal Government.	FEMA Form 009–0–125, Rented Equipment Summary Record.	56	32	1,792	0.5	896	55.95	50,131
State, Local or Tribal Government.	FEMA Form 009–0–126, Contract Work Summary Record/.	56	32	1,792	0.5	896	55.95	50,131
State, Local or Tribal Government.	FEMA Form 009–0–127, Force Account Equipment Summary Record/.	56	32	1,792	0.25	448	55.95	25,066
State, Local or Tribal Government.	State Administrative Plan and State Plan Amendments/No Form.	56	1	56	8	448	55.95	25,066
State, Local or Tribal Government.	FEMA Form 009–0–111, Quarterly Progress Report.	55	4	220	100	22,000	55.95	1,230,900
State, Local or Tribal Government.	Request for Appeals or Arbitrations & Recommendation/No Forms.	56	9	504	3	1,512	55.95	84,596
State, Local or Tribal Government.	Request for Arbitration & Recommendation resulting from Hurricanes Katrina or Rita/No Form.	4	5	20	3	60	55.95	3,357
State, Local or Tribal Government.	FEMA Form 009–0–141, FAC–TRAX System.	56	913	51,128	1.25	63,910	55.95	3,575,765
State, Local or Tribal Government.	FEMA Template 104–FY–21–100 Equitable COVID–19 Response and Recovery.	56	911	51,016	0.5	25,508	55.95	1,427,173
Total	.....	1,067	.....	431,720	.....	484,189	.....	27,090,374

Note: The ''Avg. Hourly Wage Rate'' for each respondent includes a 1.6 multiplier to reflect a fully-loaded wage rate.

Estimated Total Annual Respondent Cost: $27,090,374.

Estimated Respondents' Operation and Maintenance Costs: N/A.

Estimated Respondents' Capital and Start-Up Costs: N/A.

Estimated Total Annual Costs to the Federal Government: $1,957,204.

FEMA calculated the impact on the Information Collection Request if the maximum threshold were changed from $132,800 to $1,000,000 by taking the difference in the number of large projects at the $132,800 threshold compared to the $1,000,000 threshold. At the $132,800 threshold, there are

[112] FEMA uses whole numbers for burden estimates in this table. These estimates do not match the RIA, since at the $1,000,000 threshold, FEMA calculated a total of 1,761 responses for forms 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–0127. The number of respondents would remain the same at 56, while the average number of responses per respondent would be 31.45 (rounded up to 32 for the PRA analysis). In the RIA, the total number of responses was estimated to be 1,761(56 × 31.45).

14,334 large projects over 3.1 years. At the $1,000,000 threshold, there are 3,476 large projects in 3.1 years. FEMA earlier mentions the 10,858 (14,334 − 3,476) projects that will now be considered small from these numbers of projects over 3.1 years. Annually, there will be 3,503 (10,858 ÷ 3.1) additional small projects that were formerly large.

FEMA then calculated the total number of responses for each form at the $1,000,000 threshold by taking the total number of responses at the $132,800 threshold and then subtracting 3,503. For FEMA Form 009–0–123, 009–0–124, 009–0–125, 009–0–126, and 009–0–127, FEMA estimates there will be 1,761 (5,264 − 3,503) total number of responses for each of these forms at the $1,000,000 threshold. FEMA then analyzed the data to determine then number of recipients who would not have at least one ongoing large project if the maximum threshold were $1,000,000 compared to those who would at the $132,800 threshold. Over the 3.1-year period, the number of recipients with at least 1 ongoing large project would reduce by 1, from 56 to 55, meaning 1 fewer recipient would submit FEMA Form 009–0–111. The total number of responses to the quarterly form would reduce by 12.4 (4 responses × 3.1) over the 3.1-year period, or by approximately 4 responses annually.

F. Privacy Act/E-Government Act

Under the Privacy Act of 1974, 5 U.S.C. 552a, an agency must determine whether implementation of a regulation will result in a system of records. A ''record'' is any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, one's education, financial transactions, medical history, and criminal or employment history and that contains one's name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. *See* 5 U.S.C. 552a(a)(4). A ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. An agency cannot disclose any record which is contained in a system of records except by following specific procedures.

The E-Government Act of 2002, 44 U.S.C. 3501 note, also requires specific procedures when an agency takes action to develop or procure information technology that collects, maintains, or disseminates information that is in an identifiable form. This Act also applies when an agency initiates a new collection of information that will be collected, maintained, or disseminated using information technology if it includes any information in an identifiable form permitting the physical or online contacting of a specific individual.

In accordance with U.S. Department of Homeland Security (DHS) policy, FEMA has completed a Privacy Threshold Analysis for this rule. FEMA has determined this rulemaking does not require the development and publication of a new or modified System of Records Notice (SORN). The information collected has coverage under an existing Privacy Impact Assessments (PIA) and an existing SORN:

DHS/FEMA/PIA–013 Grant Management Programs;

DHS/FEMA–009 Hazard Mitigation Assistance Grant Programs SORN.

The rule does not impact the personally identifiable information (PII) that FEMA currently collects, stores, maintains, or disseminates. The rulemaking has adequate coverage under the above listed PIA and SORN.

G. Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''

Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' 65 FR 67249 (Nov. 9, 2000), applies to agency regulations that have Tribal implications, that is, regulations that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Under this Executive Order, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has Tribal implications, that imposes substantial direct compliance costs on Indian Tribal governments, and that is not required by statute, unless funds necessary to pay the direct costs incurred by the Indian Tribal government or the Tribe in complying with the regulation are provided by the Federal Government, or the agency consults with Tribal officials.

FEMA has reviewed this final rule under Executive Order 13175 and has determined that it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. This rule updates the dollar figure related to FEMA's procedures for handling grants for small and large projects. It is therefore procedural and will not affect the substantive rights or interests of Indian Tribal governments.

H. Executive Order 13132, ''Federalism''

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action.

FEMA has determined that this rulemaking does 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, and therefore does not have federalism implications as defined by the Executive Order.

I. Executive Order 11988, ''Floodplain Management''

Pursuant to Executive Order 11988, ''Floodplain Management,'' 42 FR 26951 (May 24, 1977), each agency must provide leadership and take action to reduce the risk of flood loss, to minimize the impact of floods on human safety, health and welfare, and to restore and preserve the natural and beneficial values served by floodplains in carrying out its responsibilities for (1) acquiring, managing, and disposing of Federal lands and facilities; (2) providing Federally undertaken, financed, or assisted construction and improvements; and (3) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities. In carrying out these responsibilities, each agency must evaluate the potential effects of any actions it may take in a floodplain; ensure that its planning programs and budget requests reflect consideration of flood hazards and floodplain management; and prescribe procedures

to implement the policies and requirements of the Executive Order.

Before promulgating any regulation, an agency must determine whether the regulations will affect a floodplain(s), and if so, the agency must consider alternatives to avoid adverse effects and incompatible development in the floodplain(s). If the head of the agency finds that the only practicable alternative consistent with the law and with the policy set forth in Executive Order 11988 is to promulgate a regulation that affects a floodplain(s), the agency must, prior to promulgating the regulation, design or modify the regulation in order to minimize potential harm to or within the floodplain, consistent with the agency's floodplain management regulations. It must also prepare and circulate a notice containing an explanation of why the action is to be located in the floodplain.

The purpose of this rule is to update the dollar figure related to FEMA's procedures for handling grants for small and large projects. In accordance with 44 CFR part 9, ''Floodplain Management and Protection of Wetlands,'' FEMA determines that the changes in this rule would not have an effect on floodplains. When FEMA undertakes specific actions that may affect floodplain management, FEMA follows the procedures set forth in 44 CFR part 9 to ensure compliance with this Executive Order. These procedures include a specific, eight-step process for conducting floodplain management and wetland reviews. With few exceptions (such as emergencies) and as set forth in applicable statutes or regulations, reviews for compliance must be completed before FEMA approves funding and before work is started. This rule does not change this process.

J. Executive Order 11990, ''Protection of Wetlands''

Executive Order 11990, ''Protection of Wetlands,'' 42 FR 26961 (May 24, 1977) sets forth that each agency must provide leadership and take action to minimize the destruction, loss or degradation of wetlands, and to preserve and enhance the natural and beneficial values of wetlands in carrying out the agency's responsibilities. These responsibilities include (1) acquiring, managing, and disposing of Federal lands and facilities; and (2) providing Federally undertaken, financed, or assisted construction and improvements; and (3) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities. Each agency, to the extent permitted by law, must avoid undertaking or providing assistance for new construction located in wetlands unless the head of the agency finds (1) that there is no practicable alternative to such construction, and (2) that the action includes all practicable measures to minimize harm to wetlands which may result from such use. In making this finding, the head of the agency may take into account economic, environmental and other pertinent factors.

In carrying out the activities described in Executive Order 11990, each agency must consider factors relevant to a proposal's effect on the survival and quality of the wetlands. These include public health, safety, and welfare, including water supply, quality, recharge and discharge; pollution; flood and storm hazards; sediment and erosion; maintenance of natural systems, including conservation and long term productivity of existing flora and fauna, species and habitat diversity and stability, hydrologic utility, fish, wildlife, timber, and food and fiber resources. They also include other uses of wetlands in the public interest, including recreational, scientific, and cultural uses. The purpose of this rule is to update the dollar figure related to FEMA's procedures for handling grants for small and large projects. In accordance with 44 CFR part 9, ''Floodplain Management and Protection of Wetlands,'' FEMA determines that the changes in this rule would not have an effect on wetlands. When FEMA undertakes specific actions that may affect floodplain management, FEMA follows the procedures set forth in 44 CFR part 9 to ensure compliance with this Executive Order. These procedures include a specific, eight-step process for conducting floodplain management and wetland reviews. With few exceptions (such as emergencies) and as set forth in applicable statutes or regulations, reviews for compliance must be completed before FEMA approves funding and before work is started. This rule does not change this process.

K. Executive Order 12898, ''Environmental Justice''

Pursuant to Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' 59 FR 7629 (Feb.16, 1994), as amended by Executive Order 12948, 60 FR 6381 (Feb. 1, 1995), FEMA incorporates environmental justice into its policies and programs. The Executive Order requires each Federal agency to conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that those programs, policies, and activities do not have the effect of excluding persons from participation in programs, denying persons the benefits of programs, or subjecting persons to discrimination because of race, color, or national origin.

This rulemaking will not result in disproportionately high or adverse effects on human health or the environment. The purpose of this rule is to update the dollar figure related to FEMA's procedures for handling grants for small and large PA projects. The PA program provides funding to States, local governments, Tribal governments, and PNP facilities/organizations to assist them in their emergency response and disaster response and recovery efforts. The rulemaking will not have the effect of excluding persons from participation in or denying persons the benefit of this program, nor will it subject persons to discrimination because of race, color, or national origin. The PA program is administered consistent with the nondiscrimination requirements of 44 CFR 206.11 and section 308 of the Stafford Act, 42 U.S.C. 5151.

L. National Environmental Policy Act of 1969 (NEPA)

Section 102 of the National Environmental Policy Act of 1969 (NEPA), 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*) requires Federal agencies to consider the impacts of their major actions on the quality of the human environment. Each agency can develop categorical exclusions (CATEXs) to cover major Federal actions that have been demonstrated to not typically trigger significant impacts to the human environment individually or cumulatively. If an action does not qualify for a CATEX and has the potential to significantly affect the environment, Federal agencies conduct environmental assessments (EAs) to evaluate those actions. The Council on Environmental Quality's (CEQ) procedures for implementing NEPA, 40 CFR parts 1500 through 1508, require Federal agencies to prepare Environmental Impact Statements (EISs) for major Federal actions significantly affecting the quality of the human environment. At the end of the EA process, the agency determines whether to make a Finding of No Significant Impact (FONSI) or whether to initiate the EIS process. A major federal action may be categorically excluded under a Federal agency's NEPA procedures and if there are no extraordinary circumstances. 40 CFR 1507.3, 1508.4. This rule falls within the scope of the

Department of Homeland Security List of Categorical Exclusion A3(a), which covers rules of a strictly administrative or procedural nature. The update to the monetary threshold in this rule will have no significant effect on the human environment, is categorically excluded consistent with DHS procedure and NEPA regulations, and no extraordinary circumstances have been identified. Therefore, this rule does not require the preparation of either an EA or an EIS as defined by NEPA. *See* Department of Homeland Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, section (V)(B)(2).

M. National Historic Preservation Act

The National Historic Preservation Act (NHPA) (54 U.S.C. 300101, formerly 16 U.S.C. 470) was enacted in 1966, with various amendments throughout the years. Section 106 of the NHPA (54 U.S.C. 306108) requires Federal agencies to consider the effects of its actions, referred to as an ''undertaking,'' on any historic property listed, or eligible for listing, on the National Register. Section 106 requires the Federal agency to consult with any Federal agencies, State, local, and Tribal governments, and members of the public who have an interest in the effects of the undertaking. Section 106 mandates the consultation process in the early stages of project planning and that it be completed prior to the approval of expenditure of any Federal funds for the undertaking. Subpart B of 36 CFR part 800 lays out a four-step Section 106 process to fulfill this obligation: 1—Initiate the process (800.3); 2—Identify historic properties (800.4), 3—Assess adverse effects (800.5), and 4—Resolve adverse effects (800.6).

This rule updates the Public Assistance monetary threshold for when FEMA uses the application of simplified procedures for administrative efficiency. Pursuant to section 106 of the NHPA and its implementing regulations at 36 CFR part 800, FEMA has determined that this rulemaking does not have the potential to cause effects to historic properties. In accordance with 36 CFR 800.3(a)(1), FEMA has no further obligations under section 106. When FEMA undertakes specific actions that may affect historic properties, FEMA follows the procedures set forth in 36 CFR part 800 to ensure compliance with this law. These procedures include a specific, four-step process for determining effects to historic properties. With few exceptions (such as emergencies) and as set forth in applicable statutes or regulations, reviews for compliance must be completed before FEMA approves funding and before work is started. This rule does not change this process.

N. Endangered Species Act

The Endangered Species Act (ESA) mandates that Federal agencies determine whether their actions may affect listed species and/or their designated critical habitat (critical habitat has been designated for some, but not all listed species). Without authorization or exemption from Federal resource agencies, it is unlawful for any person, whether government employee or private citizen, to take listed animal species, or remove, damage, or destroy (among other actions) an endangered plant species. 16 U.S.C. 1538, 1539.

To comply with section 7(a)(2) of the ESA, for every action that FEMA carries out, funds, or authorizes, FEMA must first determine if listed species and their designated critical habitat are present in the action area. If species are present in the action area, then FEMA must make one of the following determinations with respect to the effect of the action on listed species and critical habitat: (1) No Effect (NE); (2) May affect, but is not likely to adversely affect (NLAA); or (3) May affect and is likely to adversely affect (LAA).

This rule would update the Public Assistance monetary threshold for when FEMA uses the application of simplified procedures for administrative efficiency. This rulemaking has been evaluated by FEMA and due to its administrative nature, FEMA has determined the rulemaking does not have the potential to affect federally-listed species or designated critical habitat. As such, FEMA has made a No Effect determination for this rulemaking. Per the ESA regulations, notification to, and consultation with, the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service are not required for activities with a No Effect determination. When FEMA undertakes specific actions that may affect listed species and their designated critical habitat, FEMA follows the procedures set forth in section 7(a)(2) to ensure compliance with this law. These procedures include a process for determining the effect of the action on listed species and critical habitat. The rule does not change this process.

O. Congressional Review of Agency Rulemaking

Under the Congressional Review of Agency Rulemaking Act (CRA), 5 U.S.C. 801–808, before a rule can take effect, the Federal agency promulgating the rule must submit to Congress and to the Government Accountability Office (GAO) a copy of the rule; a concise general statement relating to the rule, including whether it is a major rule; the proposed effective date of the rule; a copy of any cost-benefit analysis; descriptions of the agency's actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act; and any other information or statements required by relevant executive orders.

FEMA has sent this final rule to the Congress and to GAO pursuant to the CRA. The rule is not a ''major rule'' within the meaning of the CRA. It will not have an annual effect on the economy of $100,000,000 or more; it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects in 44 CFR Part 206

Administrative practice and procedure, Coastal zone, Community facilities, Disaster assistance, Fire prevention, Grant programs-housing and community development, Housing, Insurance, Intergovernmental relations, Loan programs-housing and community development, Natural resources, Penalties, and Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Federal Emergency Management Agency amends 44 CFR part 206 as follows:

PART 206—FEDERAL DISASTER ASSISTANCE

■ 1. The authority citation for part 206 continues to read as follows:

Authority: Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5207; Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.;* Department of Homeland Security Delegation 9001.1; sec. 1105, Pub. L. 113–2, 127 Stat. 43 (42 U.S.C. 5189a note).

■ 2. In § 206.203:

■ a. In paragraphs (c)(1) and (2), remove ''$120,000'' and add in its place ''$1,000,000'' wherever it appears; and

■ b. Add paragraph (c)(3).

The addition reads as follows:

§ 206.203 Federal grant assistance.

* * * * *

(c) * * *

(3) *Applicability date.* The dollar threshold provided in this paragraph (c) applies to project worksheets that have not been obligated as of August 3, 2022 for major disasters and emergencies declared on or after March 13, 2020.

* * * * *

Deanne B. Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2022–16555 Filed 8–2–22; 8:45 am]

BILLING CODE 9111–23–P

Proposed Rules

Federal Register
Vol. 87, No. 148
Wednesday, August 3, 2022

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

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0354]

RIN 1625–AA00

Safety Zone; Mystic River, Mystic, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to eastablish a temporary safety zone on the Mystic River for the Mystic Seaport Bridge 100th Anniversary Fireworks Display. This action is necessary to provide for the safety of life on the navigable waters in the vicinity of the Mystic Bascule Bridge during a fireworks display on October 15, 2022 enforced from 8:15 until 9 p.m. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Long Island Sound or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before September 2, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0354 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Marine Science Technician 3rd Class Ashley Dodd, Waterways Management Division, Sector Long Island Sound; Tele: (203) 468–4469; Email: *Ashley.m.dodd@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On March 16, 2022, the Mystic Chamber of Commerce notified the Coast Guard that it will be conducting a fireworks display from 8:15 to 9 p.m. on October 15, 2022, with a rain date on October 16, 2022 to commemorate the Mystic Seasport Bridge 100th Anniversary. The fireworks are to be launched from a barge in the Mystic River approximately 200 yards west of the Mystic River Boathouse Park, Mystic, CT. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Sector Long Island Sound (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a 200-yard radius of the barge.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 200-yard radius of the fireworks barge before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).]

III. Discussion of Proposed Rule

The COTP is proposing to establish a safety zone from 7:45 to 9:30 p.m. on October 15, 2022 with a rain date scheduled for October 16, 2022. The safety zone would cover all navigable waters within 200 yards of a barge in the Mystic River located approximately 200 yards west of the Mystic River Boathouse Park, Mystic, CT. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 8:15 to 9 p.m. fireworks display. All persons or vessels would be prohibited from entering the safety zone without permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, and duration of the safety zone. Due to the size of the fall-out zone, vessel traffic will be impeded throughout the duration of the fireworks display.

B. Impact on Small Entities

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

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this 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. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting one hour and 45 minutes that would prohibit entry within 200 yards of a fireworks barge. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2022–0354 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T151–0354 to read as follows:

§ 165.T151–0354 Safety Zone; Mystic River, Mystic, CT.

(a) *Location.* The following area is a safety zone: All waters within a 200 yard radius of the fireworks barge located at 41°21′54″ N, 71°57′59″ W.

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

(2) To seek permission to enter, contact the COTP or the COTP's

representative by (203) 468–4444. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(c) *Enforcement period.* This section will be enforced from 7:45 p.m. to 9:30 p.m. on October 15, 2022 with a rain date scheduled on October 16, 2022.

Dated: July 21, 2022.

E.J. Van Camp,

Captain, U.S. Coast Guard, Captain of the Port Long Island Sound.

[FR Doc. 2022–16623 Filed 8–2–22; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register

Vol. 87, No. 148

Wednesday, August 3, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Assessment of Fees for Dairy Import Licenses for the 2023 Tariff-Rate Import Quota Year

AGENCY: Foreign Agricultural Service, Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: This notice announces a fee of $350 to be charged for the 2023 tariff-rate quota (TRQ) year for each license issued to a person or firm by the Department of Agriculture authorizing the importation of certain dairy articles, which are subject to tariff-rate quotas set forth in the Harmonized Tariff Schedule (HTS) of the United States.

DATES: This notice is applicable on August 3, 2022.

FOR FURTHER INFORMATION CONTACT: Elizabeth Riley, Dairy Import Licensing Program, Foreign Agricultural Service, U.S. Department of Agriculture, at (202) 720–6868; or by email at: *Elizabeth.riley@usda.gov.*

SUPPLEMENTARY INFORMATION: The Dairy Tariff-Rate Quota Import Licensing Regulation promulgated by the Department of Agriculture and codified at 7 CFR 6.20–6.36 provides for the issuance of licenses to import certain dairy articles that are subject to TRQs set forth in the HTS. Those dairy articles may only be entered into the United States at the in-quota TRQ tariff-rates by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The use of such licenses is monitored by the Import Program within the Foreign Agricultural Service, U.S. Department of Agriculture, and U.S. Customs and Border Protection, U.S. Department of Homeland Security.

The regulation at 7 CFR 6.33(a) provides that a fee will be charged for each license issued to a person or firm by the Licensing Authority to defray the Department of Agriculture's costs of administering the licensing system under this regulation.

The regulation at 7 CFR 6.33(a) also provides that the Licensing Authority will announce the annual fee for each license and that such fee will be set out in a notice to be published in the **Federal Register**. Accordingly, this notice sets out the fee for the licenses to be issued for the 2023 calendar year.

The total cost to the Department of Agriculture of administering the licensing system for 2023 has been estimated to be $789,068.00 and the estimated number of licenses expected to be issued is 2,250. Of the total cost, $572,200.00 represents staff and supervisory costs directly related to administering the licensing system, and $216,868.00 represents other miscellaneous costs, including travel, publications, forms, and Automatic Data Processing (ADP) system support.

Accordingly, notice is hereby given that the fee for each license issued to a person or firm for the 2023 calendar year, in accordance with 7 CFR 6.33, will be $350 per license.

Aileen Mannix,

Acting Licensing Authority, Foreign Agricultural Service.

[FR Doc. 2022–16600 Filed 8–2–22; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Commodity Credit Corporation

Notice of Request for Extension of Currently Approved Information Collection

AGENCY: Foreign Agricultural Service and Commodity Credit Corporation, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Commodity Credit Corporation's (CCC) intention to request an extension for a currently approved information collection in support of the CCC Facility Guarantee Program (FGP).

DATES: Comments on this notice must be received by October 3, 2022 to be assured consideration.

ADDRESSES: You may send comments, identified by OMB Control Number 0551–0032, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* This portal enables respondents to enter short comments or attach a file containing lengthier comments.
- *Email: Juan.McCoy@usda.gov.* Include OMB Control Number 0551–0032 in the subject line of the message.
- *Mail, Courier, or Hand Delivery:* Juan McCoy, U.S. Department of Agriculture, Foreign Agricultural Service, 1400 Independence Avenue SW, Room 5768, Washington, DC 20250.

Instructions: All submissions received must include the agency names and OMB Control Number for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Amy Slusher, 202 720–0775, *Amy.Slusher@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: CCC Facility Guarantee Program (FGP).

OMB Number: 0551–0032.

Expiration Date of Approval: November 30, 2022.

Type of Request: Extension of a currently approved information collection.

Abstract: Under the FGP, CCC provides payment guarantees to facilitate the financing of manufactured goods and U.S. services to improve or establish agriculture-related facilities in emerging markets. By supporting such goods and services exports, the FGP is designed to enhance sales of U.S. agricultural commodities and products to emerging markets where the demand for such commodities and products may be limited due to inadequate storage, processing, handling, or distribution capabilities for such products.

The FGP is currently available in 84 countries. Under 7 CFR part 1493, U.S. sellers, foreign financial institutions (FFI), and U.S. financial institutions (USFI) are required to submit the following: (1) information about the seller, FFI, and USFI for program

participation; (2) applications for payment guarantees; (3) environmental impact statement/assessment; (4) notice of assignment of payment guarantee; (5) evidence of performance; (6) notice of default and claims for loss; and (7) documents supporting dispute resolution and appeals. In addition, each seller and seller's assignee (U.S. financial institution) must maintain records on all information submitted to CCC and in connection with sales made under FGP. The information collected is used by CCC to manage, plan, evaluate, and account for government resources. The reports and records are required to ensure the proper and judicious use of public funds.

Estimate of Burden: The public reporting burden for these collections is estimated to average 1.282 hours per response.

Type of Respondents: U.S. exporters (sellers), U.S. financial institutions, and foreign financial institutions.

Estimated Number of Respondents: 18 per year.

Estimated Number of Responses per Respondent: 15.6 per year.

Estimated Total Annual Burden of Respondents: 360.5 hours.

Copies of this information collection can be obtained from Dacia Rogers, the Agency Information Collection Coordinator, at *Dacia.Rogers@usda.gov.*

Request for Comments: Send comments regarding (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information including validity of the methodology and assumption used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be available without change, including any personal information provided, for inspection online at *http://www.regulations.gov* and at the mail address listed above between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Comments will be summarized and included in the submission for Office of Management and Budget approval.

Persons with disabilities who require an alternative means for communication of information (Braille, large print, audiotape, etc.) should contact *FAS-ReasonableAccommodation@usda.gov* or Cynthia Stewart (RA Coordinator), *cynthia.stewart@usda.gov.*

Zach Ducheneaux,

Executive Vice President, Commodity Credit Corporation.

Daniel Whitley,

Administrator, Foreign Agricultural Service.

[FR Doc. 2022–16542 Filed 8–2–22; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC187]

Final 2021 Marine Mammal Stock Assessment Reports

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

ACTION: Notice; response to comments.

SUMMARY: As required by the Marine Mammal Protection Act (MMPA), NMFS has considered public comments for revisions of the 2021 marine mammal stock assessment reports (SARs). This notice announces the availability of 50 final 2021 SARs that were updated and finalized.

ADDRESSES: The 2021 Final SARs are available in electronic form via *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region.*

Copies of the Alaska Regional SARs may be requested from Nancy Young, Alaska Fisheries Science Center; copies of the Atlantic, Gulf of Mexico, and Caribbean Regional SARs may be requested from Sean Hayes, Northeast Fisheries Science Center; and copies of the Pacific Regional SARs may be requested from Jim Carretta, Southwest Fisheries Science Center (see **FOR FURTHER INFORMATION CONTACT** below).

FOR FURTHER INFORMATION CONTACT: Zachary Schakner, Office of Science and Technology, 301–427–8106, *Zachary.Schakner@noaa.gov;* Nancy Young, 206–526–4297, *Nancy.Young@noaa.gov,* regarding Alaska regional stock assessments; Sean Hayes, 508–495–2362, *Sean.Hayes@noaa.gov,* regarding Atlantic, Gulf of Mexico, and Caribbean regional stock assessments; or Jim Carretta, 858–546–7171, *Jim.Carretta@noaa.gov,* regarding Pacific regional stock assessments.

SUPPLEMENTARY INFORMATION:

Background

Section 117 of the MMPA (16 U.S.C. 1361 *et seq.*) requires NMFS and the U.S. Fish and Wildlife Service (FWS) to prepare stock assessments for each stock of marine mammals occurring in waters under the jurisdiction of the United States, including the U.S. Exclusive Economic Zone (EEZ). These SARs must contain information regarding the distribution and abundance of the stock, population growth rates and trends, estimates of annual human-caused mortality and serious injury (M/SI) from all sources, descriptions of the fisheries with which the stock interacts, and the status of the stock. Initial SARs were completed in 1995.

The MMPA requires NMFS and FWS to review the SARs at least annually for strategic stocks and stocks for which significant new information is available, and at least once every 3 years for non-strategic stocks. The term ''strategic stock'' means a marine mammal stock: (A) for which the level of direct human-caused mortality exceeds the potential biological removal level or potential biological removal rate PBR (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); (B) which, based on the best available scientific information, is declining and is likely to be listed as a threatened species under the Endangered Species Act (ESA) within the foreseeable future; or (C) which is listed as a threatened species or endangered species under the ESA or is designated as depleted under the MMPA. NMFS and FWS are required to revise a SAR if the status of the stock has changed or can be more accurately determined.

In order to ensure that marine mammal SARs constitute the best scientific information available, the updated SARs under NMFS's jurisdiction are peer-reviewed within NOAA Fisheries Science Centers and by members of three regional independent Scientific Review Groups (SRGs), established under the MMPA to independently advise NMFS and FWS. Because of the time it takes to review, revise, and assess available data, the period covered by the 2021 Final SARs is 2015 through 2019. While this results in a time lag, the extensive peer review process ensures the best scientific information is available in the SARs.

NMFS reviewed the status of all marine mammal strategic stocks and considered whether significant new information was available for all other stocks under NMFS' jurisdiction. As a result of this review, NMFS revised a total of 50 SARs in the Alaska, Atlantic, and Pacific regions to incorporate new information. The 2021 revisions to the SARs consist primarily of updated or revised human-caused M/SI estimates and updated abundance estimates. No stocks changed in status from ''non-strategic'' to ''strategic.'' Three stocks (all Northern Gulf of Mexico Bay, Sound, and Estuary Common Bottlenose Dolphin stocks—Galveston Bay, East Bay, Trinity Bay stock; Mississippi River Delta stock; and Sabine Lake stock) changed in status from ''strategic'' to ''non-strategic.''

NMFS received comments on the draft 2021 SARs from the Marine Mammal Commission (Commission); the Department of Fisheries and Oceans Canada (DFO); the Makah Indian Tribe (Makah); the Washington Department of Fish and Wildlife (WDFW); the Oregon Department of Fish and Wildlife (ODFW); three fishing industry associations (Hawaii Longline Association (HLA), Maine Lobstermen's Association (MLA), and United Southeast Alaska Gillnetters (USAG)), and a coalition comment letter from two non-governmental organizations (Center for Biological Diversity and Whale and Dolphin Conservation, hereafter referred to as ''CBD and WDC''). Responses to substantive comments are below. Responses to comments not related to the SARs are not included. Comments suggesting editorial or minor clarifying changes were incorporated in the reports, but they are not included in the summary of comments and responses. In some cases, NMFS' responses state that comments would be considered or incorporated in future revisions of the SARs rather than being incorporated into the final 2021 SARs.

Comments on National Issues

Requirements of Section 117

[Comment 1]: The Commission continues to be concerned about NMFS' performance in meeting several of the requirements of section 117 of the MMPA. Including the SARs revised in 2021, an Nmin estimate is lacking for 77 of the 252, or 31 percent, of identified stocks. The primary hindrance to full assessment of all stocks continues to be an ongoing lack of resources, including lack of access to vessel and aerial platforms from which population surveys are conducted. The Commission encourages NMFS' continued engagement and collaboration with other federal agencies that require basic information on marine mammal stocks, and the Commission reiterates its recommendation that these marine assessment programs continue to include appropriate personnel, logistical capability, and vessel time to allow for photo-identification, biopsy sampling, satellite tagging, acoustic monitoring and other efforts to increase the value of the core line-transect survey data collected.

Response: NMFS acknowledges the Commission's comment and will continue to prioritize our efforts for the collection of data to address outdated Nmin estimates, as resources allow.

[Comment 2]: The Commission comments that regarding trend analyses, guidance is needed on how population trend analyses should be performed, and how key uncertainties should be addressed. To address the reporting inconsistencies and lack of analyses, the Commission recommends that NMFS convene a workshop to develop guidelines for data requirements and best practices for population trend analyses pursuant to section 117 of the MMPA. The Commission recommends that invited participants include scientists from the NMFS Science Centers, SRG members, and non-NMFS statisticians who might provide guidance and different perspectives.

Response: NMFS agrees that long-term time series trend analyses are useful, while also acknowledging that it is difficult to achieve the appropriate precision and accuracy needed to detect trends (Authier *et al.* 2020). NMFS will work to improve consistency across regions and provide best practices for trend analyses in the SARs. We plan to address this topic in a future GAMMS revision. In the short term, we appreciate the Commission's offer to help with a workshop and will consider the possibility of convening one, as resources allow.

[Comment 3]: NMFS' process for distinguishing serious from non-serious injury requires reporting information on human-caused events that result in injury to the animal. This includes detailed documentation of strikes of marine mammals by vessels. These data are listed in technical memoranda, which typically include summaries of human-caused mortalities and injuries. Data is stored within different NMFS programs, offices, and databases, such that there is no single source to query for all vessel strike data. This impedes the compilation of accurate data summaries and makes cross-regional comparisons of data challenging. Given that these data are being summarized separately by each region for reporting under the NMFS injury determination process, the Commission recommends that NMFS develop a system for centralizing all data on vessel strikes of marine mammals into a single, queryable source. This resource would have regional, national, and global value in understanding and mitigating risk of vessel strikes.

Response: NMFS agrees with the value of a centralized database for vessel strikes. We are working to create this and will keep the Commission updated on our progress.

[Comment 4]: The Commission is concerned about the references made to publications that are ''in review'' to support information in 12 of the draft SARs, particularly when addressing annual human-caused serious injury and mortality. Labeling a report as ''in review'' suggests that the underlying analysis has been completed and submitted for publication, but analyses could change prior to publication. Therefore, the Commission recommends that NMFS carefully consider whether it should base draft revisions to the SARs being considered for public comment on analyses that are still ''in review.'' At a minimum, NMFS should make every attempt to make the underlying reports/publications available to the public during the comment period.

Response: Because SARs are considered to be influential scientific assessments, all scientific information used in support of the SARs should meet the peer review requirements described in the Office of Management and Budget (OMB) Bulletin on peer review and NOAA Information Quality Act guidelines to ensure the information is not only high quality but is available for management decisions in a timely fashion. The best scientific information available for any given time period covered in a SAR may not necessarily have been published or subjected to professional peer review prior to inclusion in a draft SAR, as this process can take months or years to complete. In other cases, data such as annual human-caused serious injury and mortality pertinent to assessments of stocks are routinely collected and analyzed, and while not always suitable for journal publication, we publish them as technical memoranda, annual reports, or memos to the record. These data, and methods are annually reviewed by the SRG, and NMFS considers this review to constitute peer review and to meet the requirements of the OMB Peer Review Bulletin and NOAA IQA guidelines.

Comments on Alaska Issues

Alaska Native Subsistence Takes

[Comment 5]: The Commission has repeatedly recommended that NMFS, in collaboration with its co-management partners, improve its monitoring and reporting of subsistence hunting in Alaska. The Commission notes that take levels are lacking for the majority of communities that hunt or may hunt ice seals and harbor seals and continues to recommend that NMFS find ways to gather reliable information on the numbers of marine mammals taken for subsistence and handicraft purposes through partnerships with existing and emerging co-management partners and the state of Alaska. Further, the Commission encourages NMFS to continue to provide updated information in the SARs whenever it becomes available, even if it pertains only to a few villages or a subset of years.

Response: NMFS agrees that it is important to collect reliable information on the numbers of marine mammals taken for subsistence and handicraft purposes. Funding for subsistence use surveys remains limited. In most cases, the best available data are not comprehensive. Nevertheless, we continue to work with our Alaska Native co-management partners (and the State of Alaska in some cases) to conduct surveys of subsistence use as resources allow, including animals struck and lost, and we incorporate that information into the SARs as it becomes available. In particular, we have encouraged the Alaska Department of Fish & Game to explore the feasibility of obtaining harvest information and biological samples of subsistence-harvested seals in communities where such data collection has not recently occurred. The Alaska Department of Fish & Game is pursuing this.

Eastern Bering Sea (EBS) Beluga Whales

[Comment 6]: The Commission understands that the final 2020 SAR for the Eastern Bering Sea (EBS) stock of beluga whales was withdrawn to allow for Tribal consultation. That SAR was not included in the draft reports for 2021. We await further word from NMFS on whether that SAR will be included in the final 2021 SARs for Alaska.

Response: The EBS beluga whale SAR was not revised in 2021. After ongoing consultations with NMFS co-management partner, the Alaska Beluga Whale Committee (ABWC), NMFS has withdrawn the final 2020 EBS beluga whale SAR and anticipates releasing a revised draft SAR for the 2022 or 2023 SAR cycle. This has been noted on the NMFS SAR web page (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-species-stock#cetaceans--small-whales*). Additionally, NMFS temporarily withdrew the final 2020 Beaufort Sea, Chukchi Sea, and Bristol Bay beluga whale SARs to review potential implications of the ABWC recommendations on the Eastern Bering Sea beluga whale SAR but republished them with an explanatory note indicating that any changes resulting from such a review will be reflected in a future SAR. As is our practice, we will include the most recently revised version of each Alaska SAR in the compiled final Alaska SARs. The most recent EBS beluga whale SAR is the final 2017 SAR.

NMFS is providing this information for awareness only and is not seeking public comment on the NMFS–ABWC co-management agreement nor the final 2020 EBS beluga whale SAR.

Southeast Alaska Harbor Porpoise

[Comment 7]: USAG is concerned that the areas of highest densities of harbor porpoises have not been surveyed and suggests that a more thorough survey would involve track lines that followed the edges of the straits, in shallower water, and include larger bays and inlets. Since the stock boundaries for SEAK extend from west of Yakutat to Dixon Entrance, USAG wonders why the outside waters were not surveyed in 2019. This would indicate that the population estimate could be biased low. USAG comments that population survey would be best for the region if it included the coastal waters that were not included in 2019.

Response: In the 2019 survey, NMFS developed a protocol to sample the study area more thoroughly than ever before and to account for biases not previously considered in previous analyses. This protocol focused on: Sampling the habitats in the main channels of SEAK where harbor porpoise has been historically documented, including shallower (close to shore) and deeper (middle of the channel) waters. Because sampling in these areas was proportional to the area of each habitat, estimates of density within these habitats are expected to be unbiased.

Approximately 40% of the area of inlets and small bays were sampled in response to previous criticism that NMFS' SEAK surveys did not cover these habitats. The results showed that only a small fraction (approximately 5–10%) of the population occurs in these areas in the summer.

Applying a correction factor to account for animals missed (''g(0) correction'') developed with data from previous surveys in SEAK inland waters.

The fact that the 2019 survey had nearly 200 sightings of harbor porpoise suggests that the design implemented during the cruise did sample the species habitat within inland waters.

The SAR acknowledges that the estimate of abundance from inland waters is an underestimate for the whole stock because the outer coast between Cape Suckling and Dixon Entrance has not been sampled. The survey was limited to inside waters due to logistical and funding constraints. Sampling the outer coast is needed to develop a stock-wide estimate. Additional sampling for stock structure (*e.g.,* environmental DNA (eDNA)) is also needed to assess the relationship of animals in the outer coast with those within inland waters.

[Comment 8]: USAG points out that the SARs include evidence of sub-populations of harbor porpoises. This is based on eDNA samples, with a notable difference between northern and southern parts of the region. Since the SEAK stock includes a large area, eDNA should be procured from all areas to further define sub-populations. There should also be eDNA collected in the Gulf of Alaska stock for comparison with the unique stocks in SEAK that may have been identified. USAG would question whether the samples were collected in a fashion that could have eliminated the possibility of familial relationships.

Response: The evidence supporting population differentiation among regions throughout coastal Alaska waters and within the currently recognized SEAK stock is based on genetic data generated from both eDNA samples and tissue samples collected from fisheries bycatch and beachcast strandings. Nuclear genetic data suggest a degree of genetic relatedness among harbor porpoises sampled within a region that is greater than we would expect by chance, suggesting genetic structure and likely natal philopatry. Mitochondrial genetic data, generated from both tissue and eDNA samples, indicate significant genetic differences between Gulf of Alaska and SEAK, as well as within SEAK. The majority of the samples represent nearshore coastal waters; however, some coastal regions are poorly represented, or unrepresented (*e.g.,* between Copper River and Yakutat).

Environmental DNA samples were collected as surface seawater in the

fluke prints of submerging harbor porpoises from small boats in SEAK inshore waters. At this time, determining familial relationships is not feasible with eDNA samples. As a result, a conservative approach was adopted, counting each ''discovered'' unique genetic sequence from each eDNA sample only once. This strategy avoids over-representing mitochondrial haplotypes based on sequencing read depth but may underestimate genetic differentiation metrics if multiple related porpoises comprising the same mitochondrial haplotype co-occur, as multiple related porpoises represented by genetic material in a single eDNA sample will only be counted as a singleton. The Gulf of Alaska stock is well represented by tissue samples throughout nearshore waters (*e.g.,* Cook Inlet and Copper River); however, coastal regions between SEAK and the Gulf of Alaska are unsampled and collecting samples from these regions will be very valuable for identifying key regions delimiting harbor porpoise stocks within SEAK and beyond.

[Comment 9]: USAG comments that the SAR notes that entanglement in fishing gear is the only known human cause of mortality, but there are other industrial fisheries being prosecuted in the region. To make the assumption that only one gear type interacts with a species that exists in the same habitat seems arbitrary. Charter boats, sport fishing, yachters, cruise ships, both large and small, and other water related outdoor excursions, have all increased substantially, and the USAG notes that ship strikes are a cause of mortality.

Response: NMFS agrees that harbor porpoise are difficult to see in the wild. We take the characteristics of the species into consideration when we design and execute our surveys. For example, we search for porpoise using binoculars, which allows for early detection. We only search in good visibility and oceanographic conditions. Before analysis, we inspect the data to assess whether there is evidence that animals are reacting to the boat. We only analyze data collected in relatively good observation conditions (*e.g.,* Beaufort sea state 3 or less). The elusive nature of harbor porpoises often results in animals or groups of animals being missed by observers. We therefore estimate the proportion of porpoise missed and add that to the estimates of density and abundance to minimize or eliminate any negative bias in the estimates.

The estimates of population size indicate abundance is stable in the northern portion of SEAK inland waters (*e.g.,* around Cross Sound, Icy Strait, and Glacier Bay), but there is evidence of declines in the southern range of the species more towards the south, around Wrangell and Zarembo Island.

Other types of fisheries can result in M/SI; but, as noted in the comment, they have not been documented in SEAK. In other parts of the world, harbor porpoises are known to be extremely vulnerable to gillnets, and there is no reason to believe the situation is different in SEAK. This is one of the reasons the concern with this type of gillnet fishery is greater.

[Comment 10]: USAG emphasizes that the SEAK gillnet fishery has been fishing the same statistical waters since statehood, and those areas are a relatively small portion of the region. Portions of the areas SEAK gillnetters are permitted to fish are often closed to gillnetting for salmon management concerns, and other portions of those areas are not fished due to lack of productivity. Since 1975, with the inception of Limited Entry, USAG effort has been static. Given the lifespan of a harbor porpoise, USAG feels that it is safe to assume that any impact the gillnet fleet has had on the stock has likely happened. USAG notes there are no population estimates pre-statehood, so it would be impossible to determine just what impact commercial fishing has had on these animals since its inception.

Response: It is still unclear whether the population is stable in part of the range (near Wrangell and Zarembo Island). NMFS agrees that there is uncertainty with respect to the potential impact of fisheries to harbor porpoise and believes that additional data are needed to address this question.

[Comment 11]: In 2012 and 2013, the SEAK gillnet salmon fishery was observed in districts 6, 7, and 8. In 2012, there were 0 observed interactions with harbor porpoise. There were 2006.5 boat days for that particular season. In 2013, there were four observed interactions with harbor porpoises, two released alive, and two released, judged by the observer as significantly injured, likely resulting in a mortality. There were 2,708.6 boat days in 2013. This makes 2013 an anomaly in that USAG had several multi-day openings and more boats than normal fishing in the districts observed. USAG thinks this inflates the mortality associated with the gillnet fishery artificially.

Response: NMFS takes fishing effort into account when calculating a bycatch rate and estimating M/SI. This minimizes bias in the estimates given potential differences in effort across years (*e.g.,* between 2012 and 2013, as suggested in the comment). NMFS agrees that rare events, when observed, inflate the mortality estimate. However, the capture of four porpoise in a single year (2013) suggests that bycatch events, while rare, may be occurring at a frequency large enough to impact the population, particularly in areas where harbor porpoise occur in relatively large numbers such as around the Alaska Department of Fish & Game fishing districts 6, 7, and 8 in SEAK.

Comments on Atlantic Issues

[Comment 12]: Department of Fisheries and Oceans Canada (DFO) believes the reference number provided for electronic submission of comments on the draft SARs (NOAA–NMFS–2021–0130) is incorrect as it leads to the wrong docket.

Response: Thank you. Because of a technical error, we extended the public comment period two weeks and published a correction notice in the FR with the correct link for the appropriate docket.

Gray Seal

[Comment 13]: The Commission remains concerned that numerous known serious injuries of gray seals are not being accounted for in estimates of total M/SI. The 2021 draft SAR reports a PBR level of 1,458. Total reported annual M/SI in U.S. waters is 1,179 (1,169 of which were deaths caused by U.S. commercial fisheries). The Commission recommends that NMFS use the best available science when calculating the total estimated annual M/SI to account for these entanglements. Further, the Commission encourages NMFS to work diligently to address this welfare issue and greatly reduce gray seal injuries and deaths in U.S. fisheries.

Response: NMFS recognizes that estimates of gray seal bycatch mainly reflect mortalities because observers rarely document live animals. Therefore, data derived from observer coverage do not reflect the numerous animals that are seen living with entanglements and that may eventually die as a result. Currently, there is not a system in place to document seals that are living with entanglements in the NMFS National Stranding database (live entangled cetaceans are recorded, but not pinnipeds). This policy decision was made primarily due to the inability to distinguish between individuals, resulting in uncertainty over whether an observed entangled animal was a unique case, or one seal observed multiple times over many years. NMFS is working to address this issue, including developing a customized database for tracking entanglements rather than the

National Stranding database. We are also preliminarily planning to conduct entanglement surveys, as resources allow. The goal is to quantify the number of entangled animals at various haul-outs in a given day so that, at a minimum, we may add these to the bycatch estimates.

North Atlantic Right Whale

[Comment 14]: DFO comments that right whale #3893 was assigned as a Canadian mortality and was observed in U.S. waters on January 22, 2018, before being found dead on January 28, 2018. Prior to this, it was seen gear free in Canadian waters on July 29, 2017. No pictures or information about the gear analysis have been provided to assist in the Canadian analysis. DFO emphasizes this whale should be XU.

Right whale #3694 was ''unidentified'' prior to the 2020 SAR. Upon inquiry to NOAA, DFO received the following response: ''Gear from #3694 was identified as Canadian snow crab by the NMFS Greater Atlantic Regional Fisheries Office, and this result was announced through an email to the Atlantic Large Whale Take Reduction Team in April 2018.'' No information on this was provided to Canadian officials for review.

Response: The U.S. gear team reports that the recovered gear from right whale #3893 and #3694 are inconsistent with legal U.S. gear and are consistent with offshore Canadian trap/pot gear. Without new incident documentation or bilateral analysis, under longstanding NMFS protocols, NMFS would not change the current attribution. NMFS believes bilateral gear investigation of gear retrieved from entangled large whales in U.S. and Canadian waters would be invaluable to improve our understanding of at least that subset of entanglements that are observed and documented. NMFS will continue to pursue collaborative bilateral efforts on gear analysis and other fronts, toward improving science and management to help the U.S. and Canada develop additional solutions to reduce the impacts of our fisheries on endangered right whales.

[Comment 15]: For Right whale #4094, the gear was identified as Canadian crab pot in Daoust *et al.* Upon review of this report, no information was included to support this finding. Additionally, the DFO Marine Mammal Response archives have the following, ''A live entangled North Atlantic right whale (NARW) was reported on July 19th, 2017 by NOAA Fisheries in the Gulf of St. Lawrence. No response was performed as no action was permitted. No subsequent sightings were completed after this date.'' It is unclear how a determination was made if no response was performed. DFO believes this whale should be XC and NR.

DFO would like to suggest that the ''points'' for the serious injury associated with right whale #4057 be equally split (.5/.5) between Canada and the U.S. On August 13, 2016, #4057 was disentangled by the Campobello Whale Rescue Team. In their report they noted that the entanglement responded to impacted and exasperated old wounds from 2014. On February 16, 2014, #4057 was found near Florida dragging over 100 yards (91.44 meters) of heavy 9⁄16″ diameter fishing rope. Responders from the Florida Fish and Wildlife Conservation Commission disentangled the whale the following day.

The gear for Right whale #3125 is attributed to Canada. DFO requests that the U.S. provide information on how the conclusive origin of the gear was determined in this case. If no review of the gear has been conducted, DFO concludes this whale should be XC.

Right whale #1226 is currently assigned ''CN.'' DFO comments that this whale should be XC. The whale was sighted anchored alive in Canadian waters, and the carcass was later found without gear present.

Response: NMFS notes that #4094's gear attribution was based on identification of gear in the Daoust *et al.* report, which was co-authored by DFO staff. We would consider changing it to XC if the published incident report that identified the gear as Canadian snow crab is revised.

#4057—The two events are evaluated separately in keeping with longstanding NMFS protocols. The 2014 incident was deemed not serious, assigned a 0 against PBR, and does not impact the current SARs because the time frame for the data is 2015–2019. The 2016 incident was deemed serious based on severe health decline despite disentanglement. U.S. gear experts report that Parks Canada confirmed the recovered gear to be Canadian snow crab.

#3125—The U.S. gear team reports that the recovered gear from this event is inconsistent with legal U.S. gear and is consistent with Canadian snow crab gear. Without new incident documentation or bilateral analysis, under longstanding NMFS protocols, we would not change the current attribution.

#1226—This whale was seen without gear in the Gulf of St Lawrence (GoSL) from June 9–July 21, 2019. The entanglement was observed in GoSL on August 6, 2019, when the whale was anchored alive. In keeping with longstanding NMFS protocols, anchoring in place is considered evidence of incident location so this incident was assigned as a Canadian injury. Though no gear was present on the carcass on September 16, 2019, the documented fatal injuries on the carcass line up with the entanglement configuration documented on August 6, 2019. Injury was attributed to the August 6, 2019 entanglement.

[Comment 16]: MLA states that the Draft SAR fails to disclose key limits of the Pace model. The Pace model remains sensitive to new data, and its output is highly variable. Further, the period from 2011–2015, during which time NARW shifted their geographic distribution to areas lacking survey effort, may be producing an underestimate of the population.

MLA notes that the Draft SAR underweight the existence of natural predation as demonstrated by Taylor (2013), Curtis (2014), and Sharp (2019). MLA comments the SAR must cite relevant literature on natural mortality and discuss how the treatment of this significant factor affects population models. This estimate of total annual human-caused mortality may be somewhat positively biased (*i.e.,* a slight overestimate) given that some calf mortality is likely not human-caused.'' Although the Draft SAR acknowledges this is likely a ''slight overestimate,'' its conclusion that all mortality is human-caused is not supported by Taylor (2013), Curtis (2014), and Sharp (2019). With natural causes constituting a total of 14.5 percent of all examined individuals and 25 percent of those incidents where cause was confirmed, this is more than a ''slight overestimate,'' and the best available scientific information does not support attributing all calf and adult mortalities of unknown cause to human activity. MLA comments that the assumption that natural mortality is limited to newborn calves is without empirical justification and results in an overestimation of anthropogenic mortality.

Finally, Pace (2021) incorrectly assumes an equal sex ratio and probability of mortality. Neither of these assumptions are supported by the best available data. Hamilton (2020) reports that through 2017, 94 percent of males have been entangled at least once compared to 87 percent of females. Males are known to make up a larger portion of the population and statistically more likely to encounter and become entangled in a vertical line. This, too, must be corrected or, at a minimum, disclosed to the public.

Response: The Pace *et al.* 2017 and slightly updated Pace 2021 Mark-

Recapture-Resight MRR model has been reviewed and re-reviewed by both journal peer review process for publication as well as more than 6 years of Atlantic SRG meetings with rotating membership, meaning an additional 20 experts have reviewed the model and its contents are publicly available to review as the documents are cited within the SAR.

The MRR model published by Pace *et al.* 2017 uses standard well-verified methods of using sighting histories of individuals to estimate interval (in this case annual) capture probabilities which are allowed to vary at each interval. Indeed the estimated capture probabilities since 2011 of NARWs have shown considerable variation compared with the previous decade. The statistical methodology employed simultaneously estimates survival and capture rates to estimate the number of whales still alive thereby accommodating variable annual capture rates. Beyond that the MRR model used, unlike some of its predecessors, allows for individual animals to have unique catchability parameters thus reducing biases in capture rate found in simpler MRR models. Although there is no accommodation for permanent emigration, so far there has been no evidence that even modest numbers of NARW have permanently left all of the areas surveyed. Hence, the conservation conclusion is that the estimated survival rates presented in the SAR and reflected in the abundance estimates represent actual survival rates of the stock and not merely apparent survival rates.

On the issue of natural mortality, NMFS and the SAR acknowledge that some natural mortality of calves exists. However, there are no observations of adult mortality from natural causes. NMFS reviewed relevant data, existing models and the literature with the Atlantic SRG on Sept 2, 2021 and requested guidance. The Atlantic SRG recommended NMFS continue to assign 100 percent of the mortalities of non-calf NARW to anthropogenic origins (Atlantic SRG letter to NMFS September 16, 2021).

[Comment 17]: The Draft 2021 SAR includes new text speculating that the probability of carcass recovery is higher for vessel strike events than entanglement events. MLA comments that there is presently no evidence to support such a finding, and the literature cited in the Draft SAR are not the results of empirical studies to inform this issue. MLA thinks it is equally, if not more likely, that the observed data with respect to carcass status as discussed in Pace (2021) are correct—that entanglements and vessel strikes kill whales in roughly equal proportions. MLA requests that NMFS remove this entire section until empirical data are available to inform the probability of carcass recovery for different modes of death.

Response: NMFS agrees that there is no empirical study showing that the bodies of whales dying from vessel strikes are more likely to be detected than the bodies of whales dying from entanglement. However, it is the intention of this stock assessment report to provide information on our current understanding of the right whale population, including trends in strandings data, and we will therefore continue to include this empirical information relevant to the probability of carcass recovery. We believe that including hypotheses that may explain the disparity between the proportion of detected entanglement and vessel strike serious injuries compared to the proportions by cause diagnosed for dead whales is relevant and informative. The Moore *et al.* (2020) hypothesis is founded in the physics of buoyancy on marine mammal bodies under different conditions. However, we agree that there is not currently sufficient basis to conclude that the proportion of observed serious injuries that were the result of entanglement reflect the correct apportionment of total mortalities. We also agree that there may be factors that increase the likelihood of detection of entanglement serious injuries. We do not believe there is currently sufficient basis to assert that right whales struck by vessels are more likely to sink.

NMFS proposed many alternative scenarios to the Atlantic SRG (ASRG) on how best to apportion cryptic mortality (NMFS intersessional September 21, 2021). The ASRG recommended that the ratio between entangled and vessel struck NARW, calculated from documented observations of Serious Injuries and Mortalities over the last five years, be used to apportion cause. NMFS scientists will continue to work on improving our methods for apportioning these sources of mortality, and the ASRG will continue to consider better alternatives as they are developed.

[Comment 18]: MLA is concerned that the Draft SAR only reports total observed M/SI data without apportioning those observations between the U.S. and Canada. The Draft SAR does not present the annual mortality and serious injury estimates by each ''fishery.'' MLA believes it is arbitrary for NMFS to ignore these data demonstrating that many more M/SI are occurring in Canadian fisheries than U.S. fisheries. MLA reiterates that NMFS should not rely on limited data to conclude that all cryptic mortality results from anthropogenic sources and that vessel strike carcass recovery is more likely than for entanglements.

Response: NMFS seeks to provide the maximum precision and resolution in apportioning all M/SI to cause—whether fishery, vessel or other. However, there continues to be a distinct lack of information available to the agency to assign entanglement to fisheries based upon recovered gear. We believe expansion of gear marking and reporting requirements will assist us in this area moving forward. In addition, because right whales are able to travel thousands of miles in short periods of time, even when trailing gear, it is very difficult to attribute entanglement based upon the region of initial sighting.

NMFS has invested considerable effort developing better methods for apportioning M/SI to appropriate sources in light of increased mortality overall, including increasing observations in Canada. We are also working to improve our ability to quantify unseen mortality with consideration of if and how to apportion natural versus anthropogenic mortality. As part of this effort, the agency convened a special session of the Atlantic SRG in September 2021 for scientific and technical input. The Atlantic SRG supported its prior position that 100 percent of the mortalities of noncalf NARW should be considered to be of anthropogenic origin. The Atlantic SRG also considered the various approaches provided by NMFS for apportioning SIM between U.S. and Canada but did not have enough information to provide a robust scientific alternative. They suggested alternatively, a fully fleshed out co-occurrence model for both U.S. and Canadian waters could be used, but this is also not presently available. Given this data limitation, it would be arbitrary for NMFS to assign proportions without better data to support conclusions.

[Comment 19]: MLA notes that the NARW Draft SAR contains none of the statutorily required-information from Section 117 of the MMPA regarding entanglements in fishing gear. As a result, the public has no information about the fisheries that interact with the NARW and the levels, types, and seasonal and geographic patterns of entanglement that occur within and among those fisheries. MLA notes that the Draft SAR presents only M/SI entanglement data—non-serious injury entanglements are omitted. MLA requests that the SAR also include data on the severity of entanglements. MLA

requests a more detailed table included in the SAR, since this information is important for assessing individual fisheries.

The Draft SAR cites three studies concluding that NARW mitigation measures implemented prior to 2009 have not worked and that the effectiveness of measures implemented since 2009 have not yet been evaluated. MLA comments that the SAR should report data showing that there has been a 90 percent decline in instances of lobster gear removed from entangled NARW since 2010 based on observed data. There were four known cases of lobster gear removed from NARW from 1997 to 2000, six from 2000 to 2010, and one from 2010 to 2019. The only confirmed M/SI resulting from entanglement in lobster gear occurred in 2002. MLA requests that NMFS present information about the fact that the scarring data suggests most entanglements are minor.

Response: The fisheries are summarized in Appendix 3—Fishery Descriptions. NMFS cites our annual M/SI report for reported injuries during the time frame encompassed by the SAR. However, because only a small fraction of entanglements have gear recovered and a smaller fraction of those are traceable to the fishery, the agency has not been able to estimate the annual M/SI to the resolution of fishery/region. Given recommendations from the Atlantic SRG and additional analysis resulting from Pace *et al.* (2021), the agency is working to improve our understanding of this issue to the resolution requested above in future SARs. For now, this topic is addressed to the extent that data can support in table three of the SAR.

The issue of non-serious injuries is discussed in the third paragraph of the section titled ''Fishery-Related Mortality and Serious Injury.'' The draft cites Knowlton *et al.* (2012), which reported 26 percent of the population being entangled each year and now includes Hamilton *et al.* (2019), which reports 30 percent of the population receiving non-serious injuries annually. This is an increasing trend. Despite roughly 100 injuries per year in recent years, they are almost never observed, but the wounds persist for periods of weeks to months/years during which time animals may travel thousands of miles. Therefore, the agency takes a conservative approach to not apportion injury by fishery or area where data are not available. Additional language to address this concern has been added to the first paragraph of the ''Fishery-Related Mortality and Serious Injury'' section of the SAR.

Regarding the ''decline'' in lobster gear removed from NARW, the SAR does not address this because it is not a metric supported by a rigorous sampling design with high probability of detection. Rather, it is anecdotal in nature with detection rates subject to numerous biases described above. The comment raises the similar ''observed decline'' in entanglements observed to be connected with groundline. However, despite some reason for optimism with both these observations, they are anecdotal in nature, and also in juxtaposition with the dramatic increase in mortality that has subsequently occurred. The SAR acknowledges these are from multiple sources across multiple regions. Because of this, the SAR focuses on the more appropriate metrics of total M/SI and cryptic mortality. In response that most injuries are ''minor''—it should be noted that NMFS uses similar but slightly different criteria for the assignment of injury severity than New England Aquarium. The SAR does report the number of injuries which meet the criteria for ''serious'' under the NMFS criteria, and there has been an increase in serious injuries including entanglement for the past decade. The SAR addresses these ''non-serious'' injuries in the previous section, acknowledging that collectively they ''should be considered to fully understand anthropogenic impacts to the population, especially in cases where females' fecundity may be affected.''

[Comment 20]: MLA believes the SAR should include additional available scientific information about NARW behavior that affects its risk of harm from fishing gear. Recent scientific literature confirms that NARW have shifted their habitat usage away from the Maine lobster fishery. These findings were most recently summarized and reported in Meyer-Gutbrod (2021), which MLA expresses must be referenced and discussed in the Draft SAR.

Response: NMFS appreciates this comment and agrees with the distribution changes and observations characterized above. The Meyer-Gutbrod reference and some additional language have been added to the habitat section. However, NMFS believes there is a flawed assumption that right whales are only subject to mortality when they are densely aggregated in foraging areas, and those areas are the only regions that should be managed for right whale conservation. In reality, portions of the NARW population are only aggregated in a few small regions during some parts of the year, and we are recognizing that our management measures need to be spatially resilient to reflect the documented acoustic presence of right whales across their entire range through much of the year, including the Gulf of Maine. Furthermore, given the high degree of surveillance in the areas of high aggregation and the comparative lack of surveillance in many other regions (aside from acoustics, which only detect vocalizing whales, and cannot detect mortality/injury), the agency is increasingly concerned that much of the unseen mortality is likely to be happening in areas where there is a high degree of risk from either fishing or vessel activity for solitary whales transiting through those regions. We have added additional language to reflect this in the habitat section.

[Comment 21]: MLA is concerned that the 2021 draft SAR omits important details describing NARW stock definition and geographic range. MLA believes the multiple references to right whale feeding grounds located in New England waters must specify that these important areas are located in southern New England. MLA thinks the Draft SAR incompletely cites the available data on mortality in Canadian waters and calving. MLA recommends the Draft SAR add a reference to Hamilton (2022), which provides important ''insight into right whale calf survival, growth rates, and association patterns.'' MLA comments that the section summarizing M/SI from vessel strikes has the heading ''Other Mortality'' and also reiterates that the text and reference to Frazier (2005) be removed.

Response: The description of NARW feeding grounds reflects our current understanding and best available scientific information. Acoustic and visual monitoring in the central Gulf of Maine indicates right whales are present in areas besides southern New England.

All mortalities are accounted for in Table 3. The spike of right whale mortalities in 2017 noted in the text is including all carcasses found that year in both U.S. and Canadian waters. The 2019 calf detection is included in the SAR text. The years 2020–2021 fall outside the reporting period for the 2021 SARs and are therefore not included in this report. The 2022 Hamilton paper was not available during the 2021 stock assessment report timeframe, but the findings will be incorporated into the 2022 report.

The ''Other Mortality'' heading has been a standard heading for stock assessment reports for all species. This suggestion will be forwarded to the editorial board for consideration. As the section opens with the sentence, ''Vessel strikes are a major cause of mortality and injury to right whale'' and

discusses no other sources of mortality, NMFS has been diligent in informing the public of this threat to right whales.

NMFS appreciates the MLA catching this transcription error. Although NMFS believes that Fitzgerald (2018) best represents the current understanding of pedigree-informed abundance estimation, as noted in previous responses, Frasier (2005) has not been conclusively refuted. NMFS has restored Frasier (2005), and added Frasier et al. (2007), to the text and references of the final 2021 SAR.

NMFS believes the description of right whale distribution and movement in the SAR is as comprehensive and accurate as the data and available analyses currently allow.

[Comment 22]: MLA reiterates that Kenney (2018) should not be cited in the SAR. Specifically, the methods used in this study fail to account for basic biological processes—namely, natural death. Further, calves have natural mortality rates that are ignored during scenarios when they are included in this model. Additionally, Kenney (2018) assumes a constant calving rate of one calf per 5 years (0.2/yr), which is a vast oversimplification of the life history process of NARW, and the Kenney (2018) value of the calving rate is far higher than the ''best'' current estimate of 0.04 in the Draft SAR. For these reasons, Kenney (2018) should not be cited in the SAR. If NMFS is going to continue to include citations of this study, then it must address these scientific points.

Response: The Kenney (2018) reference is a relevant, peer-reviewed study that helps provide context to the impacts of fishery-related mortality on the right whale population. The study does account for other mortality, removing only confirmed fishery-related deaths and serious injuries (likely to lead to death). Several scenarios are provided with varying levels of hypothetically-reduced entanglement mortality rates corresponding to degrees of compliance to MMPA regulations. While the paper presents a simple representation of complex processes, the model parameters are reasonable and the results are informative for the reader to appreciate the cumulative impact of entanglement on the population. Any element of natural mortality or other processes affecting the population other than documented entanglement mortality are accounted for by using the time series of abundance estimates as a baseline.

Inclusion of the unrealized calves in the paper is an acknowledgment of basic population biology, and the outsized effect of removing productive females on a population's trajectory cannot be ignored. Kenny (2018) treats this effect conservatively. Proven female calving intervals have varied between 3 and 10 years, but are primarily in the 3- to 7-year range, so the choice of a 5-year calving interval is well founded. The paper's total of 26 calves lost due to the deaths of 15 females over 27 years equals an unrealised population increase of much less than 0.01/yr (1 divided by the average annual population size), and this undoubtedly underrepresents the actual value given that only known females documented as mortalities or serious injuries were used in the analysis.

[Comment 23]: CBD and WDC take issue with the statement which currently reads ''In addition, right whales apparently abandoned the central Gulf of Maine in winter (see Cole *et al.* 2013) . . . .'' CBD and WDC do not believe it is accurate to indicate that right whales have abandoned the central Gulf of Maine during winter months. In fact, acoustic detections in the central Gulf of Maine have been documented during the winter for the past several years. In addition, CBD and WDC recommend the section regarding high resolution genetic profiling as it relates to parentage and relatedness be updated using Hamilton *et al.* 2022.

Response: NMFS agrees that new, widespread acoustic monitoring has changed our assessment of right whale presence and will adjust the text to reflect this fact. We will evaluate Hamilton *et al.* 2022 in the subsequent SAR cycle since its publication occurred during the finalization of the 2021 SARs.

[Comment 24]: CBD and WDC ask NMFS to include the findings in the recently published NARW (*Eubalaena glacialis*) Vessel Speed Rule Assessment which concluded that voluntary measures did not have a meaningful impact, small vessel collisions can seriously injure right whales, and the current SMAs should be modified.

Response: In general, NMFS limits the content of the SARs to the statutory requirements of section 117. The SAR is not intended to evaluate or discuss the merits of specific management activities. The SAR acknowledges that vessel strikes remain a serious issue for right whales; and, for transparency, the vessel size class involved in lethal strike events is always noted, if known. In addition, the NARW (*Eubalaena glacialis*) Vessel Speed Rule Assessment is posted on the NMFS website and easily accessible to the public.

Bryde's Whale, Gulf of Mexico Stock (Rice's Whale)

[Comment 25]: While CBD and WDC appreciate the extensive updates to the 2020 Gulf of Mexico Bryde's whale SAR, this species was not updated in the recent 2021 draft. CBD and WDC remind NMFS that, as an ESA-listed species, the SAR for these whales should be updated every year. CBD and WDC also reiterate introductory comments on the general timing of review and public comment for the SARs and the substantial delay in including new information, as it is now known that these whales have been designated a new species: Rice's whales. CBD and WDC request that this new designation be recognized and the 2021 SAR updated accordingly.

Response: The statutory requirement does not require the SAR to be updated every year, but to be reviewed annually. In regard to the updated designation, on August 23, 2021, NMFS published a direct final rule to update the taxonomic classification, description, and common name of species included in the list of endangered species maintained at 50 CFR 224.101 to reflect the updated science (86 FR 47022). The direct final rule changed the common name of the listed entity from Bryde's whale (Gulf of Mexico subspecies) to Rice's whale, the scientific name from *B. edeni* (unnamed subspecies) to *B. ricei,* and the description of the listed entity from Bryde's whales that breed and feed in the Gulf of Mexico to the entire species. The direct final rule and these changes became effective on October 22, 2021. This change became effective too late for an update to the draft 2021 SARs, but the draft 2022 SAR has been updated accordingly to reflect the revised taxonomy.

Comments on Pacific Issues

Hawaiian Monk Seal

[Comment 26]: CBD and WDC oppose NMFS categorizing fisheries interactions with Hawaiian monk seals as non-serious when the national guidelines would recommend the ''serious injury'' category. This is a problem especially because NMFS does not adequately consider the cumulative and chronic impacts of entanglements on Hawaiian monk seals. The draft SARs rely on Mercer 2021, which gives details on the two cases. Reclassifying these injuries from fishing gear as non-serious fails to account for the cumulative impacts of chronic entanglements. Entanglements make marine mammals more vulnerable to other sources of mortality, including disease. It is premature to deviate from the serious injury guidelines to

reclassify incidents as non-serious before NMFS adequately assesses cumulative and chronic entanglement impacts for Hawaiian monk seals.

Response: NMFS appreciates this comment and notes that determinations follow the NMFS' policy and procedural directive for distinguishing serious from non-serious injuries.

Hawaii False Killer Whale

[Comment 27]: HLA appreciates NMFS' acknowledgment that ''timely publication of results that inform SARs is important'' and hopes that similar delays will not occur in the future. HLA reiterates that the Draft 2021 SAR shows that the deep-set fishery's M/SI rate for the Hawaii Pelagic False Killer Whale (FKW) Stock (Pelagic Stock) is well below the stock's PBR. HLA believes the Pelagic Stock has never been ''strategic'' because the deep-set fishery's M/SI rate has never exceeded a PBR based on those abundances. HLA comments there is no legal basis to include the Pelagic Stock within the scope of the Take Reduction team (TRT).

In addition, NMFS did state in response to comments on the Draft 2020 SAR that NMFS cannot determine trend information for the Pelagic Stock based upon the three comprehensive surveys it has performed in the EEZ over a 15-year timeframe, along with multiple modeling exercises (performed over periods of years). HLA emphasizes that there are no data available supporting the notion that the stock has declined over time.

Response: NMFS uses the best available science at the time it is available to inform each SAR and support management actions. Subsequent years of data collection and analysis effort and refinement produce newer estimates of pelagic false killer whale abundance. These current estimates now represent the best available science. However, at the time the False Killer Whale Take Reduction Team (FKWTRT) was established in 2010, the pelagic stock of false killer whales was strategic and met the trigger for convening a take reduction team per MMPA section 118(f).

NMFS maintains that a temporal trend in the estimates of pelagic stock abundance cannot be determined because of the confounding effect of random variation in the encounter rate. As explained in Bradford *et al.* (2020), the model-based approach minimizes the effect of annual sampling variability but assumes that there are no underlying temporal trends in abundance aside from those predicted by habitat changes. While model-based methods can be used to estimate population trends, more data are needed to do so for pelagic false killer whales. Since a trend cannot be estimated, there is no basis to definitively state that the population is not declining. Anecdotal accounts cannot be used to infer population status. Metrics that can be quantitatively derived (*e.g.,* depredation rates) would need to control for other factors (*e.g.,* cultural transmission rates) for which there are currently no data.

[Comment 28]: HLA disagrees with NMFS' assignment of a recovery factor of 0.5 to the Pelagic Stock, which is the value typically assigned to depleted or threatened stocks, or stocks of unknown status, with a mortality estimate Coefficient of Variation of 0.3 or less. HLA comments that the Pelagic Stock is not depleted or threatened, its status is not unknown, and it has never qualified as a ''strategic stock.'' Accordingly, all of the available data contradict any hypothesis that the Pelagic Stock is decreasing or otherwise not at its optimum sustainable population. HLA believes NMFS' assignment of a recovery factor of 0.5 to the stock is therefore arbitrary and not consistent with the best available scientific information.

Response: The status of the pelagic false killer whale population relative to its optimum sustainable population size is unknown, and a temporal trend cannot be estimated as explained in the previous response. The Guidelines for Assessing Marine Mammal Stocks indicate that stocks of unknown status should use a recovery factor of 0.5 based on results of previous simulation studies (Wade 1998) designed to evaluate the ability of the PBR management scheme to achieve the conservation goals of the MMPA in the face of uncertainty. The guidelines further state that for stocks of unknown status, recovery factors of 1.0 should be reserved for cases where there is assurance that the minimum population estimate (N_{min}), the maximum net productivity rate (R_{max}), and the estimates of mortality and serious injury are unbiased and where the stock structure is unequivocal, which is not the case for pelagic false killer whales. NMFS notes that more recent simulation work supports these guidelines (Punt *et al.* 2020) and that the recovery factor is not linked to a specific abundance level or a stock designation of ''strategic'' or ''depleted.''

[Comment 29]: HLA comments that the population estimate for the Main Hawaiian Islands insular FKW stock inappropriately reflects the abundance of animals in only a portion of the Insular Stock's range. The 2021 Draft SAR estimates the Main Hawaiian Islands insular FKW stock (''Insular Stock'') abundance to be 167 animals, based upon Bradford *et al.* (2018), which found that the population size of the Insular Stock in certain study areas has consistently ranged between 144 and 187 animals over a 16-year period. Bradford *et al.* (2018) concludes that (1) the study on which the Insular Stock abundance estimate is based did not sample the entire range of the stock and (2) the population estimate underestimates the abundance to an unknown degree.

The MMPA requires the SAR to ''describe the geographic range of the affected stock'' and to provide minimum population estimate for ''such stock'' (not a ''portion of such stock''). 6 U.S.C. 1386(a). NMFS has made no attempt to estimate the abundance of the Insular Stock across its range or to apply ''appropriate correction factors'' to do so.

Response: Mark-recapture estimation does not require the full range of a population to be sampled. Thus, Bradford *et al.* (2018) indicated that the partial sample of main Hawaiian Island insular false killer whales would not be problematic if all distinctive individuals in the population used the sampled area at some point. This assumption could not be evaluated, so Bradford *et al.* (2018) indicated that the true abundance of distinctive individuals in each year may be underestimated. The text from Bradford *et al.* (2018) that was omitted from the second paragraph (*i.e.,* ''. . . it is likely that all individuals in the population have been exposed to sampling efforts at some point during the study period . . .'') is not speculation, but rather inference from movement analyses of satellite-tagged false killer whales (Baird *et al.* 2010, 2012). The number of satellite tag deployments on main Hawaiian Islands insular false killer whales has almost doubled since the Baird *et al.* (2012) study, and movement tracks from these individuals and fitted utilization distributions continue to reflect a lack of spatially-restricted use, such that individuals could be subject to sampling at some point during the sampling period. These utilization distributions are currently being used in an updated analysis of main Hawaiian Island insular false killer whale abundance that accounts for animal availability and the spatial bias in sampling.

[Comment 30]: HLA disagrees with NMFS' decision to apportion a small amount of ''take'' by the deep-set fishery to the Insular Stock despite the fact that there has never been a recorded interaction between the deep-set fishery and the (the ''Insular Stock'') and the

fact that the fishery operates almost exclusively outside the Insular Stock's range. HLA continues to disagree with this approach for the reasons it has previously stated and incorporates those previous comments by reference.

HLA also reiterates its position that this type of overly conservative decision, which has no support in the best available science, undermines the integrity of the TRT process and decreases the fishing industry's motivation for participation in that process. Finally, in its responses to comments on the Draft 2020 SAR, NMFS agreed that it ''can more explicitly state that no confirmed MHI insular false killer whales have been observed as taken in [the deep-set] fishery.'' 86 FR 38991 (July 23, 2021). HLA requests that NMFS do so in the final SAR.

Response: NMFS reiterates its response to this same comment from the 2020 Draft SARs. NMFS' Observer Program does not observe every deep-set trip. With ~20 percent coverage, some statistical extrapolation/approximation of what is observed is required. False killer whale takes are relatively rare. The rarity of observed takes together with the sampling design mean that the lack of observation does not equate to the lack of actual interactions. NMFS is not attributing interactions that occur outside of the MHI insular stock area to the MHI insular stock. We are prorating the estimated portion of the take to account for fishing effort that occurs within the MHI insular stock range and based on the relative density of the false killer whale stocks in this area. In reality, if an MHI insular false killer whale were taken by the fishery, we would very likely be underestimating the impact on this stock given our current proration method.

Further, although NMFS noted that we can more explicitly state that no confirmed MHI insular false killer whales have been observed as taken in this fishery, the overlap between the 2020 SAR comment period and the preparation of the 2021 draft SAR precluded this change. We will add this note, with previously noted caveat that very few of the observed takes are identified to stock due to the lack of tissue samples or adequate photographs.

Southern Resident Killer Whale (SRKW)

[Comment 31]: CBD and WDC reiterate that NMFS update its protocol of using a July deadline for its annual census. We once again ask NMFS to update the protocol to reflect this shift in timing and to capture the most complete population count possible in a year by setting a December date and remind NMFS again that a July deadline reflects a number more than a year and a half out of date currently, and six months out of date for the SAR.

There are two updated regulatory measures that should be included in this SAR: the final rule for the revision of critical habitat should be noted in place of the reference to the proposed rule, and Washington State has issued new vessel guidelines requiring a distance of 300 yards (274 meters) from the sides and 400 yards (365.76 meters) in front or behind a group of SRKWs, and a vessel speed of 7 knots within a ½ mile (0.8 km) of the whales.

New research on the SRKW population should be included in this SAR. Additional data from Hanson *et al.* (2018) is available on passive acoustic monitoring in coastal waters. Updated analysis on coastal prey sampling has been completed and is no longer ''in press''—Hanson *et al.* (2021). New studies on body condition (Fearnbach *et al.* 2018) and adult sizes (Groskreutz *et al.* 2019) provide additional information on the impacts of prey depletion on the health of SRKWs. NMFS and the Washington Department of Fish and Wildlife have also completed a report on Priority Chinook Stocks that should be noted.

Response: With regard to the timing and reporting of census numbers, NMFS has previously addressed this same public comment (86 FR 38991, July 23, 2021). The Hanson *et al.* (in press) reference has been updated to Hanson et al. (2021). We will update the revision of critical habitat as well as the updated information on body condition and prey in the subsequent SAR cycle.

Humpback Whale, CA/OR/WA

[Comment 32]: WDFW, Washington Dungeness Crab Fishermen's Association (WDCFA), and the Makah Tribe note the characterization of the distinct population segment (DPS) composition of humpback whales occurring in the stock is inconsistent with other NOAA reports. Regarding the text in the Draft 2021 SAR that describes the proportion of DPSs designated under the ESA for humpback whales by breeding grounds that utilize feeding grounds off the coast of Washington and southern British Columbia: The Draft 2021 SAR states, as previous SARs have stated, ''The northern Washington and southern British Columbia feeding group includes primarily threatened Mexico DPS whales, with smaller numbers from the unlisted Hawaii DPS and endangered Central America DPS.'' It is not clear where this characterization was originally derived from, as no reference is provided. This characterization of most of the whales in Washington coming from the threatened Mexico DPS is inconsistent with estimates provided by NOAA scientists to the International Whaling Commission. Furthermore, this statement is in conflict with a memo released by NMFS in July 2021, which states that the proposed approach for evaluating impacts to listed DPSs in ESA section 7 consultations (and in all relevant ESA analyses) would consider DPS proportions for humpback whales foraging off of northern Washington and southern BC derived from Wade (2021). The numbers included in the memo do not align with the characterization in the Draft 2021 SAR. The text in the report should be updated to reflect Wade as the best available science on the migratory destination of North Pacific humpback whales.

Response: NMFS will replace the following language ''The northern Washington and southern British Columbia feeding group includes primarily threatened Mexico DPS whales, with smaller numbers from the unlisted Hawaii DPS and endangered Central America DPS'' with findings from Wade (2021): ''Based on a Pacific-wide photo-ID effort in 2004–2006, Wade (2021) reported that of 180 unique whale identifications from the Southern British Columbia—Washington stratum (''SBC/WA''), 28 were matched to Mexico wintering areas, 19 to Hawai'i, and 3 to Central America. Wade (2021) also estimated movement probabilities from the SBC/WA stratum to each wintering area. The highest movement probabilities were between SBC/WA and Hawai'i (0.688), followed by SBC/WA and Mexico (0.254), and SBC/WA and Central America (0.059).''

[Comment 33]: WDFW and the Makah Tribe comment that the draft 2021 SAR relies heavily on Calambokidis and Barlow (2020) to provide the minimum population (stock) abundance estimate (*i.e.,* 4,776 animals) and will be used for practical/regulatory purposes (*e.g.,* assessing the impacts of anthropogenic activities). Our primary concern with respect to the use of Calambokidis and Barlow (2020) for providing an authoritative minimum abundance estimate for the stock comes from the fact that it does not consider sightings data collected off the coast of Washington. This is especially concerning because the genetic makeup of the feeding aggregation (in terms of DPSs or Demographically Independent Populations—DIPs) off of WA and SBC is significantly different from that of the CA/OR feeding aggregation. A minimum abundance estimate for the entire CA/OR/WA stock should include an

estimate of animals found off the coast of Washington (animals that belong to the WA/SBC feeding group).

WDFW respectfully requests a comparative analysis of the assumptions and precision of each of these estimates, as this would increase transparency and improve the public's understanding of this important process for determining the best available science. WDFW also requests NMFS find some way to derive N_{min} that more precisely accounts for humpback whales found off the coast of Washington.

Response: NMFS cites and compares two abundance estimates (Becker *et al.* 2020, Calambokidis and Barlow 2020) in the draft humpback whale SAR. The Becker *et al.* (2020) estimate is based on line-transect survey efforts that included Washington state waters (Becker *et al.* 2020), and for which the estimate is approximately 200 whales lower than the Calambokidis and Barlow (2020) estimate. While the lower estimate of Becker *et al.* (2020) could be used to represent CA + OR + WA abundance in this SAR, the mark-recapture estimate of Calambokidis and Barlow (2020) is used, for reasons given in the SAR.

[Comment 34]: WDFW staff, in coordination with Oregon and California Departments of Fish and Wildlife (ODFW and CDFW) staff, reviewed the Draft 2021 SAR alongside the 2021 M&SI Report (Carretta *et al.* 2021) and the most up-to-date version of the West Coast Region entanglement database currently available to state agencies. Multiple inconsistencies were identified, and WDFW concurs with the comments provided by ODFW regarding these inconsistencies.

Response: NMFS reviewed the draft SAR and M/SI report and revised the values consistent between the SAR narrative and M/SI report totals. Totals that appear in the M/SI report may not agree with West Coast Region entanglement reports, as the latter is released months in advance of the preparation of the annual M/SI report. During that period, additional details or evidence regarding entanglements may come to light that result in addition or deletion of cases.

[Comment 35]: CBD and WDC request that NMFS revise the CA/OR/WA humpback stock so as not to aggregate two demographically independent populations that do not interbreed when mature. The current draft 2021 SAR does not reference these papers or provide hypothetical stocks if each were separate stocks. The draft SAR misleadingly includes information from Calambokidis and Barlow (2020) about an apparent increase in abundance from 2014 to 2018. Including appropriate caveats to the apparent increase in the CA/OR/WA stock is important because they explain that the increase may not apply to the DIPs. The draft SARs do not include scientific information regarding the accuracy of determining to which DIP or DPS a whale belongs based on photographic identification. There is genetic evidence that animals that are photographically identified as wintering in mainland Mexico-feeding off California/Oregon are not representative of that herd. It is not clear that photo identification will accurately assess the ESA-listed Central America DPS and Mexico DPS. CBD and WDC request adequate funding to meet the MMPA mandates for completing stock assessment reports.

Response: The draft 2021 SARs were prepared before the referenced Technical Memoranda were published. New information on multiple demographically independent humpback populations and their status in U.S. west coast waters will be addressed in the 2022 draft SARs.

[Comment 36]: CBD and WDC recognize that one important function of the SARs is enumerating serious injury and mortality for each stock, and this is especially critical for ESA-listed humpback whales vulnerable to vessel collisions off California. The draft SAR includes Rockwood *et al.* (2017) but not more recent research available. A 2019 follow-up to Rockwood *et al.* (2017) concluded that even the 2017 study estimates were an underestimate, particularly in relation to humpback whale mortality during winter months. Table 1 of the Rockwood *et al.* (2021) paper allows the results from the 2017 paper to be comparable to the results of the paper. This information on ship strike mortality and injury should be updated in the humpback whale SAR.

Response: Rockwood *et al.* (2021) did not estimate vessel strike deaths for the entire U.S. EEZ as they did in the 2017 publication, though they compare estimates for Southern California between the two studies. The increase in estimates for Southern California between the two studies does not translate to an increase over the whole study area, thus it is unclear how the new estimates for Southern California (including new winter estimates) may be incorporated into the SAR, when estimates from the remainder of the U.S. EEZ are lacking. It is also unclear how winter/spring estimates of humpback whale vessel strike deaths can be higher than summer/autumn estimates for the same region, when humpback whales are more abundant in this region in summer and autumn. NMFS will consult with the authors on how the new results may directly apply to future SARs.

[Comment 37]: CBD and WDC recommend that the SAR should also note the impacts from marine heat waves and changing ocean conditions under Habitat Concerns. Warmer ocean temperatures influence primary prey choice by humpback whales and creates shifts in distribution and habitat use, which may increase risk of human interaction.

Response: NMFS has added language to the Habitat Concerns section with regard to marine heat waves. ''The impacts of marine heatwaves on the foraging activities of humpback whales, including changes in the abundance and distribution of prey and whale foraging locations, may increase risk of human interactions (Santora *et al.* 2020).''

[Comment 38]: WDCFA and the Makah Tribe are concerned that the abundance of SBC/WA populations is not included in the west coast abundance estimates. The excluded population of the SBC/WA population is in the order of 1,593 distinct animals and is not factored into the total of what the 2021 SAR characterizes as coast wide abundance estimated at 4,973, which produces an N_{min} of 4,776. While a portion of the SBC/WA population is international in range a significant portion of that population occurs off of WA and should be accounted for in the west coast (CA/OR/WA) population. A more accurate abundance estimate would benefit from and be more reflective of population abundance from a proportional inclusion of SBC/WA populations.

Response: NMFS notes that whales summering in NBC/WA waters are not considered a separate ''stock'' under the MMPA, as stated by the commenter. With respect to the estimate of 4,973 (CV=0.048) whales for CA + OR + WA waters by Calambokidis and Barlow (2020), they state: ''While this estimate was calculated using identifications from California and Oregon, it likely incorporates the smaller number of Washington animals since there is some level of interchange with that area and adding our estimate for Washington-Southern British Columbia would likely be biased high both for that reason as well as because it would inappropriately (for purpose of calculating an N_{min} for US waters) include whales outside US waters.'' The only other independent estimate of abundance for CA + OR + WA waters combined is 4,784 (CV=0.31) (Becker et al. 2020), and it is lower than the mark-recapture estimate of Calambokidis and Barlow (2020). The Becker et al. (2020) estimate *could* be used in the SAR, but

the mark-recapture estimate is considered the best estimate for management purposes for reasons given in the SAR.

[Comment 39]: The data for consideration in this SARs report on Pacific coast Humpback activity was gathered in 2018. WDCFA is concerned about how long it takes to get data processed and analyzed so that stakeholders and fisheries managers can make timely and well-informed decisions on practices that may impact the well being of stakeholders who make a living from the sea and the well being of the marine species that share ocean space with us.

Response: Data on the abundance of humpback whales were collected during a line-transect and mark-recapture survey in the past several years. It takes 1–2 years to analyze and publish these data for use in SARs. Guidelines for preparing marine mammal stock assessments note that abundance estimates are considered valid for use in SARs for an 8-year period after being collected.

[Comment 40]: The Makah Tribe has two concerns with the use of 8 percent for the maximum net productivity rate. First, the 8 percent is determined based on the observed rate of increase of humpback whales on the U.S. west coast and is not the maximum net productivity rate required by the formula for PBR. In the absence of a model with anthropogenic mortality included, the best available science indicates that an 11.8 percent growth rate should be used as the maximum theoretical or estimated net productivity rate in calculating PBR for the CA/OR/WA stock of humpback whales. The Makah Tribe also note that Calambokidis and Barlow calculated an observed growth rate of 8.2 percent per year from the 1980s to the current best estimate of CA/OR humpback whales. Thus, even if NOAA decides to use an observed growth rate for purposes of the SAR, the rate should be increased to 8.2 percent.

Response: Guidelines for preparing marine mammal stock assessments note that default rates of Rmax should be used in the absence of stock-specific measured rates. The guidelines also note that ''to be consistent with a risk-averse approach, these default values should be near the lower range of measured or theoretical values.'' The Rmax of 11.8 percent noted in the comment is taken from the upper 99th quantile of the results reported by Zerbini *et al.* (2010) which does not reflect the lower range of the theoretical values reported. It also does not represent a stock-specific estimate of increase. The impacts of anthropogenic removals on estimates of Rmax has not been estimated for humpback whales; thus, observed rates of increase have been used in the SARs. The commenter is correct that Calambokidis and Barlow (2020) note that an 8.2 percent growth rate is implied for U.S. west coast humpback whales, based on rates of increase shown since the late 1980s. NMFS has updated the Rmax estimate to 8.2 percent in the final 2021 SAR.

[Comment 41]: The Makah Tribe notes that the assumption that the stock spends 50 percent of its time outside of US waters is too low. Modeled ship strikes should not be counted against the potential biological removal. The Makah Tribe suggests that it is best to compare the PBR to observed rates of ship strikes because the actual reports can be validated, whereas the modeled rates may not be accurate.

Response: NMFS will review the available data with regard to how much time this stock spends outside of U.S. west coast waters, as resources allow. The 50 percent proration factor has been used in the SAR for many years but can be improved. The vessel strike estimates of Rockwood et al. are considered as any other published estimates of anthropogenic removals might be in a SAR, including bycatch estimates. The commenter does not make a defensible case for why estimates of vessel strike deaths should be excluded from the SAR.

Blue Whale, Eastern North Pacific

[Comment 42]: CBD and WDC comment that the changes NMFS proposes to the section on ''Current Population Trend'' do not seem to reflect the concern among the Pacific SRG regarding the large declining trend in the species distribution model (SDM) abundance estimates. Also, CBD and WDC are concerned that the draft SAR does not adequately explain the choice to adopt the mark-recapture estimate (1,898, CV=0.085) rather than the SDM estimate (670, CV=0.43). The results of the SDM show a declining trend and a worrisome low estimate of abundance for blue whales, which could easily be explained by an actual decline in the blue whale population. The lack of consideration of the blue whale SDM estimate stands in contrast to the adoption of the SDM results for fin whale abundances estimates. If the agency's explanation is that it favors mark-recapture estimates over line-transect or SDM for transboundary stocks, this should be more fully developed in the draft SARs.

Response: NMFS has been consistent in favoring mark-recapture abundance estimates over line-transect estimates (or SDM estimates derived from line-transect surveys) in SARs when (1) the precision of the mark-recapture estimate is superior and data were collected over a sufficient time period; (2) the line-transect survey effort is spatially-reduced compared with previous surveys, as was the case in 2018 (Becker *et al.* 2020); or (3) the line-transect estimate is outdated. When available, the mark-recapture estimates have been used in the blue whale SAR since 2009. In the case of fin whales, the SDM estimate of Becker et al. (2020) is used because it represents the only recent estimate, compared with the older line-transect trend estimates from Moore and Barlow (2011) and Nadeem *et al.* (2016), and there are no mark-recapture estimates for fin whales in this region. For blue whales, use of the Calambokidis and Barlow (2020) mark-recapture estimate is explained in the draft SAR as being due to its superior precision over the SDM estimate and the fact that the SDM estimate is spatially and seasonally constrained: ''The mark-recapture estimate (1,898) is considered the best estimate of abundance for 2018 due to its higher precision and because estimates based on line-transect data reflect only animal densities within the study area at the time surveys are conducted.'' Given that spatially-constrained line-transect abundance estimates have declined while mark-recapture estimates have increased, it is not irrational to assume that some portion of the blue whale population is outside of the U.S. EEZ during summer/autumn surveys or that their distribution has shifted north over time, as the SAR outlines with multiple published references. One of these references (Monnahan *et al.* 2015) notes that this blue whale population may have been near carrying capacity in 2013. Given the uncertainty from all of these sources, the SAR conservatively states that ''the current population trend is unknown.''

[Comment 43]: ODFW notes that Table 1 in the blue whale Draft SAR shows 2 serious injuries attributed to CA Dungeness crab gear (2 M&SI total). The M&SI Report shows 3 entanglements involving CA Dungeness crab gear that resulted in 2.75 serious injuries (2.75 M&SI total). This also results in a different total M&SI from human-related interactions in the Draft SAR (10.75 M&SI total) and the M&SI Report (11.5 M&SI total).

Response: Totals have been corrected in the final SAR.

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Dated: July 28, 2022.

Evan Howell,

Director, Office of Science and Technology, National Marine Fisheries Service.

[FR Doc. 2022–16543 Filed 8–2–22; 8:45 am]

BILLING CODE 3510–22–P

COUNCIL ON ENVIRONMENTAL QUALITY

[CEQ–2022–0004]

Environmental Justice Scorecard Feedback

AGENCY: Council on Environmental Quality.

ACTION: Request for information.

SUMMARY: The Council on Environmental Quality is issuing this request for information (RFI) to solicit feedback on the vision, framework, and outcomes of the Environmental Justice Scorecard.

DATES: Responses to this RFI should be received by October 3, 2022.

ADDRESSES: You may submit comments, identified by docket number CEQ–2022–0004, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–456–6546.
- *Mail:* Council on Environmental Quality, 730 Jackson Place NW, Washington, DC 20503.

All submissions received must include the agency name, ''Council on Environmental Quality,'' and the docket number, CEQ–2022–0004, for this RFI. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Do not submit electronically any information you consider to be private, Confidential Business Information (CBI), or other information the disclosure of which is restricted by statute.

You may respond to some or all of the questions listed in the RFI. You may include references to academic literature or links to online material but please ensure all links are publicly available. Each response should include:

- The name of the individual(s) or entity responding.
- A brief description of the responding individual(s) or entity's mission or areas of expertise.
- A contact for questions or other follow-up on your response.

FOR FURTHER INFORMATION CONTACT: Issues regarding submission or questions on this RFI can be sent to Sharmila L. Murthy at 202–395–5750 or *Sharmila.L.Murthy@ceq.eop.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Many communities across the country face environmental injustices. These communities have been overburdened by pollution and underserved by critical infrastructure and services, leading to negative health impacts and outcomes. Communities that suffer from environmental injustices include low income communities, communities of color, and Tribal Nations. Furthermore, these same communities are too often left out of decision making that directly impacts their health and well-being. President Biden has committed to charting a new and better course, one that puts environmental and economic justice for communities at the center of the Federal Government's work.

Within his first days in office, President Biden signed Executive Order 14008 on *Tackling the Climate Crisis at Home and Abroad,* stating that agencies must make achieving environmental justice part of their missions by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related, and other cumulative impacts on disadvantaged communities, as well as the accompanying economic challenges of such impacts.

The Executive Order mandates the development of performance measures for an annual Environmental Justice Scorecard, which will aim to detail the efforts of the Federal Government to address historic and current environmental injustices.

As outlined in the Executive Order, the Environmental Justice Scorecard will be developed in collaboration with the Executive Office of the President and with the White House Environmental Justice Interagency Council (IAC). It will be guided by recommendations by the White House Environmental Justice Advisory Council (WHEJAC), with input by environmental justice stakeholders. The WHEJAC's Phase One Recommendations on the Environmental Justice Scorecard informed the development of this RFI, and will continue to inform the vision, scale, and scope of the Environmental Justice Scorecard.

The Environmental Justice Scorecard will be the first government-wide assessment of Federal agencies' efforts to advance environmental justice. The Environmental Justice Scorecard will evolve over time, with the goal of creating a robust and comprehensive assessment of the Federal Government's efforts to secure environmental justice for all. It eventually will be located on a public, web-based platform that is easy to use.

The first version of the Environmental Justice Scorecard will provide a baseline assessment of the Federal Government's efforts to secure environmental justice. It will focus on and describe the processes and progress that Federal agencies have made starting in 2021. This baseline is critical to establish because it will enable the measurement of progress over time. The Federal Government will then build on and improve the Scorecard, year after year.

Initially, the Environmental Justice Scorecard will focus on three main categories. It will highlight activities by Federal agencies to: (1) reduce harms and burdens borne disproportionately by communities, (2) deliver investment benefits, and (3) undertake institutional reform to center community voices in decision making. This framework reflects the Administration's commitment to begin repairing historic wrongs, to strive towards delivering tangible benefits to communities, and to

work towards ensuring that the voices and needs of communities are elevated and centered in decision making.

As part of this broader effort to assess progress on environmental justice, the Environmental Justice Scorecard also will measure progress made towards the Justice40 Initiative. In Executive Order 14008, President Biden set of a goal of ensuring that 40 percent of the overall benefits of certain Federal investments—those made in climate, clean energy and energy efficiency, clean transit, affordable and sustainable housing, training and workforce development, the remediation and reduction of legacy pollution, and the development of critical clean water infrastructure—flow to disadvantaged communities that are marginalized and overburdened by pollution and underinvestment in basic services.

This RFI is part of the Administration's commitment to ensuring that environmental justice efforts within the Federal Government, including the development of the Environmental Justice Scorecard, are informed by the priorities and perspectives of communities that face environmental injustices. By soliciting input through this RFI, CEQ seeks to provide transparency about the Federal Government's vision, goals, and process so that the public is better able to monitor the government's progress and hold the government accountable for delivering results.

II. Key Questions for Input

A. Vision

i. The vision for the Environmental Justice Scorecard is as a robust and comprehensive assessment of the Federal Government's efforts to address current and historic environmental injustice, including the Justice40 Initiative.

ii. Question

1. Does this vision reflect the needs and priorities of communities that face environmental injustices?

B. Framework

i. In the first version of the Environmental Justice Scorecard, Federal Government activities will be organized in three reporting categories.

1. *Reducing Burdens and Harms in Communities:* This category would measure the regulatory, enforcement, and other actions taken to reduce harms and environmental injustices.

2. *Benefits to Communities:* This category would measure the Administration's progress on implementation of the Justice40 Initiative, among other environmental justice efforts.

3. *Centering Justice in Decision Making:* This category would capture measures taken to reform agency decision making to incorporate the perspectives, priorities, and lived experiences of environmental justice communities.

ii. Questions

1. Do these categories broadly reflect the needs, priorities, and impacts that communities are facing from environmental injustices?

2. For the first version of the Environmental Justice Scorecard, what processes and markers of progress should be reflected in each of these categories?

3. In the long term, what are the desired outcomes that could be included in each of these categories?

C. Engagement

i. Please provide recommendations on how to improve engagement with, and around, the Environmental Justice Scorecard. In particular, what are ways to improve sharing information about the Environmental Justice Scorecard?

ii. For a future website, what are some usability and accessibility features that should be considered for an online platform?

D. Additional feedback

i. Please provide additional feedback on the vision, framework, and outcomes of the Environmental Justice Scorecard. Feedback on the vision for the first version, and on future versions, is welcome.

Matthew G. Lee-Ashley,

Chief of Staff.

[FR Doc. 2022–16635 Filed 8–2–22; 8:45 am]

BILLING CODE 3325–F2–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2022–SCC–0092]

Agency Information Collection Activities; Comment Request; Charter School Programs Application: State Entity Grants, Developer Grants, and Charter Management Organization Grants

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (Department or ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 ED is requesting the Office of Management and Budget (OMB) to conduct review of an extension of an information collection.

DATES: The Department requested emergency processing from OMB for this information collection request (ICR) and received approval on July 5, 2022; and therefore, the regular clearance process is hereby being initiated to provide the public with the opportunity to comment under the full comment period. Interested persons are invited to submit comments on or before September 2, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to these information collection activities, please contact Stephanie Jones, 202–453–7835.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the PRA (44 U.S.C. 3506©(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 ICR that is described below. The Department is especially interested in public comments 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: Charter School Programs Application: State Entity Grants, Developer Grants, and Charter Management Organization Grants.

OMB Control Number: 1810–0767.

Type of Review: Extension of an information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 365.

Total Estimated Number of Annual Burden Hours: 21,900.

Abstract: The Expanding Opportunity Through Quality Charter Schools Program (CSP) is authorized under Title IV, Part C of the Elementary and Secondary Education Act of 1965, as amended by the Every Student Succeeds Act (20 U.S.C. 7221–7221j). On March 14, 2022, the Department published in the **Federal Register** a Notice of Proposed Priorities, Requirements, Definitions, and Selection Criteria for CSP Grants to State Entities (SE 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) (Vol. 87, No. 49, pages 14197–14210) (CSP NPP). Specifically, the Department proposed new priorities, application requirements, assurances, definitions, and selection criteria to create results-driven policies to help promote positive student outcomes, student and staff diversity, educator and community empowerment, promising practices, and accountability, including fiscal transparency and responsibility, in charter schools supported with CSP funds, which can serve as models for other charter schools. Based on the CSP NPP and public comments, the Department issued a notice of final priorities, requirements, definitions, and selection criteria for CSP SE Grants, CMO Grants and Developer Grants (CSP NFP), which published in the **Federal Register** on July 1, 2022. The final priorities, requirements, definitions, and selection criteria in the CSP NFP are intended to supplement existing statutory and regulatory requirements governing CSP SE Grants, CMO Grants, and Developer Grants. The Charter School Programs Office of the Department is requesting continued approval of this information collection for CSP SE Grants, CMO Grants, and Developer Grants generally; and for the CSP NFP, which requires the submission of a needs analysis and information regarding contracts with for-profit management organizations. The CSP (Assistance Listing Numbers (ALN) 84.282, including SE Grants (84.282A), CMO Grants (84.282M), and Developer Grants (84.282B and 84.282E)) is a competitive discretionary grant program. The grant applications submitted for this program are evaluated based on how well an applicant addresses the selection criteria (and any competitive preference priorities) and are used to determine applicant eligibility and award amounts for projects selected for funding.

Dated: July 28, 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. 2022–16544 Filed 8–2–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Energy Employees Occupational Illness Compensation Program Act of 2000; Revision to the List of Covered Facilities

AGENCY: Office of Health and Safety, U.S. Department of Energy.

ACTION: Notice of revision of listing of covered facilities.

SUMMARY: The U.S. Department of Energy (DOE or Department) has periodically published in the **Federal Register** a list of facilities covered under the Energy Employees Occupational Illness Compensation Program Act of 2000, as amended (EEOICPA or Act). This Notice amends the list of covered facilities by removing the designation of Sciaky Brothers, Inc. (Chicago, Illinois), Swenson Evaporator Co. (Harvey, Illinois), and the Museum of Science and Industry (Chicago, Illinois) as Atomic Weapons Employer (AWE) facilities.

DATES: August 3, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Dressman, Director, Office of Health and Safety (EHSS–10), 1000 Independence Avenue SW, Washington, DC 20585; (301) 903–5144; or by email at *kevin.dressman@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: This Notice amends the list of covered facilities under EEOICPA by removing the designation of Sciaky Brothers, Inc. in Chicago, Illinois; Swenson Evaporator Co. in Harvey, Illinois; and the Museum of Science and Industry in Chicago, Illinois, as AWE facilities. Previous lists or revisions were published by DOE on February 17, 2016 (81 FR 8060); July 16, 2015 (80 FR 42094); February 11, 2013 (78 FR 9678); February 6, 2012 (77 FR 5781); May 26, 2011 (76 FR 30695); August 3, 2010 (75 FR 45608); April 9, 2009 (74 FR 16191); June 28, 2007 (72 FR 35448); November 30, 2005 (70 FR 71815); August 23, 2004 (69 FR 51825); July 21, 2003 (68 FR 43095); December 27, 2002 (67 FR 79068); June 11, 2001 (66 FR 31218); and January 17, 2001 (66 FR 4003).

Purpose

EEOICPA established a program to provide compensation to individuals who developed illnesses because of their employment in nuclear weapons production-related activities of the DOE or its predecessor agencies. Covered employees include, among others, current or former employees of an ''atomic weapons employer'' or ''AWE'', also as defined by the Act. On December 7, 2000, the President issued Executive Order 13179, ''Providing Compensation to America's Nuclear Weapons Workers,'' which directed DOE to list covered AWE facilities, DOE facilities, and beryllium vendor facilities in the **Federal Register**. The Department's initial listing was published on January 17, 2001 (66 FR 4003), and DOE has periodically updated the listing as new information has become available.

Section 3621(4) of EEOICPA (42 U.S.C. 7384l(4)) defines an AWE as ''an entity, other than the United States, that—(A) processed or produced, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining and milling; and (B) is designated by the Secretary of Energy as an [AWE] for purposes of the compensation program.'' Section 3621(5) of the Act (42 U.S.C. 7384l(5)) defines an ''atomic weapons employer facility'' as ''a facility, owned by an [AWE], that is or was used to process or produce, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining or milling.''

DOE has determined that Sciaky Brothers, Inc. in Chicago, Illinois; Swenson Evaporator Co. in Harvey, Illinois; and the Museum of Science and Industry in Chicago, Illinois, do not meet the statutory definition of AWE facilities because none of these entities processed or produced, for use by the United States, material that emitted radiation and was used in the production of an atomic weapon. Therefore, the designation of these three

facilities as AWE facilities was erroneous.

This Notice formally makes the changes to the listing of covered facilities as indicated below:

- Sciaky Brothers, Inc., Chicago, Illinois, is no longer designated as an AWE facility.
- Swenson Evaporator Co., Harvey, Illinois, is no longer designated as an AWE facility.
- Museum of Science and Industry, Chicago, Illinois, is no longer designated as an AWE facility.

Signing Authority

This document of the Department of Energy was signed on July 27, 2022, by Jennifer Granholm, Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 29, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–16602 Filed 8–2–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[DOE/EIS–0542]

Record of Decision for the Final Versatile Test Reactor Environmental Impact Statement

AGENCY: Idaho Operations Office, Department of Energy.

ACTION: Record of decision.

SUMMARY: The Department of Energy (DOE) is issuing this record of decision (ROD) for the Versatile Test Reactor (VTR) pursuant to the *Final Versatile Test Reactor Environmental Impact Statement* (VTR EIS) (DOE/EIS–0542). DOE prepared the VTR EIS to evaluate the potential environmental impacts of alternatives for constructing and operating a VTR and the associated facilities required for post-irradiation examination of test and experimental fuels and materials. DOE has decided to implement its Preferred Alternative, to construct and operate a VTR at the Idaho National Laboratory (INL) Site, and to establish, through modification and construction, co-located facilities for post-irradiation examination of test products and for management of spent VTR driver fuel at INL. The VTR will operate as a national user facility, providing a fast-neutron-spectrum test capability for the testing and development of advanced nuclear technologies. DOE has not decided whether to establish VTR driver fuel production capabilities at the INL Site, the Savannah River Site (SRS), or a combination of the two sites. Once a preferred alternative or option for VTR driver fuel production is identified, DOE will announce its preference in a **Federal Register** (FR) notice. DOE would then publish a ROD no sooner than 30 days after its announcement of a preferred alternative/option for VTR driver fuel production.

ADDRESSES: Questions or comments should be sent to Mr. James Lovejoy, VTR EIS Document Manager, by mail at U.S. Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, MS 1235, Idaho Falls, Idaho 83415; or by email to *VTR.EIS@nuclear.energy.gov.* The Final VTR EIS and this ROD are available for viewing or download at *https://www.energy.gov/nepa/nepa-documents* and *https://www.energy.gov/ne/nuclear-reactor-technologies/versatile-test-reactor.*

FOR FURTHER INFORMATION CONTACT: For information regarding the VTR Project, the Final VTR EIS, or the ROD, visit *https://www.energy.gov/ne/nuclear-reactor-technologies/versatile-test-reactor;* or contact Mr. James Lovejoy at the mailing address listed in **ADDRESSES** or via email at *VTR.EIS@nuclear.energy.gov;* or call (208) 526–6805. For general information on DOE's National Environmental Policy Act (NEPA) process, contact Mr. Jason Anderson at the mailing address listed in **ADDRESSES** or via email at *VTR.EIS@nuclear.energy.gov;* or call (208) 526–6805.

SUPPLEMENTARY INFORMATION:

Background

DOE's mission includes advancing the energy, environmental, and nuclear security of the United States (U.S.) and promoting scientific and technological innovation in support of that mission. DOE's 2014 to 2018 Strategic Plan states that DOE will ''support a more economically competitive, environmentally responsible, secure and resilient U.S. energy infrastructure.'' The plan further indicates that DOE will continue to explore advanced concepts in nuclear energy. The advanced concepts may lead to new types of reactors that improve safety, lower environmental impacts, and reduce proliferation concerns.

Advanced reactors that operate in the fast-neutron [1] spectrum offer the potential to have inherent safety characteristics incorporated into their designs. They can operate for long periods without refueling and reduce the volume of newly generated nuclear waste. Effective testing and development of advanced reactor technologies requires the use of fast neutrons comparable to those that would occur in actual advanced reactors. A high flux of fast neutrons allows accelerated testing, meaning that a comparatively short testing period would accomplish what would otherwise require many years to decades of exposure in a test environment with lower energy neutrons, a lower flux, or both. This accelerated testing would contribute to the development of materials and fuels for advanced reactors and generate data allowing advanced reactor developers, researchers, DOE, and regulatory agencies to improve performance, understand material properties, qualify improved materials and fuels, evaluate reliability, and ensure safety. Accelerated testing capabilities would also benefit these same areas for the current generation of light-water reactors.

Many commercial organizations and universities are pursuing advanced nuclear energy fuels, materials, and reactor designs that complement DOE and its laboratories' efforts to advance nuclear energy. These designs include thermal [2] and fast-spectrum reactors that target improved fuel resource utilization and waste management, and the use of materials other than water for cooling. Their development requires an adequate infrastructure for experimentation, testing, design evolution, and component qualification. Available irradiation test capabilities are aging (most are over 50 years old). These capabilities are focused on testing materials, fuels, and components in the thermal neutron spectrum and do not have the ability to support the needs for fast reactors (*i.e.,* reactors that operate

[1] Fast neutrons are highly energetic neutrons (ranging from 0.1 million to 10 million electron volts [MeV] and travelling at speeds of thousands to tens of thousands kilometers per second) emitted during fission. The fast-neutron spectrum refers to the range of energies associated with fast neutrons.

[2] Thermal neutrons are neutrons that are less energetic than fast neutrons (generally, less than 0.25 electron volt and travelling at speeds of less than 5 kilometers per second), having been slowed by collisions with other materials such as water. The thermal neutron spectrum refers to the range of energies associated with thermal neutrons.

using fast neutrons). Only limited fast-neutron-spectrum testing capabilities, with restricted availability, exist outside the U.S.

A number of studies evaluating the needs and options for a fast-neutron spectrum test reactor have been conducted. The *Advanced Demonstration and Test Reactor Options Study* identified a strategic objective to ''provide an irradiation test reactor to support development and qualification of fuels, materials, and other important components/items (*e.g.,* control rods, instrumentation) of both thermal and fast neutron-based . . . advanced reactor systems.'' The DOE Nuclear Energy Advisory Committee (NEAC) issued an *Assessment of Missions and Requirements for a New U.S. Test Reactor,* confirming the need for fast-neutron testing capabilities in the U.S. and acknowledging that no such facility is readily available domestically or internationally. Developing the capability for large-scale testing, accelerated testing, and qualifying advanced nuclear fuels, materials, instrumentation, and sensors is essential for the U.S. to modernize its nuclear energy infrastructure and to develop transformational nuclear energy technologies that re-establish the U.S. as a world leader in nuclear technology commercialization.

DOE's *Mission Need Statement for the Versatile Test Reactor (VTR) Project, A Major Acquisition Project* embraces the development of a well-instrumented, sodium-cooled, fast-neutron-spectrum test reactor in the 300 megawatt-thermal power level range. The deployment of a sodium-cooled, fast-neutron-spectrum test reactor is consistent with the conclusions of the test reactor options study and the NEAC recommendation.

As required by the Nuclear Energy Innovation Capabilities Act of 2017 (NEICA) (Pub. L. 115–248), DOE assessed the mission need for a VTR-based fast-neutron source to serve as a national user facility. Having identified the need for the VTR, NEICA directs DOE ''to the maximum extent practicable, complete construction of, and approve the start of operations for, the user facility by not later than December 31, 2025.'' The Energy Act of 2020, within the Consolidated Appropriations Act (Pub. L. 116–68), directs the Secretary of Energy to provide a fast-neutron testing capability, authorizes the necessary funding, and revises the completion date from 2025 to 2026. To this end, DOE prepared an EIS in accordance with NEPA and the Council on Environmental Quality (CEQ) and DOE NEPA regulations (40 CFR parts 1500 through 1508 [3] and 10 CFR part 1021, respectively).

Purpose and Need for Agency Action

The purpose of this DOE action is to establish a domestic, versatile, reactor-based fast-neutron source and associated facilities that meet identified user needs (*e.g.,* providing a high neutron flux of at least 4×10^{15} neutrons per square centimeter per second and related testing capabilities). Associated facilities include those for the preparation of VTR driver fuel and test/experimental fuels and materials and those for the ensuing examination of the test/experimental fuels and materials; existing facilities would be used to the extent possible. The U.S. has not had a viable domestic fast-neutron-spectrum testing capability for almost three decades. DOE needs to develop this capability to establish the U.S. testing capability for next-generation nuclear reactors—many of which require a fast-neutron spectrum for operation—thus enabling the U.S. to regain technology leadership for the next generation nuclear fuels, materials, and reactors. The lack of a versatile fast-neutron-spectrum testing capability is a significant national strategic risk affecting the ability of DOE to fulfill its mission to advance the energy, environmental, and nuclear security interests of the U.S. and promote scientific and technological innovation. This testing capability is essential for the U.S. to modernize its nuclear energy industry. Further, DOE needs to develop this capability on an accelerated schedule to avoid further delay in the U.S. ability to develop and deploy advanced nuclear energy technologies. If this capability is not available to U.S. innovators as soon as possible, the ongoing shift of nuclear technology dominance to other nations will accelerate, to the detriment of the U.S. nuclear industrial sector.

Proposed Action

DOE proposes to construct and operate the VTR at a suitable DOE site. DOE would use or expand existing, co-located, post-irradiation examination capabilities as necessary to accomplish the mission. DOE would also use or expand existing facility capabilities to produce VTR driver fuel and to manage radioactive wastes and spent nuclear fuel. The DOE facilities would be capable of receiving test articles from the user community, as well as fabricating test articles for insertion in the VTR.[4]

Candidate sites for construction and operation of the VTR include the INL Site near Idaho Falls, Idaho, and the Oak Ridge National Laboratory (ORNL), near Oak Ridge, Tennessee. DOE would perform most post-irradiation examination in existing, modified, or new facilities near the VTR, although there may be instances when test items would be sent to another location for evaluation. DOE would produce VTR driver fuel at the INL Site or SRS near Aiken, South Carolina.

Alternatives and Options Analyzed in the Final VTR EIS

DOE proposes to use the GE Hitachi Nuclear Energy (GEH) Power Reactor Innovative Small Module (PRISM), a pool-type reactor, as the basis for VTR's design under both action alternatives. The PRISM design would require several changes, notably the elimination of electricity production and the accommodation for experimental locations within the core. The PRISM design [5] of a sodium-cooled, pool-type reactor satisfies the need to use a mature technology. The VTR would be an approximately 300-megawatt (thermal) reactor based on and sharing many of the design and passive safety features of the GEH PRISM. It also would incorporate technologies adapted from previous sodium-cooled fast reactors (*e.g.,* the Experimental Breeder Reactor II [EBR–II] and the Fast Flux Test Facility). The VTR's reactor, primary heat removal system, and safety systems would be similar to those of the PRISM design. VTR, like PRISM, would use

[3] On July 16, 2020, the CEQ published an ''Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act'' (85 FR 43304). CEQ clarified that these regulations apply to NEPA processes begun after the effective date of September 14, 2020, and gave agencies the discretion to apply them to ongoing NEPA processes (40 CFR 1506.13). This VTR EIS was started prior to the effective date of the revised CEQ regulations, and DOE has elected to complete the EIS pursuant to the regulations in effect prior to September 14, 2020 (1978 regulations).

[4] As a user facility, the VTR would provide experimental capabilities for entities outside of DOE. These other entities could also fabricate test items for placement in the reactor. The VTR project would develop procedures for the acceptance of test items for use in the VTR. All test item and assembly designs would be reviewed and verified to ensure that the VTR would perform as designed and would meet all core performance and safety requirements before the test assembly could be inserted into the reactor core.

[5] The PRISM design is based on the EBR–II reactor, which operated for over 30 years. The PRISM design most like the VTR is the 471-megawatt thermal MOD–A design. The U.S. Nuclear Regulatory Commission review of the PRISM reactor, as documented in NUREG–1368, *Preapplication Safety Evaluation Report for the Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor,* concluded that ''no obvious impediments to licensing the PRISM design had been identified.''

metallic alloy fuels. The conceptual design for the first VTR driver fuel core is an alloy of 70 percent uranium (uranium enriched to 5 percent uranium-235 [6]), 20 percent plutonium, and 10 percent zirconium (by weight).

The major facilities in the VTR complex include an electrical switchyard, the reactor facility, 10 large sodium-to-air heat exchangers, and an operational support facility. The reactor facility would be about 180 feet by 280 feet. The reactor vessel, containing the core of the VTR, would extend 90 feet below grade. Other below-grade elements of the facility include the reactor head access area (over the core), secondary coolant equipment rooms, test assembly storage areas, and fuel cask pits. The reactor and experiment hall operating area that extends 90 feet above grade would allow the receipt and movement of fuel and experiments into and out of the core and storage areas.

The VTR core design would differ from that of PRISM because it needs to meet the requirement for a high-flux test environment that accommodates several test and experimental assemblies. Experiments would be placed in some locations normally occupied by driver fuel in the PRISM. Heat generated by the VTR during operation would be dissipated through a heat rejection system consisting of intermediate heat exchangers within the reactor vessel, a secondary sodium-cooling loop, and air-cooled heat exchangers. This system and the Reactor Vessel Auxiliary Cooling System (RVACS) would provide shutdown and emergency cooling. The RVACS would remove decay heat from the sodium pool by transferring the thermal energy through the reactor vessel and guard vessel walls to naturally circulating air being drawn down through the inlets of four cooling chimneys, through risers on the exterior of the guard vessel, and up through the outlets of the cooling chimneys. The RVACS chimneys would be about 100 feet tall, extending above the experiment support area. No water would be used in either of the reactor cooling systems.

The core of the VTR would comprise 66 driver fuel assemblies. The core would be surrounded by rows of reflector assemblies (114 total assemblies), which would be surrounded by rows of shield assemblies (114 total assemblies). Non-instrumented experiments (containing test specimens) could be placed in multiple locations in the reactor core or in the reflector region, by replacing a driver fuel or reflector assembly (test pins may also be placed within a driver fuel assembly). Instrumented experiments, which would provide real-time information while the reactor is operating, would require a penetration in the reactor cover for the instrumentation stalk and could only be placed in six fixed locations. One of these six locations can accommodate a ''rabbit'' test apparatus that would allow samples to be inserted and/or removed while the reactor is in operation. The number of instrumented test locations, plus the flexibility in the number and location of non-instrumented tests would strengthen the versatility of the reactor as a test facility.

The VTR mission requires capabilities to examine the test specimens after irradiation in the VTR to determine the effects of a high flux of fast neutrons. Highly radioactive test specimens would be removed from the VTR after a period of irradiation ranging from days to years. Test specimens would then be transferred to a fully enclosed, radiation-shielded facility where they could be remotely disassembled, analyzed, and evaluated. The examination facilities are ''hot cell'' facilities. These hot cells include concrete walls and multi-layered, leaded-glass windows several feet thick. Remote manipulators allow operators to perform a range of tasks on test specimens within the hot cell while protecting them from radiation exposure. An inert atmosphere is required in some hot cells. An inert atmosphere of argon would be used [7] in the hot cell to which test assemblies are initially transferred after removal from the VTR. The inert atmosphere may be necessary to prevent test specimen degradation or unacceptable reactions (*e.g.,* pyrophoric) that could occur in an air atmosphere. The post-irradiation hot cell facilities would be in close proximity to the VTR. After initial disassembly and examination in the inert atmosphere hot cell, test specimens may be transferred to other post-irradiation examination facilities for additional analysis.

The VTR would generate up to 45 spent nuclear fuel assemblies per year.[8] DOE would use existing or new facilities at the locations identified in the site-specific alternatives for the management of spent driver fuel. DOE will not separate, purify, or recover fissile material from VTR spent nuclear fuel. Spent driver fuel assemblies would be temporarily stored within the reactor vessel for about 1 year. Upon removal from the reactor vessel, surface sodium coolant would be washed off the assembly, and the assembly would be transported in a transfer cask to a new onsite spent fuel pad. After several years (at least 3 years), during which time the radioactive constituents would further decay, the assemblies would be transferred in a cask to a spent nuclear fuel conditioning facility. The sodium that was enclosed within the spent driver fuel pins to enhance heat transfer would be removed using a melt-distill-package process. The spent nuclear fuel would be chopped, and the chopped material consolidated, melted, and vacuum distilled to separate the sodium from the fuel. To meet safeguards requirements, diluent would be added to the remaining spent fuel to reduce the fissile material concentration. The resulting material would be packaged in containers and temporarily stored in casks on the spent fuel pad, pending transfer to an offsite storage or disposal facility. Currently, there is not a repository for disposal of spent nuclear fuel, but the conditioned spent driver fuel from the VTR is expected to be compatible with the acceptance criteria for any interim storage facility or permanent repository.

No Action Alternative

Under the No Action Alternative, DOE would not pursue the construction and operation of a VTR. To the extent they are capable and available for testing in the fast-neutron-flux spectrum, DOE would continue to make use of the limited capabilities of existing facilities, both domestic and foreign. Domestic facilities that would likely be used, without modification, would include the INL Advanced Test Reactor and the ORNL High Flux Isotope Reactor. DOE would not construct new or modify any existing post-irradiation examination or spent nuclear fuel conditioning facilities to support VTR operation. Existing post-irradiation

[6] Enriched refers to the concentration of the isotope uranium-235, usually expressed as a percentage, in a quantity of uranium. Low-enriched uranium (LEU), highly enriched uranium (HEU) and high assay, low-enriched uranium (HALEU) are all enriched forms of uranium. Depleted uranium is a byproduct of the enrichment process and refers to uranium in which the percentage of uranium-235 is less than occurs naturally.

[7] Not all test specimens would require an inert atmosphere during disassembly, analysis, and evaluation. However, separate facilities are not proposed for test specimens that do not require initial post-irradiation examination in an inert atmosphere.

[8] Typically, less than a quarter of the VTR driver fuel assemblies would be replaced at the end of a test cycle. However, there could be atypical conditions when it would be necessary to replace a larger number of assemblies after a test cycle. In such instances, more than 45 assemblies could be removed from the core in a single year.

examination and spent nuclear fuel conditioning facilities would continue to support operation of the existing reactors. Because there would not be a VTR under the No Action Alternative, there would be no need to produce VTR driver fuel. Therefore, no new VTR driver fuel production capabilities would be pursued. The No Action Alternative would not meet the purpose and need identified for the VTR.

Idaho National Laboratory Versatile Test Reactor Alternative

Under the INL VTR Alternative, DOE would site the VTR adjacent to and east of the Materials and Fuels Complex (MFC) at the INL Site and use existing hot cell and other facilities at the MFC for post-irradiation examination and conditioning spent nuclear fuel (*i.e.,* preparing it for disposal). The VTR complex would occupy about 25 acres. Additional land would be disturbed during the construction of the VTR complex for such items as temporary staging of VTR components, construction equipment, and worker parking. In total, construction activities (anticipated to last 51 months) would result in the disturbance of about 100 acres, inclusive of the 25 acres occupied by the completed VTR complex.

The MFC is the location of the Hot Fuel Examination Facility (HFEF), the Irradiated Materials Characterization Laboratory (IMCL), and the Fuel Conditioning Facility (FCF). The HFEF and IMCL (and other analytical laboratory facilities) would be used for post-irradiation examination and the FCF for spent nuclear fuel conditioning. The existing Perimeter Intrusion Detection and Assessment System (PIDAS) security fencing around the Fuel Manufacturing Facility (FMF) and the Zero Power Physics Reactor (ZPPR) would be extended to encompass most of the VTR facility.

Following irradiation, test and sample articles would be transferred to the HFEF first. The HFEF, a Hazard Category 2 nuclear facility,[9] contains two large hot cells. HFEF hot cells provide shielding and containment for remote examination (including destructive and non-destructive testing), processing, and handling of highly radioactive materials.

The IMCL, a Hazard Category 2 nuclear facility, has a modular design that provides flexibility for future examination of nuclear fuel and materials. The IMCL would be used for the study and characterization of radioactive fuels and materials at the micro- and nanoscale to assess irradiation damage processes.

Existing facilities within the MFC would need minor modifications to support fabrication of test articles or to support post-irradiation examination of irradiated test specimens withdrawn from the VTR. These types of activities are ongoing within the MFC.

A new spent fuel pad would be constructed within the VTR site. The spent fuel pad would consist of an approximately 11,000-square foot concrete slab with a 2,500-square foot approach pad. Spent driver fuel would be temporarily stored at the VTR within the reactor vessel, followed by a period of storage on the spent fuel pad. After the fuel cools sufficiently, it would be transferred in a cask to FCF. FCF is a Hazard Category 2 nuclear facility located within a PIDAS. At FCF, the fuel would be conditioned using a melt-distill-package process. The fuel would be chopped, using existing equipment at the FCF. The chopped material would be consolidated, melted, and vacuum distilled to separate the sodium from the fuel. Following addition of a diluent, the mixture would be packaged in containers, placed in storage casks, and temporarily stored on the new spent fuel pad until shipped to an offsite location (an interim storage facility or a permanent repository when either becomes available for VTR fuel).

Under the conceptual design, the existing infrastructure, including utilities and waste management facilities, would be used to support construction and operation of the VTR. The current infrastructure is adequate to support the VTR with minor upgrades and modifications. Radioactive wastes would be shipped off site for treatment and/or disposal.

Oak Ridge National Laboratory Versatile Test Reactor Alternative

Under the ORNL VTR Alternative, the VTR would be sited at ORNL at a site previously considered for other projects, about a mile east of the ORNL main campus. The major structures for the VTR would be the same as those described for the INL VTR Alternative. At ORNL, a new hot cell, a joint post-irradiation examination and spent nuclear fuel conditioning facility, would be constructed adjacent to the VTR. Although there are facilities with hot cells at ORNL that would be used for post-irradiation examination of test materials, none of the available hot cells operates with an inert atmosphere. A new spent fuel pad of the same dimensions as described under INL VTR Alternative would also be constructed.

The new hot cell facility would be approximately 172 feet by 154 feet, four levels, and would rise to about 84 feet above grade. The facility would house four hot cells: two for post-irradiation examinations and two for spent nuclear fuel conditioning. Construction would occur in parallel with the construction of the VTR and be completed in the same 51-month period. Construction activities would result in disturbance of about 150 acres, with the completed VTR complex, including the hot cell facility, occupying less than 50 acres. The VTR facility, hot cell facility, and spent fuel pad would be located within a single PIDAS.

In addition to the new hot cell facility, existing facilities at ORNL within the Irradiated Fuels Examination Laboratory (Building 3525) and the Irradiated Material Examination and Testing Facility (Building 3025E) would be used to supplement the capabilities of the new post-irradiation examination facility. The Irradiated Fuels Examination Laboratory is a Hazard Category 2 nuclear facility and contains hot cells that are used for examination of a wide variety of fuels. The Irradiated Material Examination and Testing Facility is a Hazard Category 3 nuclear facility and contains hot cells that are used for mechanical testing and examination of highly irradiated structural alloys and ceramics. In addition, the Low Activation Materials Design and Analysis Laboratory would be used for the examination of materials with low radiological content that do not require remote manipulation.

Spent driver fuel would be managed the same as described under the INL VTR Alternative—temporarily stored at the VTR reactor vessel, stored on the spent fuel pad, then conditioned and packaged. Conditioning spent nuclear fuel in preparation for disposal would occur in an inert atmosphere hot cell located in the new hot cell facility adjacent to VTR. Containerized spent nuclear fuel would be placed in storage casks and temporarily stored on the new spent fuel pad until shipped to an offsite location (an interim storage facility or a permanent repository when either becomes available for VTR fuel).

[9] DOE defines hazard categories of nuclear facilities by the potential impacts identified by hazard analysis and has identified radiological limits (quantities of material present in a facility) corresponding to the hazard categories. Hazard Category 1—Hazard Analysis shows the potential for significant offsite consequences (reactors fall under this category). Hazard Category 2—Hazard Analysis shows the potential for significant onsite consequences beyond localized consequences. Hazard Category 3—Hazard Analysis shows the potential for only significant localized consequences. Below (Less Than) Hazard Category 3 applies to a nuclear facility containing radiological materials with a final hazard categorization less than Hazard Category 3 facility thresholds.

Under the conceptual design, the existing ORNL infrastructure would be extended to the VTR site. The location selected for the VTR is relatively undeveloped and does not have sufficient infrastructure (*e.g.,* roads, utilities, security) to support construction and operation of the VTR. Radioactive waste would be shipped off site for treatment and/or disposal. Waste management capabilities provided by the project (*e.g.,* treatment or packaging of radioactive liquid waste) and facilities within ORNL would be used to support waste management during construction and operation of the VTR.

Reactor Fuel Production Options

The VTR design envisions the use of metallic fuel. The initial VTR core would consist of a uranium/plutonium/zirconium alloy (U/Pu/Zr) fuel that would be 70 percent uranium (uranium enriched to 5 percent uranium-235), 20 percent plutonium, and 10 percent zirconium—a blend identified as U–20Pu–10Zr. VTR driver fuel used in later operations could consist of these elements in different ratios and could use plutonium with uranium of varying enrichments, including depleted uranium or uranium enriched up to 19.75 percent. Annual heavy metal requirements would be approximately 1.8 metric tons of fuel material (between 1.3 metric tons and 1.4 metric tons of uranium and between 0.4 and 0.54 metric tons of plutonium, depending on the ratio of uranium to plutonium).[10] Feedstock for this fuel could be acquired from several existing sources.

DOE's plan for providing uranium for fabricating VTR driver fuel is to acquire metallic uranium from a domestic commercial supplier. If another source of uranium were to be selected, DOE would conduct a review to determine if additional NEPA analysis would be needed. Other possible sources are DOE managed inventories of excess uranium acquired from many sources, including U.S. defense programs and the former DOE uranium enrichment enterprise. Some of the uranium is enriched and could be down-blended for use in VTR driver fuel.

Existing sources of U.S. excess plutonium[11] managed by DOE and the National Nuclear Security Administration (NNSA) would be sufficient to meet the needs of the VTR project. Potential DOE/NNSA plutonium materials include surplus pit[12] plutonium (*i.e.,* metal), other plutonium metal, oxide, and plutonium from other sources. If the U.S. sources cannot be made available for the VTR project or to supplement the domestic supply, DOE has identified potential sources of plutonium in Europe.

VTR driver fuel production evaluated in the EIS involves two steps or phases: feedstock preparation and fuel fabrication. Depending on the impurities of the source material, a polishing process, or a combination of processes, would be required. These processes would be performed in a series of gloveboxes[13] to limit worker radiological exposure.

Three potential feedstock preparation processes are under consideration: an aqueous capability, a pyrochemical capability, and a combination of the two. In the aqueous process, the plutonium feed (containing impurities) is dissolved in a nitric acid solution and through a series of extraction and precipitation steps, a polished plutonium oxide is produced. The oxide is converted to a metal in a direct oxide reduction process. In one form of the pyrochemical process (molten salt extraction), the metallic plutonium feed is combined with a salt and the mixture raised to the melting point. Impurities (*e.g.,* americium) react with the salt, and the polished plutonium is collected at the bottom of the reaction crucible. If the pyrochemical process were selected, a direct oxide reduction process would also be required to convert plutonium dioxide feeds to plutonium metal. If a combination of the two processes were to be selected, a smaller aqueous line to prepare this fuel could be incorporated into the pyrochemical process.

Fuel fabrication would use an injection casting process to combine and convert the metallic ingots into fuel slugs. In a glovebox, a casting furnace would be used to melt and blend the three fuel components: uranium, plutonium, and zirconium. The molten alloy then would be injected into quartz fuel slug molds. After cooling, the molds would be broken, and the fuel slugs retrieved. Fuel pins would be created, using stainless steel tubes (cladding) into which a slug of solid sodium would be inserted, followed by the alloy fuel slugs. The fuel slugs and sodium would occupy about half of the volume of the fuel pin with the remainder containing argon gas at near atmospheric pressure. The ends of the tubes would be closed with top and bottom end plugs. These activities would take place in gloveboxes with inert atmospheres. Once fully assembled, the fuel pins would be heated sufficiently to melt the sodium and create the sodium bond with the fuel. The sodium-bonded fuel would fill about half the length of the fuel pin. Fuel pins would be assembled into a fuel assembly with each fuel assembly containing 217 fuel pins. Sodium bonding and producing the fuel assemblies would be performed in an open environment. No gloveboxes would be required.

Operationally, the feedstock preparation and fuel fabrication capabilities would need to generate about 66 fuel assemblies for the initial VTR core. Thereafter, the capabilities would need to produce up to 45 fuel assemblies per year.

The EIS evaluates the INL Site and SRS as potential locations for performing the activities necessary for driver fuel production for the VTR. Independently, DOE would establish and operate all or part of the fuel fabrication capability at either site. DOE is not making a decision regarding driver fuel production in this ROD.

Potential Environmental Impacts

Implementation of either the INL VTR Alternative or the ORNL VTR Alternative would generally have small environmental consequences. Overall, the environmental consequences would be smaller at the INL Site for several reasons. The total area that would be temporarily disturbed and the area that would be permanently occupied by the VTR complex would be smaller at the INL Site because of the need to build a new hot cell facility if the VTR were located at ORNL. Unlike the INL Site, the ORNL location abuts wetlands that would have to be avoided or managed in accordance with Clean Water Act and State of Tennessee regulations. The removal of trees at the ORNL location would also result in the loss of roosting habitat for sensitive bat species. The potential radiological impacts would be small at both locations but would be smaller at the INL Site because the VTR would be further from the site boundary and the population density is lower near the INL Site than near ORNL.

[10] The cited quantities are those for finished fuel as it is placed in the reactor and correspond to fuel that is from 20 to 27 percent plutonium. Accounting for additional material that ends up in the waste during the reactor fuel production process, up to 34 metric tons of plutonium could be needed for startup and 60 years of VTR operation.

[11] Excess plutonium includes pit and non-pit plutonium that is no longer needed for U.S. national security purposes.

[12] A pit is the central core of a primary assembly in a nuclear weapon and is typically composed of plutonium metal (mostly plutonium-239), enriched uranium, or both, and other materials.

[13] Gloveboxes are sealed enclosures with gloves that allow an operator to manipulate materials and perform other tasks while keeping the enclosed material contained. In some cases, remote manipulators may be installed in place of gloves. The gloves, glass, and siding material of the glovebox are designed to protect workers from radiation contamination and exposure.

Implementation of the reactor fuel production options at either the INL Site or SRS would generally have small environmental consequences. At both locations, existing facilities would be modified or adapted to provide capabilities for feedstock preparation and fuel fabrication. Disturbance of a minimal area (up to 3 acres) would occur at SRS. Because there is existing staff at the INL Fuel Manufacturing Facility, fewer new employees would need to be hired for fuel fabrication at the INL Site. Potential radiological impacts would be small at both sites, but due to differences in population density and distribution, potential impacts would be somewhat smaller at the INL Site.

Environmentally Preferable Alternative

The No Action Alternative would be the Environmentally Preferable Alternative. Under the No Action Alternative, DOE would not pursue the construction and operation of a VTR. To the extent they are capable and available for testing in the fast-neutron-flux spectrum, DOE would continue to make use of the limited capabilities of existing facilities, both domestic and foreign. Construction and operation of a VTR and associated support facilities would not occur, resulting in less impacts than under the Action Alternatives. However, the No Action Alternative would not meet the purpose and need for a domestic fast-neutron-spectrum testing capability.

Comments on Final VTR EIS

DOE made more than 1,850 notifications of the completion and availability of the Final VTR EIS to Congressional members and committees; states, including Idaho, Tennessee, and South Carolina; Tribal governments and organizations; local governments; other Federal agencies; non-governmental organizations; and individuals. Following issuance of the Final VTR EIS, DOE received four letters and/or emails. DOE considered the comments received following issuance of the Final VTR EIS and finds that they do not present ''significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts'' within the meaning of 40 CFR 1502.9(c) and 10 CFR 1021.314(a), and therefore do not require preparation of a supplement analysis or a supplemental EIS.

DOE addressed two of the emails received—a press inquiry and a process question—directly with the people who submitted them.

A third email/letter received included multiple comments on a variety of topics. One related to the author's Freedom of Information Act request and has no bearing on or relevance to the environmental impacts evaluated in the EIS. It also contained another question of whether the Office of Nuclear Energy would have the ability and funds to establish a VTR fuel fabrication project at SRS. As appropriate, the VTR EIS evaluated the potential environmental impacts of a fuel fabrication capability at SRS; the administrative and funding items are factors DOE would consider when it makes a decision regarding fuel fabrication.

Other comments posed questions about the plutonium for VTR driver fuel fabrication, a nonproliferation assessment, and management of transuranic waste resulting from fuel fabrication activities. Similar topics were raised in comments on the Draft VTR EIS. DOE responded to these comment topics in Volume 3 of the Final VTR EIS and revised the EIS as necessary to fully address these topics commensurate with the stage of project development.

This third letter/email also incorrectly stated that the VTR had been ''terminated'' and the ''EIS [was] improperly issued after termination.'' Additionally, it requested ''that no Record of Decision (ROD) be issued on the project.'' While it is correct that Congress did not appropriate funds for VTR in fiscal year 2022, the Energy Act of 2020, included in the Consolidated Appropriations Act (Pub. L. 116–68), authorized full funding for the VTR project. DOE is following Council on Environmental Quality guidance to integrate NEPA into the planning process early to ensure planning and decisions reflect environmental values, to avoid delays, and to head off potential conflicts. By issuing the Final VTR EIS and ROD, DOE is taking important steps, consistent with the Energy Act of 2020, by deciding whether and where to construct the VTR. In accordance with its authorization in the Energy Act of 2020, DOE will work with Congress to obtain the funding needed to execute this important project.

The fourth letter/email recommended that DOE clarify management approaches for spent driver fuel beyond January 1, 2035. As indicated in the response to comments received from the State of Idaho and as revised in the Final VTR EIS, prior to issuing this ROD, DOE committed to exploring potential approaches with the State of Idaho to clarify and, as appropriate, address potential issues concerning management of VTR spent nuclear fuel beyond January 1, 2035; those discussions are ongoing. Spent driver fuel from the VTR, regardless of whether it was generated before or after January 1, 2035, would be stored within the VTR reactor vessel until decay heat generation is reduced to a level that would allow fuel transfer and storage of the fuel assemblies with passive cooling. After allowing time for additional radioactive decay, the spent fuel would be transferred to a spent nuclear fuel conditioning facility. At the facility, the spent fuel would be chopped, melted, and vacuum distilled to remove the sodium, after which the fuel would be diluted and placed in canisters ready for future disposal. The canisters would be placed in dry storage casks and stored on site in compliance with all regulatory requirements and agreements. This VTR spent nuclear fuel would be managed at the site until it is transported off site to an interim storage facility or a permanent repository.

Decision

DOE has decided to implement its Preferred Alternative as described in the Final VTR EIS. DOE's Preferred Alternative is to construct and operate a VTR at INL, and to establish, through modification and construction, co-located facilities for post-irradiation examination of test products and for management of spent VTR driver fuel at INL.

DOE has not decided whether to establish VTR driver fuel production capabilities for feedstock preparation and fuel fabrication at the INL Site, SRS, or a combination of the two sites. Once a preferred alternative/option for VTR driver fuel production is identified, DOE will announce its preference in an FR notice. DOE would publish a record of decision no sooner than 30 days after its announcement of a preferred alternative/option for VTR driver fuel production.

Basis for the Decision

The Final VTR EIS provided the DOE decision-maker with important information regarding potential environmental impacts of alternatives and options for satisfying the purpose and need. In addition to environmental information, DOE considered other factors including public comments, statutory responsibilities, strategic objectives, technology needs, safeguards and security, cost, and schedule, when making its decision.

Mitigation Measures

No potential adverse impacts were identified that would require additional

mitigation measures beyond those required by regulation and agreements or achieved through design features or best management practices. However, the INL VTR Alternative has the potential to affect one or more resource areas. If during implementation, mitigation measures above and beyond those required by regulations are identified to reduce impacts, they would be developed, documented, and executed.

Signing Authority

This document of the Department of Energy was signed on July 22, 2022, by Robert Boston, Manager, Idaho Operations Office, Office of Nuclear Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with the requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. The administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 29, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–16573 Filed 8–2–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–138–000]

Northern Natural Gas Company; Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Northern Lights 2023 Expansion Project, Request for Comments on Environmental Issues, and Schedule for Environmental Review

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental impact statement (EIS) that will discuss the environmental impacts of the Northern Lights 2023 Expansion Project (Project) involving construction and operation of facilities by Northern Natural Gas Company (Northern) in Freeborn, Scott, Sherburne, Stearns, and Washington Counties, Minnesota, and Monroe County, Wisconsin. The Commission will use this EIS in its decision-making process to determine whether the Project is in the public convenience and necessity. The schedule for preparation of the EIS is discussed in the *Schedule for Environmental Review* section of this notice.

As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as ''scoping.'' By notice issued on May 17, 2022 in Docket No. CP22–138–000, the Commission opened a scoping period to solicit comments. Subsequent to issuance of that notice, Commission staff has determined that it will prepare an EIS for the Project. The EIS will address the concerns raised during the initial scoping process as well as comments received in response to this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document, including comments on potential alternatives and impacts, and any relevant information, studies, or analyses of any kind concerning impacts affecting the quality of the human environment. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on August 29, 2022. Comments may be submitted in written form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

As mentioned above, the Commission opened a scoping period which expired on June 17, 2022; however, Commission staff continued to accept comments after the comment period closed. All substantive written and oral comments provided will be addressed in the EIS. Therefore, if you submitted comments on this Project to the Commission during the previous scoping period, you do not need to file those comments again.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the Project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not grant, exercise, or oversee the exercise of eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

Northern provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' which addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (*www.ferc.gov*) under the Natural Gas Questions or Landowner Topics link.

Public Participation

There are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.*'' You will be asked to select the type of filing you are making; a comment on a particular project is considered a ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP22–138–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal

Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Additionally, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Summary of the Proposed Project, the Project Purpose and Need, and Expected Impacts

According to Northern, the Project would provide for incremental winter firm service of 44,222 dekatherms per day (Dth/day) serving residential, commercial, and industrial customer market growth in Northern's Market Area and 6,667 Dth/day of additional firm service that would allow a shipper enhanced reliability and flexibility in scheduling their transportation capacity.

The Project consists of the following facilities:

- a 2.79-mile extension of 36-inch-diameter Ventura North E-Line, in Freeborn County, Minnesota;
- a 1.07-mile, 30-inch-diameter loop [1] of 20-inch-diameter Elk River 1st and 2nd Branch Lines, in Washington County, Minnesota (Elk River 3rd Branch Line);
- a 1.14-mile extension of 24-inch-diameter Willmar D Branch Line, in Scott County, Minnesota;
- a 2.48-mile extension of 8-inch-diameter Princeton Tie-Over Loop, in Sherburne County, Minnesota;
- a 2.01-mile loop of 4-inch-diameter Paynesville Branch Line, in Stearns County, Minnesota (Paynesville 2nd Branch Line);
- a 0.34-mile extension of 8-inch-diameter Tomah branch line loop, in Monroe County, Wisconsin; and
- aboveground facilities including one new pig [2] launcher, four new valve settings, replacement of valves and piping inside four facilities, removal of three valve settings, and associated piping.

The general location of the Project facilities is shown in appendix 1.[3]

Based on the environmental information provided by Northern, construction of the proposed facilities would disturb about 251.7 acres of land for the aboveground facilities and the pipeline. Following construction, Northern would maintain about 51.9 acres for operation of the Project facilities; the remaining acreage would be restored and could revert to former uses. About 12.4 percent of the construction footprint would overlap with easements for existing Northern facilities.

Based on an initial review of Northern's proposal and public comments received during scoping, Commission staff have identified several expected impacts that deserve attention in the EIS. The Project would impact three waterbodies and about 0.5 acre of wetland. Construction of the Project would have impacts on noise, traffic, and road conditions. In response to the Notice of Scoping, the Commission received multiple comments. Several were supportive of the Project. Others requested that the EIS discuss and provide appropriate details regarding the Project description, purpose and need, alternatives, affected environment, wetlands, surface water, groundwater, air quality, climate change and greenhouse gas emissions, community, social and economic impacts, environmental justice, pollinator habitat, noxious weeds, and noise. Minnesota state agencies requested that the EIS discuss potential impacts on state listed species, calcareous fens, soil compaction, and wellhead protection areas and discussion of appropriate seed mixes, utility crossing licenses, dust abatement, road crossing methods, traffic control, access points, and impacts on highway drainage, vegetation, and other utilities.

The NEPA Process and the EIS

The EIS issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed Project under the relevant general resource areas:

- geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- socioeconomics;
- environmental justice;
- air quality and noise;
- reliability and safety; and
- cumulative impacts.

Commission staff will also make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff focus its analysis on the issues that may have a significant effect on the human environment.

The EIS will present Commission staff's independent analysis of the issues. Staff will prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any draft and final EIS will be available in electronic format in the public record through eLibrary [4] and the Commission's natural gas environmental documents web page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). If eSubscribed, you will receive instant email notification when the environmental document is issued.

Alternatives Under Consideration

The EIS will evaluate reasonable alternatives that are technically and economically feasible and meet the purpose and need for the proposed action.[5] Alternatives currently under consideration include:

- the no-action alternative, meaning the Project is not implemented; and
- minor route deviations for Ventura North E-Line, Elk River 3rd Branch Line, Willmar D Branch Line, Princeton Tie-Over Loop, and Paynesville 2nd Branch Line.

With this notice, the Commission requests specific comments regarding any additional potential alternatives to the proposed action or segments of the proposed action. Please focus your comments on reasonable alternatives (including alternative facility sites and pipeline routes) that meet the Project objectives, are technically and economically feasible, and avoid or lessen environmental impact.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's

[1] A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

[2] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

[3] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary''. For instructions on connecting to eLibrary, refer to the last page of this notice. At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

[4] For instructions on connecting to eLibrary, refer to the last page of this notice.

[5] 40 CFR 1508.1(z).

implementing regulations for section 106 of the National Historic Preservation Act, the Commission initiated section 106 consultation for the Project in the notice issued on May 17, 2022 with the applicable State Historic Preservation Office(s), and other government agencies, interested Indian tribes, and the public to solicit their views and concerns regarding the Project's potential effects on historic properties.[6] This notice is a continuation of section 106 consultation for the Project. The Project EIS will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Schedule for Environmental Review

On April 11, 2022 the Commission issued its Notice of Application for the Project. Among other things, that notice alerted other agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on the request for a federal authorization within 90 days of the date of issuance of the Commission staff's final EIS for the Project. This notice identifies the Commission staff's planned schedule for completion of the final EIS for the Project, which is based on an issuance of the draft EIS in October 2022.

Issuance of Notice of Availability of the final EIS March 10, 2023

90-day Federal Authorization Decision Deadline[7] June 8, 2023

If a schedule change becomes necessary for the final EIS, an additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Permits and Authorizations

The table below lists the anticipated permits and authorizations for the Project required under federal law. This list may not be all-inclusive and does not preclude any permit or authorization if it is not listed here. Agencies with jurisdiction by law and/or special expertise may formally cooperate in the preparation of the Commission's EIS and may adopt the EIS to satisfy its NEPA responsibilities related to this Project. Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

Agency	Permit
Federal Energy Regulatory Commission.	Certificate of Public Convenience and Necessity.
U.S. Army Corps of Engineers—St. Paul District.	Clean Water Act Section 404—Dredge and Fill Permit.
U.S. Fish and Wildlife Service—Twin Cities Field Office.	Endangered Species Act (ESA) Consultation, Migratory Bird Treaty Act (MBTA) Coordination; Bald and Golden Eagle Protection Act (BGEPA) Consultation.
Minnesota Pollution Control Agency	Section 401 Water Quality Certification.
Minnesota State Historic Preservation Office (SHPO).	National Historic Preservation Act (NHPA), Section 106 Consultation.
Wisconsin SHPO	NHPA, Section 106 Consultation.

Environmental Mailing List

This notice is being sent to the Commission's current environmental mailing list for the Project which includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed Project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to *GasProjectAddressChange@ferc.gov* stating your request. You must include the docket number CP22–138–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached ''Mailing List Update Form'' (appendix 2).

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.,* CP22–138). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings. Public sessions or site visits will be posted on the Commission's calendar located at *https://www.ferc.gov/news-events/*

[6] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

[7] The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

events along with other related information.

Dated: July 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–16589 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL22–62–000; EL22–63–000; EL22–64–000; EL22–65–000; (Unconsolidated)]

California Independent System Operator Corporation, ISO New England Inc., New York Independent System Operator, Inc., Southwest Power Pool Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On July 28, 2022, the Commission issued an order in Docket Nos. EL22–62–000, EL22–63–000, EL22–64–000, and EL22–65–000 pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting investigations into whether the existing open access transmission tariffs of California Independent System Operator Corporation, ISO New England Inc., New York Independent System Operator, Inc., and/or Southwest Power Pool Inc. (collectively, Responding RTOs/ISOs) are unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful, and to establish a refund effective date. *Cal. Indep. Sys. Operator Corp.,* 180 FERC ¶ 61,049 (2022).

The refund effective date in each of Docket Nos. EL22–62–000, EL22–63–000, EL22–64–000, and EL22–65–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in any of Docket Nos. EL22–62–000, EL22–63–000, EL22–64–000, and EL22–65–000 must file a notice of intervention or motion to intervene in the relevant proceeding, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2021), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Dated: July 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16617 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2500–000]

DLS—Jean Duluth Project Co, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of DLS—Jean Duluth Project Co, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 17, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16616 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5679–041]

Energy Stream, LLC; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 5679–041.

c. *Date Filed:* July 15, 2022.

d. *Applicant:* Energy Stream, LLC.

e. *Name of Project:* M.S.C. Power Project.

f. *Location:* On the Quinebaug River in Windham County, Connecticut. The project does not occupy any federal land.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Rolland Zeleny, Energy Stream, LLC, 18 Washington St., Suite 18, Canton, MA 02021; Phone at (603) 498–8089, or email at *indigoharbor@yahoo.com.*

i. *FERC Contact:* Robert Haltner at (202) 502–8612, or *robert.haltner@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: September 13, 2022.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. All filings must clearly identify the project name and docket number on the first page: M.S.C. Power Project (P–5679–041).

m. The application is not ready for environmental analysis at this time.

n. *Project Description:* The existing M.S.C. Project consists of: (1) an approximately 256-foot-long, 14.3-foot-high granite block and concrete dam that includes: (a) an approximately 35-foot-long headgate structure with four aluminum sluice gates that are each 4 feet wide by 10 feet high; (b) a 109-foot-long granite block spillway section with a concrete cap, 1.6-foot-high flashboards, and a crest elevation of 288.74 feet mean sea level (msl) at the top of the flashboards; and (c) a 112-foot-long auxiliary concrete gravity spillway section with a crest elevation of 288.94 feet msl; (2) an impoundment with a surface area of 4.7 acres at an elevation of 288.74 feet msl; (3) an approximately 30-foot-wide, 25-foot-long stone and concrete forebay downstream of the headgate structure; (4) an intake structure at the downstream end of the forebay with a 19-foot-wide, 16.5-foot-high trashrack with 1.6-inch clear bar spacing; (5) a 2-foot-wide, 3-foot-high trash sluice gate adjacent to the trashrack; (6) a 21-foot-long, 33-foot-wide steel and reinforced concrete powerhouse containing a 400-kilowatt (kW) Kaplan turbine-generator unit and a 112-kW Francis turbine-generator unit, for a total installed capacity of 512 kW; (7) a 39-foot-long, 28-foot-wide, 10-foot-deep tailrace; (8) 50-foot-long, 2.4-kilovolt (kV) lead lines that connect the generators to three 2.4/23-kV step-up transformers, and a 200-foot-long, 13.8-kV transmission line that connects the transformers to the regional grid; and (9) appurtenant facilities. The project creates an approximately 65-foot-long bypassed reach of the Quinebaug River.

Article 401 of the current license requires Energy Stream, LLC to operate the project in a run-of-river mode, such that project outflow approximates inflow. Energy Stream, LLC maintains the impoundment at the flashboard crest elevation of 288.74 feet msl. To protect aquatic resources, Article 26 of the current license requires Energy Stream, LLC to release a continuous minimum flow of 144 cubic feet per second (cfs) or inflow to the impoundment, whichever is less, as measured immediately below the tailrace. Article 402 of the current license specifies seasonal minimum flow releases to the downstream reach when refilling the impoundment following emergency or maintenance drawdowns, including 90 percent of impoundment inflow.

Article 404 of the current license requires Energy Stream, LLC to provide upstream and downstream passage for American eels. Upstream passage for American eels is provided from June 15 to September 1 by netting placed over the dam and ramps extending to the crest of the flashboards. Downstream American eel passage is provided from September 1 through November 15, on rainy nights and three nights after rain events through a notch in the flashboards located on the west side of the spillway, and a low-level outlet gate.

The minimum and maximum hydraulic capacities of the powerhouse are 40 and 545 cfs, respectively. The average annual generation of the project was approximately 2,885 megawatt-hours from 2017 through 2021.

Energy Stream, LLC is not proposing any changes to project facilities or operation.

o. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (*e.g.,* license application) via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document (P–5679). For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or (202) 502–8659 (TTY).

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects.

For assistance, contact FERC Online Support.

p. *Procedural Schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary) September 2022
Request Additional Information September 2022
Issue Scoping Document 1 for comments December 2022
Request Additional Information (if necessary) December 2022
Issue Acceptance Letter December 2022
Issue Scoping Document 2 (if necessary) February 2023
Issue Notice of Ready for Environmental Analysis February 2023

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: July 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–16592 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5944–024]

Moretown Hydroelectric, LLC; Notice Soliciting Scoping Comments and Extending Comment Period

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Minor License.

b. *Project No.:* 5944–024.

c. *Date filed:* November 30, 2020.

d. *Applicant:* Moretown Hydroelectric, LLC.

e. *Name of Project:* Moretown No. 8 Project.

f. *Location:* On the Mad River, immediately downstream from the Town of Moretown, Washington County, Vermont. The project does not occupy federal land.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Arion Thiboumery, Moretown Hydroelectric, LLC, 1273 Fowler Rd. Plainfield, VT 05667; (415) 260–6890 or email at *arion@ar-ion.net.*

i. *FERC Contact:* Maryam Zavareh at (202) 502–8474, or email at *maryam.zavareh@ferc.gov.*

j. *Deadline for filing scoping comments:* August 29, 2022. The commission is reissuing the notice and extending the comment due date. Due to a mailing error, not all recipients received the original notice.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Moretown Hydroelectric Project (P–5944–024).

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application is not ready for environmental analysis at this time.

l. The project consists of the following existing facilities: (1) a 333-foot-long, 31-foot-high concrete gravity dam with a 164-foot-long overflow spillway and a crest elevation of 524.7 feet; (2) a 36-acre impoundment with a normal maximum elevation of 524.7; (3) a 40-foot-long, 17-foot-wide, 28-foot-high concrete intake structure with a trashrack; (4) a 40-foot-long, 8.5-foot-diameter buried steel penstock; (5) a 39.4-foot-long, 19.7-foot-wide concrete powerhouse containing a single 1.25-megawatt Kaplan turbine-generator unit; (6) a tailrace; (7) a 106-foot-long, 12.5-kilovolt transmission line; and (8) appurtenant facilities. The Moretown Project is operated in a run-of-river mode with an average annual generation of 2,094 megawatt-hours.

Moretown hydroelectric LLC proposes to continue to operate the project in a run-of-river mode.

m. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents 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. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TYY, (202) 502–8659.

n. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Scoping Process.

Commission staff will prepare either an environmental assessment (EA) or an Environmental Impact Statement (EIS) that describes and evaluates the probable effects of the licensee's proposed action and alternatives. The EA or EIS will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action. The Commission's scoping process will help determine the required level of analysis and satisfy the National Environmental Policy Act (NEPA) scoping requirements, irrespective of whether the Commission prepares an EA or an EIS.

At this time, we do not anticipate holding on-site scoping meetings. Instead, we are soliciting written comments and suggestions on the preliminary list of issues and alternatives to be addressed in the NEPA document, as described in scoping document 1 (SD1), issued July 28, 2022.

Copies of the SD1 outlining the subject areas to be addressed in the NEPA document were distributed to the parties on the Commission's mailing list and the applicant's distribution list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call 1–866–208–3676 or for TTY, (202) 502–8659.

Dated: July 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–16591 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2502–000]

DLS—Sylvan Project Co, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of DLS—Sylvan Project Co, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 17, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16614 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15278–000]

Rye Sutton Hydroelectric, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On June 6, 2022, Rye Sutton Hydroelectric, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of hydropower at the existing U.S. Army Corps of Engineers' (Corps) Sutton Dam located on the Elk River in Braxton County, West Virginia. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed Sutton Dam Hydroelectric Project would consist of the following: (1) a new 40-foot-wide, 60-foot-long powerhouse to be located downstream of the Corps dam along the southern bank; (2) a new multiple-port intake structure against the upstream face of the dam; (3) a new 12-foot-diameter, approximately 300-foot-long steel penstock; (4) two turbine-generator units with a total generating capacity of 6 megawatts; (5) a new 100-foot-wide by 300-foot-long tailrace; (6) a new substation with a step-up transformer; (7) a new 550-foot-long, 12-kilovolt transmission line; and (8) appurtenant facilities. The proposed project would have an estimated annual generation of 24,000 megawatt-hours.

Applicant Contact: Michael Rooney, Rye Development, LLC, 100 S. Olive Street, West Palm Beach, FL 33401; phone: (412) 400–4186; Erik Steimle, Rye Development, LLC, 100 S. Olive Street, West Palm Beach, FL 33401; phone: (503) 998–0230.

FERC Contact: Monir Chowdhury; phone: (202) 502–6736.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of the Commission's website at *https://elibrary.ferc.gov/eLibrary/search.* Enter the docket number (P–15278) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: July 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–16593 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR22–4–000]

Bayou Midstream Bakken, LLC; Notice of Request for Temporary Waiver

Take notice that on July 22, 2022, Bayou Midstream Bakken, LLC filed a petition seeking a temporary waiver of the tariff filing and reporting requirements of sections 6 and 20 of the Interstate Commerce Act and Parts 341 and 357 of the Federal Energy Regulatory Commission's regulations (Commission), all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene, or protest must serve a copy of that document on the Petitioner.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact 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 ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern time on August 22, 2022.

Dated: July 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16611 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR22–56–000.
Applicants: Hope Gas, Inc.
Description: § 284.123(g) Rate Filing: HGI—2020 WV PSC Base Rate Case Petition for Reconsideration to be effective 7/1/2022.
Filed Date: 7/27/22.
Accession Number: 20220727–5128.
Comment Date: 5 p.m. ET 8/17/22.
284.123(g) Protests Due: 5 p.m. ET 9/26/22.

Docket Numbers: RP22–1065–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: Compliance filing: 7.27.22 Petition for Approval of 2022 Rate Settlement to be effective N/A.
Filed Date: 7/27/22.
Accession Number: 20220727–5033.
Comment Date: 5 p.m. ET 8/8/22.

Docket Numbers: RP22–1066–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreements Update (SRP Sept 2022) to be effective 9/1/2022.
Filed Date: 7/27/22.
Accession Number: 20220727–5054.
Comment Date: 5 p.m. ET 8/8/22.

Docket Numbers: RP22–1067–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement—8/1/2022 to be effective 8/1/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5013.
Comment Date: 5 p.m. ET 8/9/22.

Docket Numbers: RP22–1068–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Remove Expired Negotiated Rate Service Agreements to be effective 8/28/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5018.
Comment Date: 5 p.m. ET 8/9/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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: July 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16618 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2501–000]

DLS—Laskin Project Co, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of DLS—Laskin Project Co, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of

future issuances of securities and assumptions of liability, is August 17, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16615 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15276–000]

Rye Hildebrand Hydroelectric, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On June 6, 2022, Rye Hildebrand Hydroelectric, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Hildebrand Lock/Dam Hydroelectric Project to be located at the existing U.S. Army Corps of Engineers Pittsburgh District Hildebrand Lock/Dam located on the Monongahela River at Hilderbrand, Monongalia County, West Virginia. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) a 405-acre impoundment with a normal volume of 7,600 acre-feet at a normal maximum surface elevation of 835.0 feet mean sea level; (2) an existing 649-foot-long, 64-foot-high concrete gravity dam with a 600-foot-long, 84-foot-wide lock and six 60-foot-wide, 21-foot-high tainter gates; (3) a new 100-foot-long, 70-foot-wide intake section with trashracks; (4) two new 3-megawatt horizontal Kaplan bulb turbine/generator units; (5) a new 90-foot-long, 60-foot-wide concrete powerhouse; (6) a new three-phase, 36.7-kilovolt (kV), 1,000-foot-long transmission line; (7) a new 50-foot-long, 50-foot-wide substation with a new 10-megavolt-amperes 4.16/36.7-kV three-phase step-up transformer; (8) a new 150-foot-long, 70-foot-wide tailrace; and (9) appurtenant facilities. The proposed project would have an annual generation of 28,000 megawatt-hours.

Applicant Contact: Michael Rooney, Rye Hildebrand Hydroelectric, LLC, 100 S Olive Street, West Palm Beach, FL 33401; phone: (412) 400–4186.

FERC Contact: Woohee Choi; email: *woohee.choi@ferc.gov;* phone: (202) 502–6336.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–15276–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–15276) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: July 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–16594 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC22–24–000]

Commission Information Collection Activities (FERC–725Z); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently

approved information collection, FERC–725Z (Mandatory Reliability Standards: IRO Reliability Standards).

DATES: Comments on the collection of information are due October 3, 2022.

ADDRESSES: You may submit your comments (identified by Docket No. IC22–24–000) by one of the following methods:

Electronic filing through *https://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:
  - *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.
  - *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *https://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *https://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725Z (Mandatory Reliability Standards: IRO Reliability Standards).

OMB Control No.: 1902–0276.

Type of Request: Extension to this currently approved information collection.

Abstract: On August 8, 2005, The Electricity Modernization Act of 2005, which is Title XII of the Energy Policy Act of 2005 (EPAct 2005), was enacted into law.[1] Under section 215 of the Federal Power Act (FPA) implemented in 18 CFR 40, the Commission requires a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards[2], which are subject to Commission review and approval. In 2006, the Commission established a process to select and certify an ERO and, subsequently, certified the North American Electric Reliability Corporation (NERC) as the ERO.[3]

The ERO develops proposed Reliability Standards[4] and, if approved by NERC, submits them to the Commission for review and approval. When the standards are approved by the Commission, the Reliability Standards become mandatory and must be enforced by the ERO, subject to Commission oversight.

NERC established the following IRO standards within FERC–725Z:

IRO–001–4 purpose is to establish the responsibility of Reliability Coordinators to act or direct other entities to act.

In a joint petition dated May 30, 2019, the North American Electric Reliability Corporation (''NERC'') and Western Electricity Coordinating Council (''WECC'') requested Commission approval for Reliability Standard IRO–002–6 (now IRO–002–7) (Reliability Coordination, Monitoring and Analysis). NERC and WECC stated that the ''Reliability Standard IRO–002–7 reflects the addition of a regional Variance containing additional requirements applicable to Reliability Coordinators providing service to entities in the Western Interconnection.'' NERC maintains that the data exchange capability requirement in Reliability Standard IRO–002–7, Requirement R1 is covered by Reliability Standard IRO–008–2, Requirement R1, which obligates the reliability coordinator to perform operational planning analyses to assess whether the planned operations for the next-day will exceed System Operating Limits and Interconnection Reliability Operating Limits within its Wide Area. NERC asserts that ''to perform the required operational planning analyses, the Reliability Coordinator must have the data it deems necessary from those entities that possess it.''

Currently effective IRO–009–2 applicable to reliability coordinators and the purpose of the standard is to prevent instability, uncontrolled separation, or cascading outages that adversely impact the reliability of the interconnection by ensuring prompt action to prevent or mitigate instances of exceeding Interconnection Reliability Operating Limits (IROLs).

Additionally, regarding data exchange, NERC cites Reliability Standard IRO–010–2 (Reliability Coordinator Data Specification and Collection) and its stated purpose of preventing instability, uncontrolled separation, or cascading outages ''by ensuring the Reliability Coordinator has the data it needs to monitor and assess the operation of its Reliability Coordinator Area.'' NERC states that under Reliability Standard IRO–010–2, Requirements R1, R2 and R3, the reliability coordinator must specify the data necessary for it to perform its operational planning analyses and provide the specifications to the entities from which it needs data who then must comply with the data request using a mutually agreeable format and security protocols.

IRO–014–3 purpose is to ensure that each Reliability Coordinator's operations are coordinated such that they will not adversely impact other Reliability Coordinator Areas and to preserve the reliability benefits of interconnected operations.

IRO–017–1 (Outage Coordination) purpose is to ensure that outages are properly coordinated in the Operations Planning time horizon and Near-Term Transmission Planning Horizon. Reliability coordinators, planning coordinators, balancing authorities, transmission owners and transmission planners are applicable entities for IRO–017–1.

IRO–018–1 (Reliability Coordinator Real-time Reliability Monitoring and Analysis Capabilities), submitted by North American Electric Reliability Corporation (NERC). Requirement R3 requires reliability coordinators to have an alarm process monitor that provides notification to system operators when the failure of a real-time monitoring alarm processor has occurred. In this order, the Reliability Standards build on monitoring, real-time assessments and support effective situational awareness. The Reliability Standards accomplish this by requiring applicable entities to:

[1] The Energy Policy Act of 2005 (EPAct), Public Law No 109–58, Title XII, Subtitle A, 119 Stat. 594, 941 (2005), codified at 16 U.S.C. 824o (2000).

[2] The Federal Power Act (as modified by the EPAct) states ''[t]he terms ''reliability standard'' means a requirement, approved by the Commission under this section, to provide for reliable operation of the bulk-power system. The term includes requirements for the operation of existing bulk-power system facilities, including cybersecurity protection, and the design of planned additions or modifications to such facilities to the extent necessary to provide for reliable operation of the bulk-power system, but the term does not include any requirement to enlarge such facilities or to construct new transmission capacity or generation capacity.''

[3] North American Electric Reliability Corp., 116 FERC ¶ 61,062, order on reh'g and compliance, 117 FERC ¶ 61,126 (2006), order on compliance, 118 FERC ¶ 61,190, order on reh'g, 119 FERC ¶ 61,046 (2007), aff'd sub nom. *Alcoa Inc.* v. *FERC*, 564 F.3d 1342 (D.C. Cir. 2009).

[4] The NERC Standard Processes Manual, Appendix 3A of the NERC Rules Of Procedure, (posted at *https://www.nerc.com/FilingsOrders/us/RuleOfProcedureDL/SPM_Clean_Mar2019.pdf*) describes the process for developing, modifying, withdrawing, or retiring a Reliability Standard.

(1) provide notification to operators of real-time monitoring alarm failures; (2) provide operators with indications of the quality of information being provided by their monitoring and analysis capabilities; and (3) address deficiencies in the quality of information being provided by their monitoring and analysis capabilities.

NERC observes that the performance of the requirements it cites is premised on the existence of data exchange capabilities, regardless of whether a separate requirement expressly requires the reliability coordinator to have data exchange capabilities in place. In review the 725Z collection for the IRO Reliability Standards, the number of entities/respondents was checked and broken down into the appliable type of entity for each reliability standard. In the past combining reliability standards caused the same reliability standard to be accounted for multiple times, resulting in the previously recorded 6,686 responses. These numbers were revised and updated to be the new calculated total of 953 responses. Staff looked at each reliability standard as its own unique project and in doing so eliminated the multiple entity count by making a more accurate representation of the number of responses.

Type of Respondents: Reliability coordinators (RC), planning coordinators (PC), balancing authorities (BA), transmission owners (TO), transmission planners (TP), Transmission Operators (TOP) are included entities for *Estimate of Annual Burden:*[5] The Commission estimates the changes in the annual public reporting burden and cost[6] as follows.

FERC–725Z—Reporting and Recordkeeping Requirements for Reliability Standards IRO–001, IRO–002, IRO–008, IRO–009, IRO–010, IRO–014, IRO–017, and IRO–018

Information collection requirements	Number of respondents & type of entity (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hours & cost per response ($) (4)	Total annual burden hours & total annual cost ($) (3) * (4) = (5)	Total annual burden cost (5)/(1)
IRO–001–4	12 (RC)	1	12	24 hrs. $1,731.6	288 hrs. $20,779.2	$1,731.6
	168 (TOP)	1	168	12 hrs. 865.8	2,016 hrs. 145,454.4	865.8
IRO–002–7	12 (RC)	1	12	24 hrs., 1,731.6	288 hrs., 20,779.2	1,731.6
IRO–008–2	12 (RC)	1	12	160 hrs., 11,544	1,920 hrs., 138,528	11,544
IRO–009–2	12 (RC)	1	12	12 hrs. 865.8	144 hrs. 10,389.6	865.8
IRO–010–3	12 (RC)	1	12	24 hrs., 1,731.6	288 hrs., 20,779.2	1,731.6
IRO–014–3	12 (RC)	1	12	12 hrs., 865.8	144 hrs., 10,389.6	865.8
IRO–017–1	12 (RC)	1	12	1,200 hrs., 86,580	14,400 hrs., 1,038,960.	86,580
	63 (PC)	1	63	96 hrs., 6,926.4	6,048 hrs., 436,363.2	6,926.4
	204 (TP)	1	204	96 hrs., 6,926.4	19,584 hrs., 1,412,985.6.	6,926.4
	326 (TO)	1	326	8 hrs, 577.2	2,608 Hrs., 188,167.2	577.2
	96 (BA)	1	96	8 hr., 577.2	758 hrs., 54,689.7	577.2
IRO–018–1	12 (RC)	1	12	34 hrs., 2,453.1	288 hrs., 20,779.2	$2,453.1
Total for FERC–725Z			953		48,774 hrs., 3,519,044.1.	

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–16590 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC22–25–000]

Commission Information Collection Activities (FERC–725P1); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–725P1 (Mandatory Reliability Standards: PRC–005–6 Reliability Standard).

DATES: Comments on the collection of information are due October 3, 2022.

ADDRESSES: You may submit your comments (identified by Docket No. IC22–25–000) by one of the following methods:

[5] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. For further explanation of what is included in the information collection burden, refer to 5 Code of Federal Regulations 1320.3.

[6] The hourly cost figures, for salary plus benefits, for the new standards are based on Bureau of Labor Statistics (BLS) information (at *http://www.bls.gov/oes/current/naics2_22.htm*), as of May 2021, and benefits information for March 2021 (at *https://www.bls.gov/news.release/ecec.nr0.htm*). For salary plus benefits, for reporting requirements, an electrical engineer (code 17–2071) is $72.15/hour; for the recordkeeping requirements.

Electronic filing through *http://www.ferc.gov,* is preferred.

• *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

• For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

○ Mail via U.S. Postal Service Only, Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (including courier) delivery: Deliver to:* Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725P1 (Mandatory Reliability Standards: PRC–005–6 Reliability Standard).

OMB Control No.: 1902–0280.

Abstract: The Commission requires the information collected by the FERC–725P1 to implement the statutory provisions of section 215 of the Federal Power Act (FPA). On August 8, 2005, Congress enacted into law the Electricity Modernization Act of 2005, which is Title XII, Subtitle A, of the Energy Policy Act of 2005 (EPAct 2005). EPAct 2005 added a new section 215 to the FPA, which required a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by the ERO subject to Commission oversight, or the Commission can independently enforce Reliability Standards.

On February 3, 2006, the Commission issued Order No. 672, implementing section 215 of the FPA. Pursuant to Order No. 672, the Commission certified one organization, North American Electric Reliability Corporation (NERC), as the ERO. The Reliability Standards developed by the ERO and approved by the Commission apply to users, owners and operators of the Bulk-Power System as set forth in each Reliability Standard.

On November 13, 2015, the North American Electric Reliability Corporation filed a petition for Commission approval of proposed Reliability Standard PRC–005–6 (Protection System, Automatic Reclosing, and Sudden Pressure Relaying Maintenance).

NERC also requested approval of the proposed implementation plan for PRC–005–6, and the retirement of previous versions of Reliability Standard PRC–005.

NERC explained in its petition that Reliability Standard PRC–005–6 represented an improvement upon the most recently-approved version of the standard, PRC–005–4.

FERC approved the proposed Reliability Standard PRC–005–6 on December 18, 2015.

Type of Respondent: Transmission Owner (TO), Distribution Provider (DP), and Generator Owners (GOs).

Estimate of Annual Burden: [1] The Commission estimates the annual public reporting burden for the information collection as: [2]

FERC–725P1: MANDATORY RELIABILITY STANDARDS: PRC–005–6 [3]

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hrs. & cost per response [4] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)
PRC–005–6 Reliability Standard.	TO (332)	1	332	2 hrs.; $144.30	664 hrs.; $47,907.60.
	GO (1094)	1	1094	2 hrs.; $144.30	2,188 hrs.; *$157,864.20.
	DP (302)	1	302	2 hrs.; $144.30	604 hrs.; $43,578.60.
			1,728		3,456 hrs.; $249,350.40.

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–16588 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

[1] "Burden" is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to Title 5 Code of Federal Regulations 1320.3.

[2] Total number of responses have increased due an accurate estimate in burden and due to an increase in review and adjustment of existing program for reclosing relays and associated equipment.

[3] Entities affected by the PRC–005–6 Reliability Standard are registered to serve any of the following roles: TO=Transmission Owner; GO=Generator Owner; DP=Distribution Provider. Some entities are registered to serve multiple roles.

[4] The estimated hourly cost (salary plus benefits) provided in this section is based on the salary figures (*http://www.bls.gov/oes/current/naics2_22.htm*) and benefits (*http://www.bls.gov/news.release/ecec.nr0.htm*) for May 2021 posted by the Bureau of Labor Statistics for the Utilities sector. The hourly estimates for salary plus benefits are $72.15/hour based on the Electrical Engineering career (Occupation Code: 17–2071).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Docket Numbers: EG22–192–000.
Applicants: Brotman Generating, LLC.
Description: Brotman Generating, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 7/28/22.
Accession Number: 20220728–5140.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: EG22–193–000.
Applicants: Mark One II, LLC.
Description: Mark One II, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 7/28/22.
Accession Number: 20220728–5141.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: EG22–194–000.
Applicants: Brotman II, LLC.
Description: Brotman II, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 7/28/22.
Accession Number: 20220728–5152.
Comment Date: 5 p.m. ET 8/18/22.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–80–000.
Applicants: American Municipal Power, Inc., Office of the People's Counsel for the District of Columbia, PJM Industrial Customer Coalition.
Description: Complaint of American Municipal Power, Inc., Office of the People's Counsel for the District of Columbia, et al. v. PJM Interconnection, L.L.
Filed Date: 7/26/22.
Accession Number: 20220726–5153.
Comment Date: 5 p.m. ET 8/15/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–995–002; ER17–814–003; ER19–367–003.
Applicants: Pixelle Specialty Solutions LLC, Pixelle Energy Services LLC, Pixelle Androscoggin LLC.
Description: Notice of Non-Material Change in Status of Pixelle Specialty Solutions LLC, et al.
Filed Date: 7/27/22.
Accession Number: 20220727–5126.
Comment Date: 5 p.m. ET 8/17/22.
Docket Numbers: ER17–1320–003; ER17–2281–002; ER17–2282–002; ER19–135–002; ER20–64–002; ER20–65–002; ER21–653–002; ER21–654–002; ER21–856–003; ER21–857–003; ER21–1396–001; ER21–1397–001; ER21–2689–001; ER21–2690–001; ER21–2764–001; ER21–2769–001; ER22–19–001; ER22–20–001; ER22–215–001; ER22–216–001.
Applicants: PGR 2021 Lessee 2, LLC, Beulah Solar, LLC, PGR 2021 Lessee 1, LLC, Stanly Solar, LLC, PGR 2021 Lessee 7, LLC, Highest Power Solar, LLC, PGR 2021 Lessee 5, LLC, Lick Creek Solar, LLC, PGR 2020 Lessee 8, LLC, Sugar Solar, LLC, Trent River Solar, LLC, Trent River Solar Mile Lessee, LLC, PGR Lessee O, LLC, Centerfield Cooper Solar, LLC, TWE Bowman Solar Project, LLC, PGR Lessee L, LLC, Peony Solar LLC, Champion Solar, LLC, Swamp Fox Solar, LLC, Odyssey Solar, LLC.
Description: Notice of Non-Material Change in Status of Odyssey Solar, LLC, et al.
Filed Date: 7/27/22.
Accession Number: 20220727–5159.
Comment Date: 5 p.m. ET 8/17/22.

Docket Numbers: ER17–1985–001.
Applicants: Howard Wind LLC.
Description: Notice of Non-Material Change in Status of Howard Wind LLC.
Filed Date: 7/27/22.
Accession Number: 20220727–5122.
Comment Date: 5 p.m. ET 8/17/22.

Docket Numbers: ER22–2504–000.
Applicants: Duke Energy Progress, LLC.
Description: § 205(d) Rate Filing: DEP—Certificate of Concurrence to the CRSG Operating Manual to be effective 10/1/2022.
Filed Date: 7/27/22.
Accession Number: 20220727–5115.
Comment Date: 5 p.m. ET 8/17/22.

Docket Numbers: ER22–2505–000.
Applicants: Big Sky Wind, LLC.
Description: § 205(d) Rate Filing: Normal filing 2022 July to be effective 7/28/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5002.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2506–000.
Applicants: Vitol Inc.
Description: § 205(d) Rate Filing: Normal filing 2022 July to be effective 7/28/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5003.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2507–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Notice of Cancellation of WMPA SA No. 5842; Queue No. AF2–286 to be effective 8/27/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5023.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2508–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) Rate Filing: 2022–07–28 PSCo-PRPA-Avery SS–IA–406–0.0.0 to be effective 7/29/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5026.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2509–000.
Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: American Transmission Systems, Incorporated submits tariff filing per 35.13(a)(2)(iii: ATSI Submits Revised IA No. 3992 to be effective 9/27/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5034.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2510–000.
Applicants: The Narragansett Electric Company.
Description: § 205(d) Rate Filing: Narragansett Amended MBR Tariff FERC Electric Tariff No. 2 to be effective 5/25/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5037.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2511–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2022–07–28_SA 3873 ITC Midwest-Elk Creek GIA (J1164) to be effective 9/27/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5044.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2512–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Rate Schedule No. 310, JUOM&R Agreement with APS & AES to be effective 9/28/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5092.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2513–000.
Applicants: Deerfield Wind Energy 2, LLC.
Description: Initial rate filing: Application for Market-Based Rate, Waivers and Authority to be effective 8/15/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5094.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2514–000.
Applicants: Arizona Public Service Company.
Description: Tariff Amendment: Service Agreement No. 388, Notice of Cancellation to be effective 9/27/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5100.
Comment Date: 5 p.m. ET 8/18/22/.

Docket Numbers: ER22–2515–000.
Applicants: American Electric Power Service Corporation, Indiana Michigan Power Company, AEP Indiana Michigan Transmission Company, Inc., PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: American Electric Power Service Corporation submits tariff filing per 35.13(a)(2)(iii: AEP submits amended Billing Agent Agreement SA No. 5677 to be effective 10/1/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5107.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2516–000.
Applicants: Chaves County Solar II, LLC.
Description: Request for Limited Waiver, et al. of Chaves County Solar II, LLC.
Filed Date: 7/28/22.
Accession Number: 20220728–5114.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2517–000.
Applicants: Black Hills Colorado Electric, LLC.
Description: § 205(d) Rate Filing: Certificate of Concurrence to JDA with PSCo and PRPA to be effective 8/1/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5120.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2518–000.
Applicants: Clearwater Wind I, LLC.
Description: Baseline eTariff Filing: Clearwater Wind I, LLC Application for Market-Based Rate Authorization to be effective 9/27/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5127.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2519–000.
Applicants: Bellflower Solar 1, LLC.
Description: Baseline eTariff Filing: Petition for MBR Tariff, Waivers, Blanket Authority, and Expedited Treatment to be effective 10/1/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5132.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2520–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Notice of Cancellation of WMPA, SA No. 6059; Queue No. AG1–065 re: withdrawal to be effective 8/23/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5139.
Comment Date: 5 p.m. ET 8/18/22.

Docket Numbers: ER22–2521–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Notice of Cancellation of WMPA, SA No. 5762; Queue No. AF2–282 re: withdrawal to be effective 8/27/2022.
Filed Date: 7/28/22.
Accession Number: 20220728–5148.
Comment Date: 5 p.m. ET 8/18/22.

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: July 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–16619 Filed 8–2–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Washoe Project, Stampede Division—Rate Order No. WAPA–201

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of rate order concerning non-firm power formula rate.

SUMMARY: The non-firm power formula rate for the Washoe Project, Stampede Division (Provisional Formula Rate) has been confirmed, approved, and placed into effect on an interim basis. The Provisional Formula Rate is unchanged from the existing Washoe Project formula rate in Rate Schedule SNF–7, which expires on September 30, 2022.

DATES: The Provisional Formula Rate under Rate Schedule WSH–1 is effective on the first day of the first full billing period beginning on or after October 1, 2022, and will remain in effect through September 30, 2027, pending confirmation and approval by the Federal Energy Regulatory Commission (FERC) on a final basis or until superseded.

FOR FURTHER INFORMATION CONTACT: Sonja Anderson, Regional Manager, Sierra Nevada Region, Western Area Power Administration, 114 Parkshore Drive, Folsom, California 95630, or Autumn Wolfe, Rates Manager, Sierra Nevada Region, Western Area Power Administration, (916) 353–4686 or email: *SNR-RateCase@wapa.gov.*

SUPPLEMENTARY INFORMATION: On April 16, 2009, FERC approved and confirmed the Sierra Nevada Region Washoe Project, Stampede Division's non-firm power formula rate, Rate Schedule SNF–7, under Rate Order No. WAPA–136, on a final basis through July 31, 2013.[1] FERC subsequently approved two consecutive 5-year rate extensions, extending the rate through September 30, 2022.[2] This rate schedule applies to the Washoe Project, Stampede Division. Western Area Power Administration (WAPA) published a **Federal Register** notice (Proposed FRN) on April 5, 2022 (87 FR 19678), proposing no changes from the existing Washoe Project, Stampede Division non-firm power formula rate in Rate Schedule SNF–7, which expires on September 30, 2022. The Proposed FRN also initiated a public consultation and comment period and set forth the date and location of the public information and public comment forums.

Legal Authority

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the WAPA Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve on a final basis, remand, or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2022–2, effective June 13, 2022, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2022, effective June 13, 2022, the Under Secretary for Infrastructure redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This rate action is issued under Redelegation Order No. S3–DEL–WAPA1–2022 and Department of Energy procedures for public

[1] Order Confirming and Approving Rate Schedule on a Final Basis, FERC Docket No. ER08–5161–000, 127 FERC ¶ 62,043 (2009).

[2] Orders Confirming and Approving Rate Schedule on a Final Basis, FERC Docket No. EF13–5–000, 144 FERC ¶ 62,213 (2013) and FERC Docket No. EF17–1–000, 159 FERC ¶ 62,047 (2017).

participation in rate adjustments outlined in 10 CFR part 903.[3]

Following a review of the Sierra Nevada Region's proposal, I hereby confirm, approve, and place Rate Order No. WAPA–201, which provides the non-firm power formula rate for the Washoe Project, Stampede Division into effect on an interim basis. WAPA will submit Rate Order No. WAPA–201 to FERC for confirmation and approval on a final basis.

DEPARTMENT OF ENERGY ADMINISTRATOR, WESTERN AREA POWER ADMINISTRATION

In the Matter of: Western Area Power Administration, Sierra Nevada Region, Rate Adjustment for the Washoe Project, Stampede Division, Non-Firm Power Formula Rate.

Rate Order No. WAPA–201

ORDER CONFIRMING, APPROVING, AND PLACING THE NON-FIRM POWER FORMULA RATE FOR THE WASHOE PROJECT, STAMPEDE DIVISION INTO EFFECT ON AN INTERIM BASIS

The non-firm power formula rate in Rate Order No. WAPA–201 is established following section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152).[4]

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the WAPA Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2022–2, effective June 13, 2022, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2022, effective June 13, 2022, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This rate action is issued under Redelegation Order No. S3–DEL–WAPA1–2022 and DOE procedures for public participation in rate adjustments set forth at 10 CFR part 903.[5]

Acronyms, Terms, and Definitions

As used in this Rate Order, the following acronyms, terms, and definitions apply:

Customer Rate Brochure: A document prepared for public distribution explaining the rationale and background for the information contained in this rate order.

DOE Order RA 6120.2: Department of Energy Order outlining the power marketing administration financial reporting and rate-making procedures.

Energy: Measured in terms of the work it is capable of doing over a period of time. Electric energy is usually measured in kilowatt-hours or megawatt-hours.

NEPA: National Environmental Policy Act of 1969, as amended.

Non-Firm: Delivery or receipt of the power may be interrupted for any reason without liability on the part of either buyer or seller.

Power: Capacity and energy.

Preference: The provisions of Reclamation Law that require WAPA to first make Federal Power available to certain entities. For example, section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)) states that preference in the sale of Federal Power shall be given to municipalities and other public corporations or agencies and also to cooperatives and other nonprofit organizations financed in whole or in part by loans made under the Rural Electrification Act of 1936.

Provisional Formula Rate: A formula rate confirmed, approved, and placed into effect on an interim basis by the Secretary or his/her designee.

PRS: Power Repayment Study, as defined in DOE Order RA 6120.2 and used for the rate adjustment period, is a tool used to determine if the projected power revenue for each project is adequate to meet the annual revenue requirement. The PRS is used to calculate how much revenue is needed to meetannual investment obligations, O&M expenses, and repayment requirements (including repayment periods).

Webex: Webex is an online secure invite-only meeting platform used by WAPA. The general website is *https://doe.webex.com.*

Effective Date

The Provisional Formula Rate Schedule WSH–1 will take effect on the first day of the first full billing period beginning on or after October 1, 2022, and will remain in effect through September 30, 2027, pending approval by FERC on a final basis or until superseded.

Public Notice and Comment

Sierra Nevada Region followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions, 10 CFR part 903, in developing this non-firm power formula rate. Following are the steps Sierra Nevada Region took to involve interested parties in the rate process:

1. On April 5, 2022, a **Federal Register** notice (87 FR 19678) (Proposed FRN) announced the proposed non-firm power formula rate and launched a 60-day public consultation and comment period.

2. On April 5, 2022, the Sierra Nevada Region notified Preference Customers and interested parties of the proposed rate and provided a copy of the published Proposed FRN.

3. On April 22, 2022, the Sierra Nevada Region held a public information forum via Webex. Sierra Nevada Region's representatives explained the proposed non-firm power formula rate, answered questions, and gave notice that more information was available in the Customer Rate Brochure.

4. On April 22, 2022, the Sierra Nevada Region held a public comment forum to provide an opportunity for customers and other interested parties to comment for the record.

5. Sierra Nevada Region published a website that contains all dates, customer letters, presentations, comments, FRNs, Customer Rate Brochure, and other information about this rate process. The website is located at *www.wapa.gov/regions/SN/rates/Pages/Rate-Case-2022–WAPA–201.aspx.*

6. During the 60-day consultation and comment period, which ended on June 6, 2022, the Sierra Nevada Region received no oral comments and no written comments.

Supplementary Information

Stampede Dam and Reservoir are located on the Little Truckee River in Sierra County, California, about 11 miles northeast of the town of Truckee. The Washoe Project was designed to improve the regulation of runoff from the Truckee and Carson River system and to provide supplemental irrigation

[3] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

[4] This Act transferred to, and vested in, the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch.1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)); and other acts that specifically apply to the project involved.

[5] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

water and drainage, as well as water for municipal, industrial, fishery use, flood protection, fish and wildlife benefits, and recreation. The Stampede Powerplant provides the economic equivalent of project-use power to Lahontan and Marble Bluff fish facilities.

When the Stampede Dam and Reservoir project was first authorized, under Public Law 84–858, on August 1, 1956, hydroelectric power development was included. During the period 1966 to 1970, when Stampede Dam was built, power facilities were not constructed because the power function was not economically justified. Provisions were made to facilitate the addition of power facilities at a later date.

In July 1976, a preliminary reevaluation of a powerplant at Stampede was conducted and published in a special U.S. Department of Interior, Bureau of Reclamation (Reclamation) report, *Adding Powerplants at Existing Federal Dams in California.* In the report, Reclamation recommended the construction of a Stampede Powerplant. As a result, definitive plan studies were initiated in Fiscal Year 1977, and construction of the powerplant was completed in 1987. A one-half-mile, 60-kilovolt transmission line, owned by Sierra Pacific Power Company (Sierra Pacific), interconnects the Stampede power facilities with Sierra Pacific's transmission system.

Under section 205(c) of the Fallon Paiute Shoshone Indian Tribes Water Rights Settlement Act of 1990, Congress declared all Washoe Project costs non-reimbursable except the Stampede Powerplant.[6] This was necessary because a 1982 court order requires that Stampede be operated for the benefit of endangered or threatened fish at Pyramid Lake.[7] The energy generated by the powerplant has a priority reservation for designated Washoe Project loads. All remaining energy generation is sold on a non-firm basis under the conditions outlined in the Sierra Nevada Region's contract with a third-party contractor. Energy generated at Stampede Powerplant is dependent on the run of the river and is therefore considered non-firm.

Since the Washoe Project has no Federally owned transmission lines, Sierra Nevada Region contracted with Truckee Donner Public Utility District and the City of Fallon (TDF) to accept Stampede generation and serve project use loads. Energy in excess of project use loads is marketed with the Central Valley Project (CVP) under the 2004 and 2025 Power Marketing Plans. Under the provisional Rate Schedule WSH–1, each year any remaining reimbursable expenses that exceed the revenue collected under the TDF contract are transferred to the CVP and incorporated into the CVP power revenue requirement (PRR). CVP customers that participate in the Renewable Energy Credit (REC) program receive a share of the annual Stampede RECs based on the annual percentage of CVP revenue transferred to the Washoe Project.

Stampede Non-Firm Power Formula Rate

There are no changes from the existing formula rate to the Provisional Formula Rate. The Provisional Formula Rate for Stampede's non-firm power is designed to recover an annual revenue requirement that includes investment repayment, interest, purchase power, reimbursable operation and maintenance expenses, and other expenses. The Provisional Formula Rate for Stampede power is:

Stampede Annual Transferred PRR = Stampede Annual PRR − Stampede Revenue

Where:

Stampede Annual Transferred PRR = Stampede Annual PRR identified as a cost transferred to the CVP.

Stampede Annual PRR = the total PRR for Stampede required to repay all annual costs, including interest, and the investment within the allowable period.

Stampede Revenue = Revenue from applying the Stampede Energy Exchange Account (SEEA) rate to project generation.

The SEEA is an annual energy exchange account for Stampede energy. Under the contract, TDF accepts delivery of all energy generated from Stampede and integrates this generation into its resource portfolio. The monthly calculation of revenue from Stampede energy received by TDF is credited into the SEEA. WAPA can use the SEEA revenue to benefit project use facilities and market energy from Stampede to CVP preference entities.

In the SEEA, the revenues from sales (generation revenues) are reduced by the project use costs, station service power costs, and SEEA administrative costs. WAPA applies the ratio of project use cost to the generation revenue recorded in the SEEA to determine a non-reimbursable percentage. One hundred percent minus the non-reimbursable percentage establishes a reimbursable percentage. This reimbursable percentage is then applied to the appropriate power-related costs to determine the reimbursable costs for repayment. The reimbursable costs are then netted against generation revenues made at the SEEA rate.

Comments

Sierra Nevada Region received no oral or written comments during the public consultation and comment period.

Certification of Rates

I have certified that the Provisional Formula Rate for the Washoe Project, Stampede Division under Rate Schedule WSH–1 is the lowest possible rate, consistent with sound business principles. The Provisional Formula Rate was developed following administrative policies and applicable laws.

Availability of Information

Information about this rate adjustment, including the Customer Rate Brochure, PRS, comments, letters, memorandums, and other supporting materials that were used to develop the Provisional Formula Rate, is available for inspection and copying at the Sierra Nevada Regional Office, 114 Parkshore Drive, Folsom, California. Many of these documents are also available on WAPA's website at *www.wapa.gov/regions/SN/rates/Pages/Rate-Case-2022-WAPA-201.aspx.*

Ratemaking Procedure Requirements

Environmental Compliance

WAPA has determined that this action fits within the following categorical exclusions listed in appendix B to subpart D of 10 CFR part 1021.410: B4.3 (Electric power marketing rate changes) and B4.4 (Power marketing services and activities). Categorically excluded projects and activities do not require the preparation of either an environmental impact statement or an environmental assessment.[8] Specifically, WAPA has determined that this rulemaking is consistent with activities identified in B4, Categorical Exclusions Applicable to Specific Agency Actions (see 10 CFR part 1021, appendix B to subpart D, part B4). A copy of the categorical exclusion determination is available on WAPA's website at *www.wapa.gov/regions/SN/rates/Pages/Rate-Case-2022-WAPA-201.aspx.*

[6] *See* Public Law 101–618, 104 Stat. 3289, 3307 (1990).

[7] *See Carson-Truckee Water Conservancy Dist.* v. *Watt,* 549 F. Supp. 704, 710 (D. Nev. 1982), *aff'd in part and vacated in part sub nom. Carson-Truckee Water Conservancy Dist.* v. *Clark,* 741 F.2d 257, 260 (9th Cir. 1984).

[8] The determination was done in compliance with NEPA (42 U.S.C. 4321–4347); the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Submission to the Federal Energy Regulatory Commission

The Provisional Formula Rate herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

Order

In view of the above, and under the authority delegated to me, I hereby confirm, approve, and place into effect, on an interim basis, Rate Order No. WAPA–201. The rate will remain in effect on an interim basis until: (1) FERC confirms and approves it on a final basis; (2) a subsequent rate is confirmed and approved; or (3) such rate is superseded.

Signing Authority

This document of the Department of Energy was signed on July 25, 2022, by Tracey A. LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 29, 2022.

Treena V. Garrett,

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

UNITED STATES DEPARTMENT OF ENERGY WESTERN AREA POWER ADMINISTRATION

SIERRA NEVADA REGION Washoe Project, Stampede Division

NON-FIRM POWER FORMULA RATE (Approved Under Rate Order No. WAPA–201)

Effective

The first day of the first full billing period beginning on or after October 1, 2022, through September 30, 2027, or until superseded by another rate schedule, whichever occurs earlier.

Available

Within the marketing area served by the Sierra Nevada Region.

Applicable

To preference customers under the 2004 Power Marketing Plan, the 2025 Power Marketing Plan, and the applicable third party(ies) who are under contract (Contractor) with the Western Area Power Administration (WAPA).

Character and Conditions of Service

Alternating current, 60 hertz, three-phase, delivered and metered at the voltages and points established by contract.

Non-Firm Power Formula Rate

To serve project use loads and effectively market the energy from Stampede, WAPA has contracted with a third-party Contractor that provides for a Stampede Energy Exchange Account (SEEA). The SEEA is an annual energy exchange account for Stampede energy. In the SEEA, the revenues from sales (generation revenues) made at the SEEA Rate are reduced by the project use and station service power costs, and SEEA administrative costs. WAPA applies the ratio of project use costs to the generation revenue recorded in the SEEA to determine a non-reimbursable percentage. One hundred percent minus this non-reimbursable percentage establishes a reimbursable percentage. This reimbursable percentage is then applied to the appropriate power-related costs to determine the reimbursable costs for repayment. The reimbursable costs are then netted against generation revenues made at the SEEA Rate. As stipulated under the 2004 Power Marketing Plan and 2025 Power Marketing Plan, any remaining reimbursable costs, including interest and annual capital costs, are then transferred to the Central Valley Project for incorporation into the CVP Power Revenue Requirement.

The formula rate for Stampede power is:

Stampede Annual Transferred PRR = Stampede Annual PRR—Stampede Revenue

Where:

Stampede Annual Transferred Power Revenue Requirement (PRR) = Stampede Annual PRR identified as a cost transferred to the CVP.

Stampede Annual PRR = The total PRR for Stampede required to repay all annual costs, including interest, and the investment within the allowable period.

Stampede Revenue = Revenue from applying the SEEA Rate to project generation.

Billing

Billing for the SEEA Rate will be as specified in the service agreement.

Adjustment for Losses

Losses will be accounted for under this rate schedule as stated in the service agreement.

[FR Doc. 2022–16629 Filed 8–2–22; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 22–17]

Bakerly, LLC, Complainant. v. Seafrigo USA, Inc., Respondent; Notice of Filing of Complaint and Assignment

Served: July 27, 2022.

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by BAKERLY, LLC, hereinafter ''Complainant,'' against SEAFRIGO USA, INC., hereinafter ''Respondent.'' Complainant states that it is a New York corporation. Complainant states that Respondent is a New Jersey corporation, and that it is a non-vessel-common-carrier licensed by the Federal Maritime Commission.

Complainant alleges that Respondent violated 46 U.S.C. 41104(a)(2)(A); 46 U.S.C. 41104(a)(14)–(15); 46 U.S.C. 41102(c); and 46 CFR 545.5 with regard to assessing fees against containers. The full text of the complaint can be found in the Commission's Electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/22-17/*. This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding office in this proceeding shall be issued by July 27, 2023, and the final decision of the Commission shall be issued by February 9, 2024.

William Cody,

Secretary.

[FR Doc. 2022–16541 Filed 8–2–22; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–0639; Docket No. CDC–2022–0090]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) Special Exposure Cohort Petitions. This information collection project permits respondents to submit petitions to HHS requesting the addition of classes of employees to the Special Exposure Cohort under EEOICPA.

DATES: CDC must receive written comments on or before October 3, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0090 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: *Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) Special Exposure Cohort Petitions. (OMB Control No. 0920–0639, Exp. 01/31/2023)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

On October 30, 2000, the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384–7385 [1994, supp. 2001] was enacted. The Act established a compensation program to provide a lump sum payment of $150,000 and medical benefits as compensation to covered employees suffering from designated illnesses incurred because of their exposure to radiation, beryllium, or silica while in the performance of duty for the Department of Energy and certain of its vendors, contractors, and subcontractors. This legislation also provided for payment of compensation for certain survivors of these covered employees. This program has been mandated to be in effect until Congress ends the funding.

Among other duties, the Department of Health and Human Services (HHS) was directed to establish and implement procedures for considering petitions by classes of nuclear weapons workers to be added to the ''Special Exposure Cohort'' (the ''Cohort''). In brief, EEOICPA authorizes HHS to designate such classes of employees for addition to the Cohort when NIOSH lacks sufficient information to estimate with sufficient accuracy the radiation doses of the employees, and if HHS also finds that the health of members of the class may have been endangered by the radiation dose the class potentially incurred. HHS must also obtain the advice of the Advisory Board on Radiation and Worker Health (the ''Board'') in establishing such findings. On May 28, 2004, HHS issued a rule that established procedures for adding such classes to the Cohort (42 CFR part 83). The rule was amended on July 10, 2007.

The HHS rule authorizes a variety of respondents to submit petitions. Petitioners are required to provide the information specified in the rule to qualify their petitions for a complete evaluation by HHS and the Board. HHS has developed two forms to assist the petitioners in providing this required information efficiently and completely. Form A is a one-page form to be used by EEOICPA claimants for whom NIOSH has attempted to conduct dose reconstructions and has determined that available information is not sufficient to complete the dose reconstruction. Form B, accompanied by separate instructions, is intended for all other petitioners. Forms A and B can be submitted electronically as well as in hard copy. Respondent/petitioners should be aware that HHS is not requiring respondents to use the forms. Respondents can choose to submit petitions as letters or in other formats, but petitions must meet the informational requirements stated in the rule. NIOSH expects, however, that all petitioners for whom Form A would be appropriate will use the form, since NIOSH will provide it to them upon determining that their dose

reconstruction cannot be completed and encourage them to submit the petition. NIOSH expects most petitioners for whom Form B would be appropriate will also use the form, since it provides a simple, organized format for addressing the informational requirements of a petition.

NIOSH will use the information obtained through the petition for the following purposes: (a) identify the petitioner(s), obtain their contact information, and establish that the petitioner(s) is qualified and intends to petition HHS; (b) establish an initial definition of the class of employees being proposed to be considered for addition to the Cohort; (c) determine whether there is justification to require HHS to evaluate whether or not to designate the proposed class as an addition to the Cohort (such an evaluation involves potentially extensive data collection, analysis, and related deliberations by NIOSH, the Board, and HHS); and (d) target an evaluation by HHS to examine relevant potential limitations of radiation monitoring and/or dosimetry-relevant records and to examine the potential for related radiation exposures that might have endangered the health of members of the class.

Finally, under the rule, petitioners may contest the proposed decision of the Secretary to add or deny adding classes of employees to the cohort by submitting evidence that the proposed decision relies on a record of either factual or procedural errors in the implementation of these procedures. NIOSH estimates that the average time to prepare and submit such a challenge is five hours. Because of the uniqueness of this submission, NIOSH is not providing a form. The submission will typically be in the form of a letter to the Secretary.

CDC requests OMB approval for an estimated 43 annual burden hours. There are no costs to respondents other than their time to participate, unless a respondent/petitioner chooses to purchase the services of an expert in dose reconstruction, an option provided for under the rule.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Petitioners	Form A: 42 CFR 83.9	2	1	3/60	1
	Form B: 42 CFR 83.9	5	1	5	25
Petitioners using a submission format other than Form B (as permitted by rule).	42 CFR 83.9	1	1	6	6
Petitioners Appealing final HHS decision (no specific form is required).	42 CFR 83.18	2	1	5	10
Claimant authorizing a party to submit petition on his/her behalf.	Authorization Form: 42 CFR 83.7	3	1	3/60	1
Total					43

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–16563 Filed 8–2–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–22HO; Docket No. CDC–2022–0091]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction. This project is designed to evaluate oil and gas extraction workers' sleep, fatigue, and other related factors, and their relationship to risks associated with the industry.

DATES: CDC must receive written comments on or before October 3, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0091 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction Industry—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Oil and gas extraction (OGE) workers play an important role in supporting the United States economy and help fulfill the energy needs of Americans and American businesses. OGE workers have significant risks for a variety of exposures at oil and gas well sites. There has been no significant fatigue research in the United States onshore upstream OGE sector. This proposed project will characterize relationships between sleep, fatigue, fatigue management, and related factors, within the onshore OGE industry.

Primary data will be collected using three approaches. First, researchers will collect direct measurements of sleep and alertness among OGE workers. Second, researchers will use questionnaires to collect information on OGE worker demographics, occupation, general heath, normal working hours, commute times, home life, physical sleeping environment, and typical sleep quality. Third, researchers will collect qualitative information through interviews with workers, front-line supervisors, health and safety leaders, as well as subject matter experts, to understand challenges and opportunities related to fatigue management in the OGE industry.

CDC requests OMB approval for an estimated 305 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Land-based OGE workers	Baseline Questionnaire	80	1	12/60	16
Land-based OGE workers	Daily Pre-Shift Questionnaires	80	14	3/60	56
Land-based OGE workers	Daily Post-Shift Questionnaires	80	14	3/60	56
Land-based OGE workers	Psychomotor Vigilance Test (PVT)	80	28	3/60	112
Land-based OGE workers	Worker Interview Guide	30	1	90/60	45
Field-level Supervisors	Manager Interview Guide	10	1	1	10
Health and Safety Leaders	HSE Interview Guide	7	1	1	7
Subject Matter Experts	SME Interview Guide	3	1	1	3
Total					305

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–16561 Filed 8–2–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by October 3, 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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. 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: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on May 20, 2022 (87 FR 30962). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active Ingredient(s)
Acetaminophen; Ibuprofen
Amphetamine; Amphetamine aspartate/Dextroamphetamine sulfate
Ampicillin/Ampicillin trihydrate
Azelastine hydrochloride
Berotralstat hydrochloride
Cabotegravir sodium
Carbamazepine
Caspofungin acetate
Cobicistat; Darunavir; Emtricitabine; Tenofovir alafenamide fumarate
Cyclosporine
Cytarabine; Daunorubicin
Dasiglucagon hydrochloride
Doxycycline hyclate
Etonogestrel
Famotidine
Gallium Ga-68 gozetotide
Ibuprofen
Ketoprofen
Lonafarnib
Loperamide hydrochloride; Simethicone
Loteprednol etabonate
Mometasone furoate; Olopatadine hydrochloride
Nifurtimox
Pafolacianine sodium
Relugolix
Setmelanotide acetate
Technetium Tc-99m sodium pertechnetate generator
Vericiguat
Vibegron

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

Active Ingredient(s)
Amoxicillin; Clavulanate potassium
Azelastine hydrochloride

Active Ingredient(s)
Cetirizine hydrochloride
Dantrolene sodium
Ethinyl estradiol; Norethindrone
Ethinyl estradiol; Norethindrone acetate
Lamotrigine
Lanthanum carbonate
Loratadine
Medroxyprogesterone acetate (multiple reference listed drugs)
Meloxicam
Methylphenidate hydrochloride
Nicotine
Olopatadine hydrochloride
Oxymetazone hydrochloride; Tetracaine hydrochloride
Prednisone
Tacrolimus
Upadacitinib

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. 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,* or *https://www.regulations.gov.*

Dated: July 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16502 Filed 8–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Advisory Committee; Blood Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Blood Products 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 Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2024, expiration date.

DATES: Authority for the Blood Products Advisory Committee will expire on May 13, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1244, Silver Spring, MD 20993–0002, 240–402–8054, *Christina.Vert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Blood Products Advisory Committee (the Committee). The Committee is a 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 helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee: (1) recommends classification of devices subject to its review into regulatory categories; (2) recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; (3) advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; (4) recommends exemption of certain devices from the application of portions of the Medical Device Amendments of 1976; (5) advises on the necessity to ban a device; and (6) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

The Committee shall consist of a core of 17 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions. 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 technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry

interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members); or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than most of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/blood-products-advisory-committee* 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 *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: July 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16577 Filed 8–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1625]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB-BUTINACA; Adinazolam; Bromazolam; Protonitazene (Propoxynitazene); Etazene (Etodesnitazene); Etonitazepyne (N-Pyrrolidino etonitazene); 2-Methyl-AP-237; Alpha-PiHP; 3-Methylmethcathinone (3-MMC); Zopiclone; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is inviting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 10 drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances. This notice requesting comments is required by the Controlled Substances Act (CSA).

DATES: Either electronic or written comments must be submitted by August 24, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 24, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2022–N–1625 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB-BUTINACA; Adinazolam; Bromazolam; Protonitazene (propoxynitazene); Etazene (etodesnitazene); Etonitazepyne (N-pyrrolidino etonitazene); 2-Methyl-AP-237; alpha-PiHP; 3-Methylmethcathinone (3-MMC); Zopiclone; Request for Comments'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including

the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

Edward (Greg) Hawkins, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993–0002, 301–796–0727, *edward.hawkins@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations (U.N. Secretary-General) and provide the U.N. Secretary-General with information in support of its opinion.

Section 201(d)(2)(A) of the CSA (21 U.S.C. 811(d)(2)(A)) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify adding a drug or other substances to one of the schedules of the Psychotropic Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

II. WHO Notification

The Secretary of HHS received the following notice from WHO (nonrelevant text removed):

Ref.: C.L.27.2022

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of announcing that the 45th Expert Committee on Drug Dependence (ECDD) will meet from 10 to 14 October 2022, in Geneva, Switzerland. Given that WHO Expert Committee meetings are of a closed nature, this letter serves to notify Member States of the substances under review at the 45th ECDD, which are in the Annex I, attached for reference.

WHO is mandated by the 1961 and 1971 International Drug Control Conventions to make recommendations to the UN Secretary-General on the need for and level of international control of psychoactive substances based on the advice of its independent scientific advisory body, the ECDD. To assess whether or not a psychoactive substance should be placed under international control, the ECDD convenes annually to review the potential of this substance to cause dependence, abuse and harm to health, as well as any therapeutic applications. In order to perform this review and make evidence-based decisions, the ECDD conducts medical, scientific, and public health evaluations of the selected psychoactive substances using the best available information.

Although the meetings are of a closed nature, Member States are invited to contribute to the ECDD review process by joining the 45th ECDD Open Session on 10 October 2022. The Information Session will be held virtually and allow interested parties to learn about present and future activities of the ECDD Secretariat, and to present information concerning substances under review to the Expert Committee for consideration in its deliberations. Registration information will be made available on the ECDD website in due course: *https://www.who.int/medicines/access/controlled-substances/en/.*

As in the past and in line with the publication ''*Guidance on the WHO review of psychoactive substances for international control*'' (EB126/2010/REC1, Annex 6) [1], Member States can also contribute to the ECDD review process by providing accurate information concerning the substances under review in advance of the meeting. For this purpose, a questionnaire will be sent to Member States to gather country information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation.

In addition to the questionnaire, Member States are also encouraged to provide any additional relevant information (unpublished or published) on substances to be reviewed by the 45th ECDD.

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 10 June 2021

[1] *https://apps.who.int/gb/ebwha/pdf_files/EB126-REC1/B126_REC1-en.pdf#page=58.*

Annex I

45th Expert Committee on Drug Dependence (ECDD) Substances For Review 10–14 October 2022

Critical reviews: The substances listed below have never been formally reviewed by WHO and are not currently under international control. Information was brought to WHO's attention that these substances are clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any Party. The Expert Committee will consider whether information presented during a critical review may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions.

Synthetic cannabinoid receptor agonists

1. ADB–BUTINACA

Benzodiazepines

2. Adinazolam
3. Bromazolam

Novel synthetic opioids

4. Protonitazene (propoxynitazene)
5. Etazene (etodesnitazene)
6. Etonitazepyne (N-pyrrolidino etonitazene)
7. 2-Methyl-AP–237

Cathinones/stimulants

8. alpha-PiHP
9. 3-Methylmethcathinone (3–MMC)

Pre-reviews: The substances listed below have been proposed for a pre-review. The purpose of a pre-review is to determine whether current information justifies an Expert Committee critical review. A pre-review is a preliminary analysis and findings at this stage should not determine whether the control status of a substance should be changed.

Medicines

1. Zopiclone

FDA has verified the website addresses contained in the WHO notice, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time. Access to view the WHO questionnaire can be found at *https://www.who.int/publications/m/item/45th-ecdd-questionnaire.*

III. Substances Under WHO Review

ADB–BUTINACA is a synthetic cannabinoid that has been sold online and is used to mimic the biological effects of tetrahydrocannabinol, the

main psychoactive constituent in marijuana. Research and clinical reports have demonstrated that synthetic cannabinoids are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and psychoactive ''high.'' Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. According to the National Forensic Laboratory Information System (NFLIS-Drug) database,[1] ADB–BUTINACA was first reported in 2020, and there were 4,358 reports in 2021. There are toxicology reports identifying ADB–BUTINACA in at least six deaths and eight non-fatal emergency room visits. There are no commercial or approved medical uses for ADB–BUTINACA. As a positional isomer of AB–PINACA, ADB–BUTINACA is controlled in schedule I of the CSA.

Adinazolam is a designer benzodiazepine (*i.e.,* a structural or functional analog of other drugs in the benzodiazepine class) and is expected to have central nervous system (CNS) depressant-like effects similar to that of other known benzodiazepines. Adinazolam was first reported to NFLIS-Drug in 2019, and there were 87 reports in 2021. Adinazolam has appeared in toxicology reports in the United States. Adinazolam is not currently controlled in the United States.

Bromazolam is a designer benzodiazepine and is expected to have CNS depressant-like effects similar to that of other known benzodiazepines. Bromazolam was first reported to NFLIS-Drug in 2016, and there were 743 reports in 2021. Bromazolam has appeared in at least two overdose death reports in the United States and adverse effects associated with the use of bromazolam have been reported. Bromazolam is not currently controlled in the United States.

Protonitazene (propoxynitazene), etazene (etodesnitazene), and etonitazepyne (*N*-pyrrolidino etonitazene) are novel synthetic opioid receptor agonists of the benzimidazole structural class. Law enforcement data indicates that these substances have appeared on the U.S. illicit markets as evidenced by their identification in forensic drug seizures and biological samples. Etazene was first reported to NFLIS-Drug in 2020, and there were 41 reports in 2021. Protonitazene and etonitazepyne were both first reported to NFLIS-Drug in 2021 with 20 and 129 reports in that year, respectively. The abuse of these benzimidazole opioids are similar to other synthetic opioids. Protonitazene, etazene, and etonitazepyne have been identified in toxicology and several post-mortem cases. The public health risks attendant to the abuse of mu-opioid receptor agonists are well established. These risks included large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. On April 12, 2022, the U.S. Drug Enforcement Administration issued a temporary order to control these substances as schedule I substances under the CSA.

2-Methyl-AP-237 is a novel synthetic mu-opioid receptor agonist. It was first reported to NFLIS-Drug in 2019, and there were 45 reports in 2021. Abuse of 2-methyl-AP-237 is similar to other synthetic opioids, and has been associated with adverse health effects, including death. In the United States, there are at least 10 confirmed reports of fatal poisonings and several reports of emergency room visits, and non-fatal poisonings associated with 2-methyl-AP-237. 2-Methyl-AP-237 is not currently controlled in the United States. There are no commercial or approved medical uses of 2-methyl-AP-237.

Alpha-PiHP is a synthetic stimulant designer drug structurally similar to other schedule I synthetic cathinones. Alpha-PiHP is a monoamine transporter (dopamine transporter and norepinephrine transporter) uptake inhibitor. Adverse effects associated with synthetic cathinones abuse include agitation, hypertension, tachycardia, and death. Alpha-PiHP was first reported to NFLIS-Drug in 2017, and there were 332 reports in 2021. Alpha-PiHP has been confirmed to have played a role in fatal and non-fatal overdose events in the United States. Alpha-PiHP has no approved medical uses in the United States. As a positional isomer of alpha-PHP, alpha-PiHP is controlled in schedule I of the CSA.

3-Methylmethcathinone (3-MMC) is a designer drug of the phenethylamine class, which is structurally and pharmacologically similar to amphetamine, 3,4-methylenedioxymethamphetamine, cathinone and other related substances. 3-MMC is a monoamine transporter (dopamine transporter, serotonin transporter, and norepinephrine transporter) uptake inhibitor. Like other schedule I synthetic cathinones, 3-MMC is abused for its psychoactive effects. Adverse effects associated with synthetic cathinones abuse include agitation, hypertension, tachycardia, and death. 3-MMC was first reported to NFLIS-Drug in 2012, and there were three reports in 2021. 3-MMC has no approved medical uses in the United States. As a positional isomer of mephedrone, 3-MMC is controlled in schedule I of the CSA.

Zopiclone is a nervous system depressant drug used in the treatment of insomnia. Its mechanism of action is based on modulating benzodiazepine receptors. Zopiclone is approved for medical use in the United States as (S)-zopiclone (or eszopiclone), the active (S) isomer of zopiclone. Zopiclone has abuse potential and may be misused due to its ability to produce euphoric effects at high doses. Amnesia and hallucinations have been reported with higher doses. Zopiclone is controlled in schedule IV of the CSA.

IV. Opportunity To Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the 10 drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation for drug substances that is responsive to the WHO Questionnaire for these drug substances. HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in late 2022. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by section 201(d)(2)(B) of the CSA.

[1] NFLIS-Drug is a national forensic laboratory reporting system that systematically collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories in the United States. NFLIS-Drug data were queried on June 29, 2022.

Dated: July 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16572 Filed 8–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1173]

Electronic Submission of Expedited Safety Reports From Investigational New Drug-Exempt Bioavailability/Bioequivalence Studies; 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 ''Electronic Submission of Expedited Safety Reports From IND-Exempt BA/BE Studies.'' This guidance provides instructions for the electronic submission of expedited individual case safety reports (ICSRs) from investigational new drug (IND)-exempt bioavailability (BA)/bioequivalence (BE) studies through the FDA Adverse Event Reporting System (FAERS) database.

DATES: Submit either electronic or written comments on the draft guidance by October 3, 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–2022–D–1173 for ''Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies.'' 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. 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: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936, *Susan.Levine@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies.'' This guidance provides instructions for the electronic submission of expedited ICSRs from IND-exempt BA/BE studies through the FAERS database. An ICSR captures information necessary to support the reporting of an adverse event related to an individual subject that is associated with the use of an FDA-regulated product.[1] The electronic submission of the ICSRs from IND-exempt BA/BE studies is a voluntary option.

In the **Federal Register** of September 29, 2010 (75 FR 59935), FDA published a final rule that revised the IND safety reporting requirements for human drug and biological products under 21 CFR 312 and added safety reporting requirements for persons conducting

[1] See additional information on Individual Case Safety Reports available at *https://www.fda.gov/industry/fda-resources-data-standards/individual-case-safety-reports.*

IND-exempt BA/BE studies under 21 CFR 320.31.[2] A serious adverse event experienced by a study subject during the conduct of an IND-exempt BA/BE study must be submitted on Form FDA 3500A or in an electronic format that FDA can process, review, and archive.[3]

Previously, to meet the requirements under § 320.31(d)(3) applicable to IND-exempt BA/BE studies, submitters sent expedited premarket safety reports directly to the Office of Generic Drugs (OGD) by email, telephone, or facsimile. This guidance provides recommendations on how to electronically submit ICSRs to the FAERS database as an alternate avenue for submitting reports to OGD once these enhancements are activated.

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 ''Electronic Submission of Expedited Safety Reports From IND-Exempt BA/BE Studies.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 for IND applications and 21 CFR 320.31 for IND-exempt BA/BE safety reporting requirements for human drug and biological products have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 314 for safety report submissions for applications for FDA approval new drug application have been approved under OMB control number 0910–0001.

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, or https://www.regulations.gov*.

Dated: July 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16599 Filed 8–2–22; 8:45 am]

BILLING CODE 4164–01–P

[2] BA and BE studies that meet the conditions for exemption under 21 CFR 320.31 are not conducted under an IND and are not subject to the IND safety reporting requirements. The safety reporting requirements under § 320.31(d)(3) apply to persons conducting BA or BE studies that are exempt from the IND requirements.

[3] 21 CFR 320.31(d)(3).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1436]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on September 7, 2022, from 12 noon to 6:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–1436. The docket will close on September 6, 2022. Either electronic or written comments on this public meeting must be submitted by September 6, 2022. Please note that late, untimely filed comments will not be considered. 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 received on or before that date.

Comments received on or before August 23, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2022–N–1436 for ''Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7699, Fax: 301–847–8533, email: *PCNS@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 216660, for sodium phenylbutyrate/taurursodiol (AMX0035) powder for oral suspension, submitted by Amylyx Pharmaceuticals Inc., for the treatment of amyotrophic lateral sclerosis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before August 23, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 15, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 16, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16570 Filed 8–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal

Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on June 1, 2022, through June 30, 2022. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Health Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857. The Court's caption (Petitioner's Name v. Secretary of HHS) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Carole Johnson,

Administrator.

List of Petitions Filed

1. Elizabeth Bacon, Baton Rouge, Louisiana, Court of Federal Claims No: 22–0599V
2. Darby Hoss, Portland, Oregon, Court of Federal Claims No: 22–0600V
3. Julia Kauterman, Berlin, New Jersey, Court of Federal Claims No: 22–0601V
4. Carinna Sharrak, Royal Oak, Michigan, Court of Federal Claims No: 22–0602V
5. Jill Diluigi, Roseville, Michigan, Court of Federal Claims No: 22–0604V
6. Courtney Byrnes, Reisterstown, Maryland, Court of Federal Claims No: 22–0606V
7. Sandra Gill Pace, Central, Louisiana, Court of Federal Claims No: 22–0607V
8. Christine Breen, New York, New York, Court of Federal Claims No: 22–0608V
9. Robin Morrison, Katy, Texas, Court of Federal Claims No: 22–0609V
10. Claudette Hulsey, Hartsville, South Carolina, Court of Federal Claims No: 22–0610V
11. Angela Stewart, Fayetteville, Georgia, Court of Federal Claims No: 22–0611V
12. Imani Corbett, Phoenix, Arizona, Court of Federal Claims No: 22–0612V
13. Linda Butler, Ambler, Pennsylvania, Court of Federal Claims No: 22–0613V
14. Jennifer Callaghan, Voorhees, New Jersey, Court of Federal Claims No: 22–0615V
15. Carmen Hill, East Jordan, Michigan, Court of Federal Claims No: 22–0616V
16. Sharin Elkholy on behalf of L. V., Houston, Texas, Court of Federal Claims No: 22–0618V
17. Kimberly Crysler-Ehlen, Chaska, Minnesota, Court of Federal Claims No: 22–0621V
18. Sharice Brown, Washington, District of Columbia, Court of Federal Claims No: 22–0622V
19. Bala Muccala, Chandler, Arizona, Court of Federal Claims No: 22–0624V
20. Giselle Lewis, Syracuse, New York, Court of Federal Claims No: 22–0628V
21. Brian Thomas, Yokosuka, Japan, Court of Federal Claims No: 22–0631V
22. Jacquese F. Harrell, Boscobel, Wisconsin, Court of Federal Claims No: 22–0635V
23. Terri Jones-White, Auburn Hills, Michigan, Court of Federal Claims No: 22–0637V
24. Earlean Lewis, Macon, Georgia, Court of Federal Claims No: 22–0638V
25. Dana Kendrick on behalf of C. E. K., Spring, Texas, Court of Federal Claims No: 22–0639V
26. Mosel Pearlman-Ramirez, San Rafael, California, Court of Federal Claims No: 22–0640V
27. Richard Rondinaro, Staten Island, New York, Court of Federal Claims No: 22–0643V
28. Michele Holland, Acton, Massachusetts, Court of Federal Claims No: 22–0645V

29. Michael Smith, Matthews, North Carolina, Court of Federal Claims No: 22–0646V
30. Laura Wallace, Bloomington, Minnesota, Court of Federal Claims No: 22–0649V
31. Leah Hutson, Miami, Oklahoma, Court of Federal Claims No: 22–0651V
32. Frances McGovern, Rochester, Minnesota, Court of Federal Claims No: 22–0652V
33. Razia Khan, Astoria, New York, Court of Federal Claims No: 22–0653V
34. Rica Hoskins, Woodbridge, Virginia, Court of Federal Claims No: 22–0654V
35. Veronica Demoss, South Bend, Indiana, Court of Federal Claims No: 22–0655V
36. Joseph Ditro, Huntingtin Valley, Pennsylvania, Court of Federal Claims No: 22–0656V
37. Emmanuel Ayala, East Brunswick, New Jersey, Court of Federal Claims No: 22–0658V
38. Lori Multz, Camarillo, California, Court of Federal Claims No: 22–0660V
39. Joseph Murphy, Bernalillo, New Mexico, Court of Federal Claims No: 22–0661V
40. Richard Newell, Presidio, Texas, Court of Federal Claims No: 22–0662V
41. Rene Newman, Vienna, Virginia, Court of Federal Claims No: 22–0663V
42. Charlotte O'Brien, Babbitt, Minnesota, Court of Federal Claims No: 22–0664V
43. Susan Odell, Alexandria, Minnesota, Court of Federal Claims No: 22–0665V
44. Virginia Perez, Indianapolis, Indiana, Court of Federal Claims No: 22–0666V
45. Ronald Poulin, Buckfield, Maine, Court of Federal Claims No: 22–0667V
46. Jesus Rodriguez, Fort Worth, Texas, Court of Federal Claims No: 22–0668V
47. Connie Rosenkranz, Richland Center, Wisconsin, Court of Federal Claims No: 22–0669V
48. Emma Runyon, Varney, West Virginia, Court of Federal Claims No: 22–0670V
49. Maryam Ahmadi, Newbury Park, California, Court of Federal Claims No: 22–0671V
50. Conceta Murphy, Venice, Florida, Court of Federal Claims No: 22–0672V
51. Jeffrey Bohlmann, Watertown, South Dakota, Court of Federal Claims No: 22–0674V
52. Shannon Robbins, Temple, Texas, Court of Federal Claims No: 22–0675V
53. Gerret Swearingen, Ossian, Indiana, Court of Federal Claims No: 22–0677V
54. Andrew Schaefer, Springfield, Missouri, Court of Federal Claims No: 22–0678V
55. LeeAnn Phillips-McAraw on behalf of K.M., Phoenix, Arizona, Court of Federal Claims No: 22–0679V
56. Jacqueline Schweichler, Edinboro, Pennsylvania, Court of Federal Claims No: 22–0681V
57. Patrick Simmons, Inver Grove Heights, Minnesota, Court of Federal Claims No: 22–0682V
58. Dustin Stamey, Inver Grove Heights, Minnesota, Court of Federal Claims No: 22–0683V
59. Richard Steck, Pittsburgh, Pennsylvania, Court of Federal Claims No: 22–0684V
60. Kimba Stojak, Lindenhurst, Illinois, Court of Federal Claims No: 22–0685V
61. Linda Tan, New York, New York, Court of Federal Claims No: 22–0686V
62. Aaron Thomas, San Diego, California, Court of Federal Claims No: 22–0687V
63. Susan White, West Islip, New York, Court of Federal Claims No: 22–0688V
64. Laura Wunsch, Trempealeau, Wisconsin, Court of Federal Claims No: 22–0689V
65. Nadia Israel, Aurora, Colorado, Court of Federal Claims No: 22–0690V
66. Monica Portee, Columbia, South Carolina, Court of Federal Claims No: 22–0691V
67. Glenna McIntyre, Monroe, Louisiana, Court of Federal Claims No: 22–0692V
68. Dennis Crout, Arlington, Texas, Court of Federal Claims No: 22–0694V
69. Connie Watson, Washington, District of Columbia, Court of Federal Claims No: 22–0695V
70. Jonathan Law, Hampstead, North Carolina, Court of Federal Claims No: 22–0696V
71. Eunice Buffkin, Loris, South Carolina, Court of Federal Claims No: 22–0697V
72. Betty Conn, Cincinnati, Ohio, Court of Federal Claims No: 22–0699V
73. Danielle Polzin, North Mankato, Minnesota, Court of Federal Claims No: 22–0700V
74. Kristina Lemon, Denver, Colorado, Court of Federal Claims No: 22–0701V
75. Michelle Gushue, Hampden, Maine, Court of Federal Claims No: 22–0702V
76. Randi Bovard, Carmichael, California, Court of Federal Claims No: 22–0703V
77. Thomas Meurer, Conway, Arkansas, Court of Federal Claims No: 22–0704V
78. Mark Smith, Jersey City, New Jersey, Court of Federal Claims No: 22–0705V
79. David Meade, Toledo, Ohio, Court of Federal Claims No: 22–0706V
80. Joyce Hammond, Wellesley, Massachusetts, Court of Federal Claims No: 22–0708V
81. Maiah Faapouli, Phoenix, Arizona, Court of Federal Claims No: 22–0709V
82. Julia Foran, Phoenix, Arizona, Court of Federal Claims No: 22–0710V
83. Van Blue, Jr. on behalf of S. B., Lancaster, Pennsylvania, Court of Federal Claims No: 22–0711V
84. Sarah Hamm, Chicago, Illinois, Court of Federal Claims No: 22–0714V
85. Shavannah Ervin, Milwaukee, Wisconsin, Court of Federal Claims No: 22–0716V
86. Denyce Iverson, Cheyenne, Wyoming, Court of Federal Claims No: 22–0718V
87. Jose Fernandez, Greenbrook, New Jersey, Court of Federal Claims No: 22–0719V
88. Selma Taylor, Richmond, Virginia, Court of Federal Claims No: 22–0722V
89. Phyllis Olszewski, Taylor, Michigan, Court of Federal Claims No: 22–0723V
90. Eileen Barton, Washington, District of Columbia, Court of Federal Claims No: 22–0724V
91. John Kiser, Mt. Pleasant, Pennsylvania, Court of Federal Claims No: 22–0726V
92. Michael Henry on behalf of C. H., Phoenix, Arizona, Court of Federal Claims No: 22–0727V
93. Jeffrey Scott Curry, Germantown, Tennessee, Court of Federal Claims No: 22–0729V
94. Christopher Chandler, Savannah, Georgia, Court of Federal Claims No: 22–0730V

[FR Doc. 2022–16613 Filed 8–2–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 2, 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.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Title X Implementation Study.

Type of Collection: New.

OMB No. 0990–NEW—Office of Population Affairs—OASH–OS.

Abstract: The Office of Population Affairs (OPA), U.S. Department of Health and Human Services (HHS), is requesting 3 years of approval by OMB on a new collection. The Title X Implementation Study will document how organizations funded by the Title X Service Grants program design and implement their program services. The study will document (1) how grantees ensure access to equitable, affordable, client-centered quality family planning services; (2) the steps that Title X grantees take to provide clients from diverse communities with equitable access to affordable, high-quality, client-centered health services; (3) any pivots and/or accommodations to providing care they made in recent years, including during the COVID–19 pandemic; and (4) how they assess their impact. To carry out these objectives, the study team will rely on the following five proposed data sources: (1) a web-based survey of the 2022 cohort of Title X grantees; (2) grantee telephone interviews; (3) in-person or virtual listening visits with clinic administrators, service providers, and community outreach or partner staff at a subset of Title X sub-recipients and service delivery sites; (4) a web-based survey of clients at up to 10 of the sites selected for listening visits; and (5) telephone interviews with subject matter experts. Data collection will begin in fall 2022, pending OMB approval, with the grantee survey and interviews, which will inform selection of sites for the listening visits.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Grantee project director: grantee web survey	30	1	1	30
Grantee staff: grantee interview topic guide	59	1	90/60	89
Clinic administrators: listening visit topic guide	27	1	45/60	20
Clinical service providers: listening visit topic guide	53	1	1	53
Clinic community outreach and partner staff: listening visit topic guide	27	1	45/60	20
Title X clients survey	100	1	10/60	17
Title X subject matter experts: interview topic guide	8	1	1	8
Total	304	7		237

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2022–16597 Filed 8–2–22; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Request for Information (RFI) on NIH-Wide Strategic Plan for Research on the Health of Women

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: The Office of Research on Women's Health (ORWH) is updating the National Institutes of Health (NIH) Strategic Plan for Research on the Health of Women. NIH is publishing this Notice to solicit input from the basic, clinical, and translational scientists; advocacy and patient communities; and the public on topics under consideration for the next strategic plan.

DATES: NIH Request for Information (RFI) on NIH-Wide Strategic Plan for Research on the Health of Women is open for public comment through September 29, 2022. Comments must be received by September 29, 2022, to ensure consideration. Comments received after the public comment period has closed may be considered by

the Office of Research on Women's Health.

ADDRESSES: Submissions must be sent electronically to RFI submission website at: *https://rfi.grants.nih.gov/?s=62c5e1a9fe640000ed002eb2.*

FOR FURTHER INFORMATION CONTACT: Questions about this RFI should be directed to Juliane Caviston, Ph.D., Office of Research on Women's Health, 6707 Democracy Boulevard, Suite 400, Bethesda, MD 20817, *NIHWideSPWH@nih.gov,* 301–435–0971.

SUPPLEMENTARY INFORMATION: ORWH was established in the Office of the NIH Director by the Public Health Service Act to (a) identify projects and multidisciplinary research related to women's health; (b) encourage research on sex differences and promote coordination among research entities; (c) assist NIH efforts to include women as participants in clinical research; and (d) develop opportunities and support for women in biomedical careers. These efforts will continue to be part of the office's core mission. Please see *https://orwh.od.nih.gov/about/mission/* for more on the ORWH mission.

ORWH is responsible for an NIH-wide strategic plan for research on the health of women that promotes allocation of NIH resources for conducting and supporting research efforts on the health of women across NIH Institutes and Centers. The NIH Strategic Plan for Women's Health Research FY 2019–2023 *https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_Strategic_Plan_2019_508C_0.pdf* was developed by a collaborative group of leaders from the NIH Institutes, Centers, and Offices (ICOs); external stakeholders; and the public. The plan incorporates the missions of the NIH ICOs with ORWH's mission to pave the way toward scientific and workforce efforts that ultimately benefit the health and biomedical research careers of women. ORWH is currently in the process of updating the NIH-Wide Strategic Plan for Research on the Health of Women. Recent, significant public health events (*e.g.,* the COVID pandemic) have had significant effects on the health of women. Several topics relevant to the health of women were reviewed by the NIH and the NIH Advisory Committee on Research on Women's Health (ACRWH) in 2021, through the congressionally directed and ORWH-led Women's Health Conference *https://orwh.od.nih.gov/research/2021-womens-health-research-conference.* This required a review of NIH activities to identify research opportunities to address maternal mortality and morbidity, survival rates of cervical cancer, and chronic and debilitating diseases in women. The recommendations that the ACRWH made consequent to this conference as well as recent scientific advances; new technologies; current health priorities; and feedback from this Request for Information will all be considered in the development of the next NIH-Wide Strategic Plan for Research on the Health of Women to help guide future NIH research efforts to improve the health of all women throughout the entire life course.

Request for Information

Please provide your perspective on the following topics:

- Research opportunities in the NIH Strategic Plan for Women's Health Research FY 2019–2023 *https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_Strategic_Plan_2019_508C_0.pdf* that should be modified to account for recent scientific advances.
- Emerging research needs and opportunities that reflect the changing landscape of the study of the health of women that should be added to the plan.
- Cross-cutting scientific themes (for example, multidisciplinary research, and/or utilizing data science, natural language processing, and artificial intelligence) or research-related themes that should be common to all future strategic goals and objectives (such as considerations of sex, gender, and age on health and disease, and health disparities).

How To Submit a Response

All responses should be submitted electronically at the RFI submission website at: *https://rfi.grants.nih.gov/?s=62c5e1a9fe640000ed002eb2* by 11:59:59 p.m. (ET) on September 29, 2022. You will see an electronic confirmation acknowledging receipt of your response.

Responses to this RFI are voluntary and may be submitted anonymously. You may voluntarily include your name and contact information with your response. If you choose to provide NIH with this information, NIH will not share your name and contact information outside of NIH unless required by law.

Other than your name and contact information, please do not include any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. The Government will use the information submitted in response to this RFI at its discretion. Other than your name and contact information, the Government reserves the right to use any submitted information on public websites, in reports, in summaries of the state of the science, in any possible resultant solicitation(s), grant(s), or cooperative agreement(s), or in the development of future funding opportunity announcements. This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the Government will not pay for the preparation of any information submitted or for use of that information.

We look forward to your input and hope that you will share this RFI opportunity with your colleagues.

Dated: July 25, 2022.

Tara A. Schwetz,

Acting Principal Deputy Director, National Institutes of Health.

[FR Doc. 2022–16546 Filed 8–2–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2021–0827]

Use of Wing-in-Ground Craft in Logistical Support of Offshore Platform Operations

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

ACTION: Request for information.

SUMMARY: The U.S. Coast Guard seeks input from the public on wing-in-ground (WIG) craft. This information will support the Coast Guard's compliance with Section 8431 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021. In addition, public input will help in assessing the current state of WIG craft development and the technology to provide transportation support to offshore energy facilities on the U.S. Outer Continental Shelf. Finally, public input will aid in developing a plan to demonstrate WIG craft capability to conduct such operations.

DATES: Comments must be received by the Coast Guard on or before November 1, 2022.

ADDRESSES: You may submit comments using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for

further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Lieutenant Commander Dimitri Wiener, U.S. Coast Guard; telephone 202–372–1414, email *dimitrios.n.wiener@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Public Participation and Comments

The Coast Guard views public participation as essential to understanding the current state of wing-in-ground (WIG) craft development and technology, their potential ability to operate on coastwise and offshore routes, and the Coast Guard's role with regard to such technologies. The Coast Guard will consider all information, comments, and material received during the comment period. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Methods for submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *www.regulations.gov.* To do so, go to *www.regulations.gov,* type USCG–2021–0827 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using *www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Public comments will be in our online docket at *www.regulations.gov* and can be viewed by following that website's instructions, provided on its Frequently Asked Questions page. We review all comments received, but we will only post comments that address the topic of this request for information. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

The Coast Guard will not issue a separate response to the comments received. We will carefully consider all comments and may use them to form recommendations to Congress. The Coast Guard is not currently contemplating regulatory changes on this topic; if the Coast Guard were to undertake any regulatory changes as a result of comments received, that change would be separately announced in the **Federal Register**.

Personal information. We accept anonymous comments. Comments we post to *www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see the Department of Homeland Security's (DHS) eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

II. Abbreviations

FAA Federal Aviation Administration
FR Federal Register
NDAA William M. (Mac) Thornberry National Defense Authorization Act
OCS U.S. Outer Continental Shelf
RFI Request for information
U.S.C. United States Code
WIG Wing-in-ground

III. Purpose

The Coast Guard is issuing this request for information (RFI) in response to Section 8431 of the William M. (Mac) Thornberry National Defense Authorization Act (NDAA) for Fiscal Year 2021, Public Law 116–283. In that section, Congress required the Coast Guard, in coordination with the Federal Aviation Administration (FAA), to develop plans for a demonstration program that will determine whether a WIG craft, carrying at least one individual, is capable of the following:

(1) Providing transportation in areas in which energy exploration, development, or production activity takes place on the Outer Continental Shelf; and

(2) Safely reaching helidecks or platforms located on offshore energy facilities under the WIG craft's own power.

Congress directed that Coast Guard and the FAA report on, among other things, any regulatory changes with regard to inspections or manning that would be necessary to allow for craft operation between onshore and offshore facilities, any regulatory changes with regard to airspace and other aircraft operations necessary to allow for safe operations on or near helidecks and platforms on offshore energy facilities, and any other statutory or regulatory changes related to FAA authority over craft operation.

The Coast Guard will use the public comments received in response to this RFI as the first step in developing a WIG craft demonstration program, and to better understand the state of WIG craft development.

IV. Background—Wing-in-Ground (WIG) Craft

As statutorily defined in 46 U.S.C. 2101(54), a WIG craft is ''a vessel that is capable of operating completely above the surface of the water on a dynamic air cushion created by aerodynamic lift, due to the ground effect between the vessel and the water's surface.'' As defined in 46 U.S.C. 2101(45), WIG craft that can carry one or more passengers for hire are ''small passenger vessels,'' and are regulated as such by the Coast Guard.

A WIG craft relies on *ground effect,* an aerodynamic effect that creates an air cushion between the craft's wings and the surface. When a WIG craft is operating very close to the surface and under the influence of ground effect, there is a reduction in the upwash, downwash, and wingtip vortices generated by its wing that results in a condition of improved performance. As a result of the reduced wingtip vortices, there is a reduction in induced drag. Operating within ground effect significantly improves a craft's performance when its wing is at a height of about one-half its wingspan or less above the surface. Accordingly, a WIG craft cannot fly very far above the surface before it loses the advantage of ground effect. It may also not be able to maintain sustained flight at higher altitudes.

When operating within ground effect, the reduced drag allows WIG craft to carry a payload with less propulsion energy than would be required by an aircraft operating out of ground effect. Operating within ground effect and not in contact with the surface also permits a WIG craft to operate at higher speeds than conventional watercraft. This makes WIG craft particularly attractive for passenger service on waterway routes.

Because WIG craft can operate very close to the surface, and because waterways provide an effective operational route for WIG craft, Congress has made the legislative choice to designate WIG craft as vessels when operating in the maritime domain. Accordingly, the Coast Guard has statutory responsibility for the certification and regulation of WIG craft that operate on U.S. waters. This authority, however, is not exclusive, and does not restrict the ability of any other agency, such as the FAA, from regulating these craft when their operation falls within its statutory jurisdiction.

V. Request for Information

The Coast Guard requests relevant comments and information from the public, and particularly from offshore facility operators, including gas and oil facility operators, wind farm operators, the WIG craft community (designers, manufacturers, and operators), and persons conducting operations in airspace that may be affected by the operation of WIG craft.

When considering your comments and suggestions, we ask that you keep in mind the Coast Guard's mission to ensure a safe, secure, and resilient marine transportation system that facilitates commerce and protects national security interests. Commenters should feel free to answer as many questions as they would like, but also provide specificity, detail, and the logic behind any finding or numerical estimates.

The following information is requested; please provide as much detail as possible:

(1) From offshore facility operators:

(a) What interest is there in participating in a WIG craft demonstration?

(b) What are the potential advantages, drawbacks, and concerns, cost-related or otherwise, with respect to using WIG craft for transportation support?

(c) What is the feasibility of a WIG craft to safely land and take off from a helideck (airborne mode), or to taxi up to an offshore platform (afloat mode)?

(d) What modifications to offshore platforms would be required in order to enable such operations?

(2) From the WIG craft community:

(a) What is the current state of WIG craft development, both domestic and foreign?

(b) What WIG craft are currently available, or will be available within 1 year, for an operational demonstration to an offshore platform?

(c) What are the capabilities of existing WIG craft to reach helidecks or platforms located on offshore energy facilities, and how many existing WIG craft are operational for any route, or working prototypes under test and evaluation, or designs in progress?

(d) What are the dimensions and operational characteristics of WIG craft; for example, speed, range, ground effect altitude, and passenger and cargo capacity?

(e) What are the weather and other factors that might limit WIG craft operations on exposed offshore routes?

(f) What are the costs and time estimates to manufacture WIG craft, and what resources are needed to manufacture them; for example, personnel, equipment, and raw material?

(3) In general, from both offshore facility operators and the WIG craft communities:

(a) What are the resources needed to plan and conduct a demonstration of offshore WIG craft operations?

(b) What would be the milestones and timeframe to conduct such a demonstration?

(4) Should current aircraft, airman, air carrier, and commercial operator requirements, as set forth in 49 U.S.C. and Title 14 of the Code of Federal Regulations apply to the certification and operation of WIG craft? (Note: 49 U.S.C. 40102(a)(6) defines an ''aircraft'' as ''any contrivance invented, used, or designed to navigate, or fly in, the air.'') If current requirements should be revised, please indicate what changes would be considered necessary.

(5) Are any additional regulatory, guidance, or policy changes needed to facilitate development of a domestic WIG industry? Where appropriate, please include why the changes are necessary.

(6) What is the predicted growth and scope of the WIG craft technology in terms of its domestic deployment in industry?

(7) Regarding credentialing:

(a) Should WIG operators be required to hold a Merchant Mariner Credential with the appropriate route and tonnage limitations for the vessel?

(b) Should current airman certification requirements apply to the operation of WIG craft? If current requirements should be revised, please indicate what changes would be considered necessary (*e.g.* category and class ratings, aeronautical knowledge, flight proficiency, aeronautical experience).

(c) Should WIG credentials be one endorsement that covers both the maritime and aviation aspects, or should there be individual certificates or endorsements for each aspect?

(d) Should aviation or maritime simulation training be required to obtain certification or an endorsement to conduct WIG operations?

(f) Should aeronautical experience be credited toward any service requirements to qualify for a WIG endorsement?

(g) If credit for aeronautical experience is to be given, what is the appropriate conversion of flight time to maritime service time?

(8) Finally, the Coast Guard seeks public comments on WIG craft development and technology and their potential ability to operate on coastwise and offshore routes that may not be covered in the questions above.

Dated: July 29, 2022.

W.R. Arguin,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention Policy.

[FR Doc. 2022–16626 Filed 8–2–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. FEMA–2022–0021]

Privacy Act of 1974; System of Records

AGENCY: Federal Emergency Management Agency, U.S. Department of Homeland Security.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the U.S. Department of Homeland Security (DHS) proposes to establish a new DHS system of records titled, ''DHS/Federal Emergency Management Agency (FEMA)-017 Individuals and Households Program Equity Analysis Records System of Records.'' This system of records allows DHS/FEMA to collect from and maintain records on applicants for its disaster assistance programs, which provide financial and other tangible assistance to survivors of presidentially declared disasters or emergencies, to assess and ensure that access to and participation in the Individuals and Households Program (IHP) is accomplished in an equitable and impartial manner.

DATES: Submit comments on or before September 2, 2022. This new system will be effective upon publication. Routine uses will be effective September 2, 2022.

ADDRESSES: You may submit comments, identified by docket number FEMA–2022–0021, by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Lynn Parker Dupree, Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number FEMA–2022–0021. All comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Tammi Hines, (202) 212–5100, *FEMA-Privacy@fema.dhs.gov,* Senior Director for Information Management, Federal Emergency Management Agency, Washington, DC 20472–0001. For

privacy questions, please contact: Lynn Parker Dupree, (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to section 408 of the Stafford Act (42 U.S.C. 5174), FEMA provides assistance to individuals and households following a presidentially declared disaster or emergency. Section 308(a) of the Stafford Act (and its implementing regulation at 44 CFR 206.11) requires that FEMA disaster assistance including ''the distribution of supplies, the processing of applications, and other relief and assistance activities'' by FEMA and recipients of FEMA financial assistance ''be accomplished in an equitable and impartial manner, without discrimination on the grounds of race, color, religion, nationality, sex, age, disability, English proficiency, or economic status.''

This system of records notice allows FEMA to collect demographic information during the registration process and combine it with assistance records and customer satisfaction survey response records to measure the effectiveness and outcomes of benefits and services FEMA provides through the Individuals and Households Program. The purpose of collecting this information is to allow FEMA to assess its compliance with civil rights, nondiscrimination, and equity requirements and obligations as outlined in the Stafford Act and other federal civil rights laws. For example, title VI of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, or national origin in any program or activity that receives federal funds or other federal financial assistance, and section 504 of the Rehabilitation Act of 1973 requires that individuals with disabilities shall not be excluded from, denied the benefits of, or be subjected to discrimination under any program or activity that receives federal financial assistance or is conducted by a federal agency.

FEMA will conduct statistical analysis to examine the relationships between demographic data and program outcomes. This will help gain insight about any potential disparities in disaster assistance delivery. Analyses will be conducted throughout the lifecycle of the application process. In the initial stages of the application process, the data will inform FEMA about registration rates compared to community demographics, indicating if further outreach is needed. After inspection and decision, the data will be used to inform FEMA about eligibility and demographics. After the application process, the data will indicate differences in appeal rates and outcomes. And then much later, Disaster outcomes can be compared to one another.

Although FEMA may combine registration, appeal, and survey information with demographic responses for equity analysis, FEMA will not use these datasets or an individual's answers compiled from Individual Assistance demographic questions to make disaster assistance eligibility determinations for that individual. For example, FEMA will use statistical analysis to determine:

- Differences between demographic groups and Individuals and Households Program outcomes. This may include:
  - Program referral rates
  - Insured rates
  - Eligibility rates
  - Eligibility amounts
  - Assistance denial reasons
  - Appeals rates and/or types
- Appeal outcomes between different demographic groups. If certain demographic groups have a higher rate of appeals, FEMA will examine the stated reasons for appeals to determine why the differences may exist.
- Relationships between demographic data and registration damage self-assessment questions, or the accuracy of the self-assessment compared to FEMA inspector damage determinations. More inaccuracies associated with a particular demographic group may indicate that the self-assessment needs revision. For example, people who speak English as a second language may struggle more with understanding how to evaluate their damage, and perhaps the instructions need modification.
- If specific policies, procedures, guidelines, or employee/contractor behavior attribute to any disparities in program outcomes.
- The impact of proposed changes in policy, law, regulations, and procedure on small, vulnerable populations. Such analysis will aid with future planning and identify deficiencies in current FEMA processes that may need modification to be fairer and more equitable.

Example Use Cases:

Demographic data in Individuals and Households Program will be used in the following ways to help improve operational outcomes for vulnerable communities:

- Prioritize the placement of Disaster Recovery Centers and Disaster Survivor Assistance Teams in communities where vulnerable applicants are applying.
- Compare registration data to Census data in the community to identify areas where vulnerable people live but are not applying for assistance to improve outreach and messaging in those communities.
- Prioritize Transitional Sheltering Assistance (TSA), non-congregate sheltering, or direct housing programs in the most impacted areas and develop resource plans to provide the additional support needed for vulnerable populations.
- Understand whether cultural differences require different operational procedures to best meet the needs of vulnerable survivors.

DHS/FEMA may share information with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice. However, FEMA will only share aggregate, anonymized data unless approved by the DHS Privacy Office.

This newly established system will be included in DHS's inventory of record systems.

II. Privacy Act

The fair information practice principles found in the Privacy Act underpin statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides covered persons with a statutory right to make requests for access and amendment to covered records, as defined by the Judicial Redress Act, along with judicial review for denials of such requests. In addition, the Judicial Redress Act prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the DHS/FEMA–017 Individuals and Households

Program Equity Analysis Records System of Records.

In accordance with 5 U.S.C. sec 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

U.S. Department of Homeland Security (DHS)/Federal Emergency Management Agency (FEMA)-017 Individuals and Households Program Equity Analysis Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained in FEMA IT systems and at the FEMA Headquarters in Washington, DC, and the FEMA data centers.

SYSTEM MANAGER(S):

Division Director, Individual Assistance Division, Office of Response and Recovery, *FEMA-Recovery-Technology-ActionOfficer@fema.dhs.gov,* 500 C Street Southwest, Washington, DC 20472.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C. 5174; 44 CFR 206.110–206.191 (implementing section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act); Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.;* 44 CFR part 7 (implementing Title VI for FEMA-assisted program. See specifically 7.10, which allows data collection to ascertain compliance); section 308(a) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5151; 44 CFR 206.11 (implementing section 308 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act); section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794; Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.;* 44 CFR 7.910–7.949 (implementing regulations for the Age Discrimination Act of 1975); Executive Order 13166—Improving Access to Services for Persons with Limited English Proficiency; Executive Order 13985—Advancing Racial Equity and Support for Underserved Communities Through the Federal Government; Executive Order 13995—Ensuring an Equitable Pandemic Response and Recovery; and Executive Order 13988—Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to allow FEMA to collect and use demographic information to assess whether and to what extent its policies and programs for providing disaster assistance to individuals and households are carried out in an equitable and impartial manner, without discrimination on the grounds of race, color, religion, nationality, sex, age, or economic status.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by the system include applicants for and recipients of FEMA assistance (*i.e.,* disaster survivors).

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in the system include:

- FEMA equity analysis demographics records:
  - Race
  - Ethnicity
  - Tribal membership status
  - Gender/gender identity
  - Education level
  - Marital status
- FEMA disaster assistance registration and assistance records:
  - Disaster number
  - FEMA registration ID and occupant ID
  - Applicant/co-applicant information:
    - Full name
    - Social Security number or A-number
    - Date of birth
    - Phone numbers
    - Email addresses
    - Mailing addresses
    - Language(s) spoken
    - Number of dependents claimed
  - Damaged dwelling:
    - Addresses of the damaged dwelling and the applicant's current location (if other than the damaged dwelling)
    - County
    - Geospatial location of dwelling
    - Phone numbers
    - Information related to residence (accessibility, type, own/rent, damage sustained)
  - Disaster-related expenses
  - Emergency needs (*e.g.,* food, clothing, shelter)
  - Disability-related needs and accommodations (*e.g.,* sign language interpreter, assistive listening device, braille, wheelchair access, mobility, mental, hearing, vision, or other needs and accommodations)
  - Occupant and household information (for all occupants at the time of disaster):
    - Name (first name, middle initial, last name)
    - Age
    - Relationship to applicant
    - Dependent? (Yes/No)
    - Sex
    - Pre- and post-disaster income information of occupants 18 years of age or older
    - Tribal membership status
  - Business damage:
    - Self-employment is primary income? (Yes/No)
    - Business or rental property affected? (Yes/No)
  - Authorization for electronic funds transfer of benefits:
    - Prefers electronic funds transfer (Yes/No)
  - Comments and correspondence from the applicant
  - Public records information for identity verification
  - Disaster loan status (*i.e.,* rejected, approved, declined, verified, cancelled)
  - Information related to determining eligibility for assistance including date of the disaster, application status, insurance information, types and amount of damage to the dwelling, types of supporting documentation (*e.g.,* death certificates, invoices, or receipts, and documentation to supporting accommodations or access and functional need requests and repairs), and results of the home inspection (including inspector's notes and determination) and types of documentation supporting identity, occupancy, or ownership
  - Correspondence and documentation related to determining eligibility and appropriate housing unit size, type, and location for temporary housing assistance including general correspondence; complaints; requests for disbursement of payments; inquiries from tenants and landlords; information related to household access and functional needs; general administrative and fiscal information; payment schedules and forms; termination notices; information shared with the temporary housing program staff from other agencies; leases; contracts; specifications for repair of disaster damaged residences; reasons for revocation or denial of aid; sales information related to occupant purchase of housing units; and the status or disposition of housing applications
  - Recoupment, appeals, and/or arbitration (oral hearings) of such determinations
  - Notice of Potential Debt Letter
  - Notations and reports of decisions for disaster or similar financial awards and assistance from other FEMA programs, federal and state agencies, insurance companies, employers, banks, financial, power/utility companies, health care providers, safety/rescue services, and public or private entities as they relate to determinations of applicants' eligibility for Individuals and Households Program disaster assistance
  - Inspection Reports:
    - Inspection reports contain applicants' personally identifiable information (as outlined above) and results of assessments of damaged real property; personal property; and goods, which may include descriptions and photographic images of an applicant's home and personal items; video and/or audio of the inspection conducted on the home; and notations of cleaning, sanitizing, and debris removal by contractors and partnering agencies. Inspection reports may also include Inspector ID
  - Assistance from Other Sources:
    - Other files independently kept by the state, territory, tribe, local government, voluntary agency, or other sources of assistance that

contain records of persons who request disaster aid including administrative files and reports required by FEMA for Other Needs Assistance under the Individuals and Households Program. The states, territories, tribes, local governments, voluntary agencies, and other sources of assistance keep the same type of information about individuals as described under registration, inspection, and temporary housing assistance records
- Records of assistance from the FEMA National Flood Insurance Program (name, address, disaster assistance coverage required code, policy number, policy number, policy effective date, policy coverage building, policy coverage contents, new policy date, and expiration date)
- Customer service survey responses
- Demographic information (race, ethnicity, religion, gender, sex, nationality, age, disability, English proficiency, economic status, income level, marital status)
- Responses to customer service and customer satisfaction survey questions
- Investigation results that may contain the name and address of the applicants (initially collected to support recoupment, appeals, oral hearings, or other legal proceedings in order to recover disaster assistance)

RECORD SOURCE CATEGORIES:

FEMA may obtain records from disaster survivors (*i.e.,* applicants) through disaster assistance registration (OMB 1660–0002/FEMA Forms 009–0–1 and 009–0–2), through the demographic survey collection (OMB 1660–NW133 Generic Clearance for Civil Rights and Equity), and from FEMA customer satisfaction/customer service survey responses (OMB 1660–0143/FEMA Forms 519–0–36, 519–0–37, 519–0–38, 519–0–39, 519–0–40, and 519–0–41; and OMB 1660–0145/FEMA Forms 519–0–44, 519–0–45, 519–0–46, 519–0–47, 519–0–48, 519–0–49, 519–0–50, and 519–0–51).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including the U.S. Attorneys Offices, or other federal agencies conducting litigation or proceedings before any court, adjudicative, or administrative body, when it is relevant and necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof
2. Any employee or former employee of DHS in his/her official capacity
3. Any employee or former employee of DHS in his/her individual capacity, only when DOJ or DHS has agreed to represent the employee
4. The United States or any agency thereof

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. secs. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when (1) DHS suspects or has confirmed that there has been a breach of the system of records; (2) DHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DHS (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

F. To another federal agency or federal entity, when DHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

G. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

DHS/FEMA stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

DHS/FEMA may retrieve records by any of the demographic characteristics, FEMA registration ID, name, disaster number, and geographic information (county, city, zip code, Census geography).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records pertaining to disaster assistance will be placed in inactive storage two years after FEMA receives the application and will be destroyed when they are six years and three months old, in accordance with NARA Authority N1–311–86–1, item 4C10a.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DHS/FEMA safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. DHS/FEMA has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the computer systems containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals seeking access to and notification of any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Chief Privacy Officer and the FEMA Freedom of Information Act (FOIA) Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''Contact Information.'' If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, U.S. Department of Homeland Security, Washington, DC 20528–0655 or electronically at *https://www.dhs.gov/dhs-foia-privacy-act-request-submission-form.* Even if neither the Privacy Act nor the Judicial Redress Act provide a right of access, certain records about you may be available under the Freedom of Information Act.

When an individual is seeking records about himself or herself from this system of records or any other Departmental system of records, the individual's request must conform with the Privacy Act regulations set forth in 6 CFR part 5. The individual must first verify his/her identity, meaning that the individual must provide his/her full name, current address, and date and place of birth. The individual must sign the request, and the individual's signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. In addition, the individual should:

- Explain why he or she believes the Department would have the information being requested
- Identify which component(s) of the Department he or she believes may have the information
- Specify when the individual believes the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records;

If the request is seeking records pertaining to another living individual, the request must include an authorization from the individual whose record is being requested, authorizing the release to the requester.

Without the above information, the component(s) may not be able to conduct an effective search, and the individual's request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

For records covered by the Privacy Act or covered JRA records, individuals may make a request for amendment or correction of a record of the Department about the individual by writing directly to the Department component that maintains the record, unless the record is not subject to amendment or correction. The request should identify each particular record in question, state the amendment or correction desired, and state why the individual believes that the record is not accurate, relevant, timely, or complete. The individual may submit any documentation that would be helpful. If the individual believes that the same record is in more than one system of records, the request should state that and be addressed to each component that maintains a system of records containing the record. For records covered by the Privacy Act or covered Judicial Redress Act records, see ''Records Access Procedures'' above.

NOTIFICATION PROCEDURES:

See ''Record Access Procedures'' above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

* * * * *

Lynn P. Dupree,

Chief Privacy Officer, U.S. Department of Homeland Security.

[FR Doc. 2022–16587 Filed 8–2–22; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–20]

60-Day Notice of Proposed Information Collection: Request for Termination of Multifamily Mortgage Insurance; OMB Control No.: 2502–0416

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 3, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, Office of Policy Development and Research (PDR), Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Insurance Termination Request for Multifamily Mortgage.

OMB Approval Number: 2502–0416.

Type of Request: Revision of currently approved collection.

Form Number: 9807.

Description of the need for the information and proposed use: This information collection is used for mortgagees to request HUD to terminate a mortgage insurance contract for an FHA-insured mortgage upon prepayment in full of the mortgage prior to its maturity date, or by an owner's and mortgagee's mutual agreement to voluntarily terminate the contract of mortgage insurance without a prepayment. Adjustments were necessary for the number of respondents and number of responses as the previous collection did not capture the correct information. This revision captures the correct information.

Respondents: Business (mortgage lenders).

Estimated Number of Respondents: 14,580.

Estimated Number of Responses: 14,580.

Frequency of Response: 1.

Average Hours per Response: .25.

Total Estimated Burdens: 3,645.

B. Solicitation of Public Comment

This Notice is soliciting comments from members of the public and affected agencies concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Janet M. Golrick,

Acting Chief of Staff for the Office of Housing-Federal Housing Administration.

[FR Doc. 2022–16564 Filed 8–2–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–43]

30-Day Notice of Proposed Information Collection: Inspector Candidate Assessment Questionnaire; OMB Control No.: 2577–0243

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* September 2, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on February 15, 2022 at 87 FR 8604.

A. Overview of Information Collection

Title of Proposal: Inspector Candidate Assessment Questionnaire.

OMB Approval Number: 2577–0243.

Type of Request: Reinstatement with change of a previously approved collection.

Form Number: Form HUD 50002A and Form HUD 50002B—HFA.

Description of the need for the information and proposed use: To meet the requirements of HUD's Uniform Physical Condition Standards (UPCS), the Physical Condition of Multifamily Properties and the Public Housing Assessment System (PHAS) regulations, the Department conducts physical condition inspections of approximately 14,000 multifamily and public housing properties annually. HUD uses contract inspectors that are trained and certified in the UPCS protocol by HUD to conduct UPCS inspections. Individuals who wish to be trained and certified UPCS by HUD are requested to electronically submit the questionnaire via the internet. The questionnaire provides HUD with basic knowledge of an individual's inspection skills and abilities.

As part of aligning REAC UPCS inspections with those conducted by state Housing Finance Agencies, state HFA staff also may fill out a form for information purposes only prior to attending the UPCS training.

Respondents: Applicants to the UPCS inspector certification program and state HFA staff.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD 50002A	200	1	200	0.33	66	$34.86	$ 2300.76
HUD 50002B–FHA	35	1	35	0.25	9	34.86	313.74
Total Burden			235	1	75		2614.50

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) Ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2022–16603 Filed 8–2–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R4–ES–2022–0031; FF04E00000–223–FXES11130400000]

Marine Mammal Protection Act; Stock Assessment Reports for Two Stocks of West Indian Manatee

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: In accordance with the Marine Mammal Protection Act of 1972, as amended, we, the U.S. Fish and Wildlife Service (Service), have developed a revised draft marine mammal stock assessment report (SAR) for two West Indian manatee stocks, the Florida manatee stock (*Trichechus manatus latirostris*) and the Puerto Rico stock of Antillean manatees (*Trichechus manatus manatus*). We now make both revised draft SARs available for public review and comment.

DATES: Comments on the revised draft SARs must be received by November 1, 2022.

ADDRESSES: *Document* availability: You may view the revised draft SARs and the lists of references at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2022–0031, or these documents may be requested as described under **FOR FURTHER INFORMATION CONTACT**.

Comment submission: You may submit comments on the revised draft SARs by one of the following methods:

- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R4–ES–2022–0031, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, Virginia 22041–3803.
- *Electronic submission:* Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments to Docket No. FWS–R4–ES–2022–0031. We will post all comments at *https://www.regulations.gov.* You may request that we withhold personal identifying information from public review; however, we cannot guarantee that we will be able to do so. See Request for Public Comments for more information.

FOR FURTHER INFORMATION CONTACT: *Florida manatee stock:* Lourdes Mena, USFWS Florida Ecological Services Field Office, 7915 Baymeadows Way, Suite 200, Jacksonville, FL, by telephone (904–731–3134), or by email (*Lourdes_Mena@fws.gov*).

Puerto Rico manatee stock: Edwin Muñiz, USFWS Caribbean Ecological Services Field Office, P.O. Box 491, Boquerón, PR, by telephone (786–244–0081), or by email (*Edwin_Muniz@fws.gov*).

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: The Florida manatee (*Trichechus manatus latirostris*) and the Antillean manatee (*Trichechus manatus manatus*) are both subspecies of the West Indian manatee (*Trichechus manatus*), whose range includes the U.S. Atlantic and Gulf of Mexico coasts, the Caribbean Sea, and northern South America. We announce the availability for review and comment of draft marine mammal stock assessment reports (SARs) for two stocks of the West Indian manatee: the Florida manatee stock and the Puerto Rico stock of Antillean manatees.

Background

Under the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and its implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR part 18, the U.S. Fish and Wildlife Service (Service) regulates the taking; import; and, under certain conditions, possession; transportation; purchasing; selling; and offering for sale, purchase, or export, of marine mammals. One of the MMPA's goals is to ensure that stocks of marine mammals occurring in waters under U.S. jurisdiction do not experience a level of human-caused mortality and serious injury that is likely to cause the stock to be reduced below its optimum sustainable population level (OSP). OSP is defined under the MMPA as the number of animals that will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element (16 U.S.C. 1362(9)).

To help accomplish the goal of maintaining marine mammal stocks at their OSPs, section 117 of the MMPA requires the Service and the National Marine Fisheries Service (NMFS) to prepare a SAR for each marine mammal stock that occurs in waters under U.S. jurisdiction. A SAR must be based on the best scientific information available; therefore, we prepare it in consultation with regional scientific review groups established under section 117(d) of the MMPA. Each SAR must include:

1. A description of the stock and its geographic range;
2. A minimum population estimate, current and maximum net productivity rate, and current population trend;
3. An estimate of the annual human-caused mortality and serious injury by source and, for a strategic stock, other factors that may be causing a decline or impeding recovery;
4. A description of commercial fishery interactions;
5. A categorization of the status of the stock; and
6. An estimate of the potential biological removal (PBR) level.

The MMPA defines the PBR 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 OSP (16 U.S.C. 1362(20)). The PBR is the product of the minimum population estimate of the stock (N_{min}); one-half the maximum theoretical or estimated net productivity rate of the stock at a small population size (R_{max}); and a recovery factor (F_r) of between 0.1 and 1.0, which is intended to compensate for uncertainty and unknown estimation errors. This can be written as:

$$PBR = (N_{min})(\tfrac{1}{2} \text{ of the } R_{max})(F_r)$$

Section 117 of the MMPA also requires the Service and NMFS to review the SARs (a) at least annually for stocks that are specified as strategic stocks, (b) at least annually for stocks for which significant new information is available, and (c) at least once every 3 years for all other stocks. If our review of the status of a stock indicates that it has changed or may be more accurately determined, then the SAR must be revised accordingly.

A strategic stock is defined in the MMPA as a marine mammal stock (a) for which the level of direct human-caused mortality exceeds the PBR level; (b) which, based on the best available scientific information, is declining and is likely to be listed as a threatened species under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), within the foreseeable future; or (c) which is listed as a threatened or endangered species under the ESA, or is designated as depleted under the MMPA (16 U.S.C. 1362(19)).

Stock Assessment Report History for Two Stocks of West Indian Manatee

The SARs for the Florida and Puerto Rico stocks of the West Indian manatee were last revised in 2014. Because the West Indian manatee is listed as a

threatened species under the ESA, both stocks are considered strategic. Therefore, the Service reviews the stock assessment annually. The Service has determined stock assessment revisions are warranted for both stocks because the status of the stocks can be more accurately determined at this time.

Summary of Draft Stock Assessment Report for Two Stocks of West Indian Manatee

The following table summarizes some of the information contained in the draft SARs for the Florida and Puerto Rico stocks of the West Indian manatee, which includes the stocks' N_{min}, R_{max}, F_r, PBR, and annual estimated human-caused mortality and serious injury. The status of both stocks is assessed as strategic. After consideration of any public comments we receive, the Service will revise and finalize the SARs, as appropriate. We will publish a notice of availability and summary of the final SARs, including responses to submitted comments.

In March 2021, the Service declared an Unusual Mortality Event (UME) along the Atlantic coast of Florida for the Florida stock. The event, which began in December 2020 and is ongoing, is associated with phytoplankton blooms and seagrass loss in the Indian River Lagoon. The effect of the UME on population size and trend is not known at this time but will be assessed in the future based on new abundance estimates that are being developed and additional population modeling. We are working closely with our conservation partners to monitor and address the UME. No UME has been declared for the Puerto Rico stock.

SUMMARY—DRAFT REVISED STOCK ASSESSMENT REPORTS FOR THE FLORIDA AND PUERTO RICO STOCKS OF WEST INDIAN MANATEE

West Indian manatee stock	N_{MIN}	R_{MAX}	F_R	PBR	Annual estimated human-caused mortality (5-year average)	Stock status
Florida manatees	8,237	0.062	0.5	127.67	144.8 (Years 2014–2018)	Strategic.
Antillean manatees (Puerto Rico)	319	0.04	0.4	2.55	4 (Years 2015–2019)	Strategic.

Request for Public Comments

If you wish to comment on the revised draft SARs, you may submit your comments by any of the methods described in **ADDRESSES**. Please identify which revised draft SAR you are commenting on, make your comments as specific as possible, confine them to issues pertinent to the revised draft SAR, and explain the reason for any changes you recommend. Where possible, your comments should reference the specific section or paragraph that you are addressing. The Service will consider all comments that are received before the close of the comment period (see **DATES**).

Comments, including names and street addresses of respondents, will become part of the administrative record for these revised draft SARs. Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comments to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

References

A complete list of references used in the revision of the draft SARs is available on the internet at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2022–0031 and upon request from the Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authority

The authority for this action is the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*)

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–16625 Filed 8–2–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2022–N036; FXES11130800000–223–FF08E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before September 2, 2022.

ADDRESSES: *Document availability and comment submission:* Submit requests for copies of the applications and related documents and submit any comments by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* XXXXXX or PER0001234).

- *Email: permitsR8ES@fws.gov.*
- *U.S. Mail:* Susie Tharratt, Regional Recovery Permit Coordinator, U.S. Fish and Wildlife Service, 2800 Cottage Way, Room W–2606, Sacramento, CA 95825.

FOR FURTHER INFORMATION CONTACT: Susie Tharratt, via phone at 916–414–6561, or via email at *permitsR8ES@fws.gov.* 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: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities

intended to promote recovery of species that are listed as endangered or threatened under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting, in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
PER0045066	Zachary E. Leisz, West Sacramento, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, and release.	New.
98083C	Sarah Willbrand, San Francisco, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, and release.	Renew.
825573	Brian Cypher, Bakersfield, California.	• Tipton kangaroo-rat (*Dipodomys nitratoides nitratoides*). • San Joaquin kit fox (*Vulpes macrotis mutica*). • Blunt-nose leopard lizard (*Gambelia silus*). • Fresno kangaroo-rat (*Dipodomys nitratoides exilis*). • Buena Vista Lake ornate shrew (*Sorex ornatus relictus*). • Giant kangaroo-rat (*Dipodomys ingens*). • Bakersfield cactus (*Opuntia treleasei*).	CA	Capture, handle, mark, insert PIT (passive integrated transponder) tag, attach/remove radio transmitters, take biological samples, hold in captivity, release, provide treatment for sarcoptic mange, and collect tissue, seeds, and whole plants.	Renew.
PER0045091	Environmental Solutions and Innovations, Inc., Cincinnati, Ohio.	• Quino checkerspot butterfly (*Euphydryas editha quino*). • Franklin's bumble bee (*Bombus franklini*).	CA, OR	Pursue	New.
067064	Lindsay Messett, Long Beach, California.	• Quino checkerspot butterfly (*Euphydryas editha quino*). • Southwestern willow flycatcher (*Empidonax traillii extimus*). • El Segundo blue butterfly (*Euphilotes battoides allyni*).	CA	Pursue, play recorded vocalizations, capture, handle, and release.	Renew and Amend.
227185	Andrew Brent Eastty, Alpine, California.	• Quino checkerspot butterfly (*Euphydryas editha quino*). • Southwestern willow flycatcher (*Empidonax traillii extimus*).	CA, AZ, NM, TX	Pursue, play recorded vocalizations.	Renew.
74753B	Stefanie Nisich, San Luis Obispo, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, and release.	Renew and Amend.
27501B	Travis Kegel, San Juan Capistrano, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*).	CA	Play recorded vocalizations.	Renew.
PER0045132	Logan Mccardle, Ponchatoula, Louisiana.	• Sierra Nevada yellow-legged Frog (*Rana sierrae*).	CA	Survey, capture, handle, and release.	New.
96514A	Jonathan Aguayo, Buena Park, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*).	CA	Play recorded vocalizations.	Renew.
PER0045140	Utah State University, (Gary Thiede), Logan, Utah.	• Cui-ui (*Chasmistes cujus*)	NV	Capture, handle, and release.	New.
28317A	David Simi, Saratoga, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, and release.	Renew.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
67570A	Brett Hanshew, Sacramento, California.	• San Francisco garter snake (*Thamnophis sirtalis tetrataenia*). • California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments. • Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Vernal pool tadpole shrimp (*Lepidurus packardi*).	CA	Survey, capture, handle, mark, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
PER0045160	Kyle Verblaauw, Pacifica, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, and release.	New.
179036	Cullen Wilkerson, Richmond, CA.	• California Ridgway's rail (*Rallus* [*longirostris*] *obsoletus obsoletus*).	CA	Survey, play recorded vocalizations.	Amend.
213308	Joseph DiDonato, Alameda, California.	• Salt marsh harvest mouse (*Reithrodontomys raviventris*).	CA	Capture, handle, tag, collect samples (hair), mark (ear clip), and release.	Renew.
86222B	Ethan Ripperger, Ventura, California.	Southwestern willow flycatcher (*Empidonax traillii extimus*).	CA, NV, TX, AZ, NM, CO, UT.	Play recorded vocalizations.	Renew and Amend.
018909	Kelly Rios, Brea, California.	• Quino checkerspot butterfly (*Euphydryas editha quino*). • El Segundo blue butterfly (*Euphilotes battoides allyni*). • San Bernardino kangaroo-rat (*Dipodomys merriami parvus*).	CA	Pursue, survey, capture, handle, and release.	Renew.
PER0045233	Paul Keating, Citrus Heights, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Survey, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	New.
221287	Diana Saucedo, San Diego, California.	• Quino checkerspot butterfly (*Euphydryas editha quino*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Pursue, survey, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
077388	Oregon Zoo (Peter Grimm), Portland, Oregon.	• California condor (*Gymnogyps californianus*).	OR	Receive viable eggs, captive-bred condors, and condors from the wild from the Los Angeles Zoo, the San Diego Zoo and Safari Park, the World Center for Birds of Prey, and condor field sites; handle and provide veterinary care; conduct captive breeding; collect and transfer molted feathers.	Renew.
778668	Bryan Mori, Watsonville, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments Santa Cruz long-toed salamander (*Ambystoma macrodactylum croceum*).	CA	Survey, capture, handle, and release.	Renew.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
081306	Howard Clark, Clovis, California.	• Buena Vista Lake ornate shrew (*Sorex ornatus relictus*). • Fresno kangaroo-rat (*Dipodomys nitratoides exilis*). • Giant kangaroo-rat (*Dipodomys ingens*). • Tipton kangaroo-rat (*Dipodomys nitratoides nitratoides*). • Morro Bay kangaroo-rat (*Dipodomys heermanni morroensis*). • San Bernardino Merriam's kangaroo-rat (*Dipodomys merriami parvus*). • Pacific pocket mouse (*Perognathus longimembris pacificus*).	CA	Survey, capture, trap, conduct instructional workshops, handle, and release.	Renew and Amend.
06873C	Environmental Science Association, San Diego, California.	• Light-footed Ridgway's rail (*Rallus obsoletus levipes*). • Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Play recorded vocalizations, pursue, survey by pursuit, survey capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew and Amend.
60147A	Heather Moine, Goleta, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Survey, capture, handle, release, collect adult vouchers, collect branchiopod cysts.	Renew.
PER0045166	Dustin Janeke, Santee, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Survey, pursue, capture, handle, release, collect adult vouchers, collect branchiopod cysts.	Renew.
87004B	Tara Baxter, San Diego, California.	• Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Pursue	Renew.
36118B	Callie Amoaku, Valley Center, California.	• Quino checkerspot butterfly (*Euphydryas editha quino*). • Casey's June beetle (*Dinacoma caseyi*).	CA	Survey by pursuit, handle, live capture, and release.	Renew.
12511A	Kathryn Allan, San Francisco, California.	• Salt marsh harvest mouse (*Reithrodontomys raviventris*).	CA	Survey, capture, handle, and release.	Renew.
094642	University of California, Los Angeles (Howard Shaffer), Los Angeles, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments. • Santa Cruz long-toed salamander (*Ambystoma macrodactylum croceum*).	CA	Capture, handle, mark, release, relocate; collect eggs, tissue, or small individuals for genetic analysis; sacrifice or remove from the wild for voucher specimens; test for diseases; keep and study in captivity; and conduct instructional workshops involving field survey methods.	Renew and Amend.
64146A	Patricia Valcarel, San Francisco, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • San Francisco garter snake (*Thamnophis sirtalis tetrataenia*).	CA	Survey, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
02351A	Timothy J. Searl, Searl Biological Services, Hemet, California.	• southwestern willow flycatcher (*Empidonax traillii extimus*).	CA, NV, TX, AZ, NM, CO, UT.	Play recorded vocalizations.	Renew and Amend.
58862A	Greg Mason, San Diego, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Survey, pursue, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
221411	Center for Natural Lands Management, Temecula, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*). • Giant kangaroo-rat (*Dipodomys ingens*). • Stephens' kangaroo-rat (*Dipodomys stephensi*). • Tipton kangaroo-rat (*Dipodomys nitratoides nitratoides*). • Morro Bay kangaroo-rat (*Dipodomys heermanni morroensis*). • San Bernardino Merriam's kangaroo-rat (*Dipodomys merriami parvus*). • Pacific pocket mouse (*Perognathus longimembris pacificus*). • California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments. • Tidewater goby (*Eucyclogobius newberryi*). • Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*). • San Diego ambrosia (*Ambrosia pumila*). • Least Bell's vireo (*Vireo bellii pusillus*).	CA	Play recorded vocalizations; survey, capture, handle, release, conduct habitat restoration, and utilize tracking tubes; locate and monitor nests, and remove brown-headed cowbird (*Molothrus ater*) eggs and chicks from parasitized nests; collect adult vouchers, and collect branchiopod cysts; pursue; collect tissue, seeds, and whole plants.	Renew.
067992	Dan Dugan, Morro Bay, California.	• Tidewater goby (*Eucyclogobius newberryi*). • Morro shoulderband snail (*Helminthoglypta walkeriana*).	CA	Survey, capture, handle, measure, relocate, release, collect voucher specimens.	Renew.
06145B	Alicia Cooper Hill, San Diego, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Survey, pursue, capture, handle, release, collect adult vouchers, collect branchiopod cysts.	Renew.
PER0045259	Ross J Wilming, San Francisco, California.	• California Ridgway's rail (*Rallus* [*longirostris*] *obsoletus obsoletus*).	CA	Play recorded vocalizations.	New.
PER0045262	JBD Environmental Consulting LLC, Pismo Beach, California.	• Tidewater goby (*Eucyclogobius newberryi*).	CA	Survey, capture, handle, measure, relocate, release, collect voucher specimens.	New.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
054120	Russell Huddleston, Oakland, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*). • Soft bird's beak (*Cordylanthus mollis* ssp. *mollis*). • Ione buckwheat (*Eriogonum apricum* var. *apricum*). • Sacramento orcutt grass (*Orcuttia viscida*). • Solano grass (*Tuctoria mucronata*) .. • Contra Costa goldfields (*Lasthenia conjugens*). • Hartweg's golden sunburst (*Pseudobahia bahiifolia*).	CA	Capture, handle, release, collect adult vouchers, collect branchiopod cysts, collect tissue, seeds, and whole plants.	Renew.
76006B	Zoological Society of San Diego (San Diego Zoo Wildlife Alliance), San Diego, California.	• Mountain yellow-legged frog [southern Distinct Population Segment] (*Rana muscosa*).		Capture, handle, measure, mark, tag, and release; attach radio transmitters to captive individuals; conduct radio telemetry; inoculate adults and juveniles in captivity and in the wild with symbiotic bacteria; collect voucher specimens; collect blood, tissue, toe clippings/toe webbing biopsies, and/or urine samples; swab; transport; captive breed and rear; remove infertile eggs from egg masses released from captivity; collect sperm for cryopreservation efforts from wild and captive males; conduct studies in assisted reproduction and hormone treatments in captive breeding; conduct captive research, including disease treatment, behavior, husbandry, reintroduction, and interspecific competition studies; administer veterinary care; euthanize; release to the wild (translocate); conduct predator exposure research in the wild.	Renew and Amend.
29522A	Kenneth Gilliland, Ventura, California.	• Tidewater goby (*Eucyclogobius newberryi*).	CA	Capture, handle, measure, relocate, release, and collect voucher specimens.	Amend.
92719B	Thomas Dayton, Yorba Linda, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*).	CA, NV	Play recorded vocalizations.	Renew.
139628	Garcia and Associates, San Francisco, California.	• California tiger salamander (Ambystoma californiense), Sonoma County and Santa Barbara County distinct population segments. • Sierra Nevada yellow-legged frog (*Rana sierrae*).	CA	Survey, capture, handle, collect tissues, and release.	Renew.
227263	Emilie Strauss, Berkeley, California.	• California Ridgway's rail (*Rallus* [*longirostris*] *obsoletus obsoletus*).	CA	Survey, play recorded vocalizations.	Renew.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
59234C	Advanced Solution for Earth's Future (Tania Asef) Los Angeles, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Survey, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
94702B	Kristin Hubbard, Redding, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Survey, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
PER0045277	Glen Y. Kinoshita, Lakeside, California.	• Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Survey, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	New.
029414	Nathan Moorhatch, La Habra, California.	• Delhi Sands flower-loving fly (*Rhaphiomidas terminatus abdominalis*). • Quino checkerspot butterfly (*Euphydryas editha quino*). • Casey's June Beetle (*Dinacoma caseyi*).	CA	Pursue, handle, live-capture and release.	Renew.
839078	Spencer Langdon, San Pedro, California.	• California least tern (*Sterna antillarum browni*).	CA	Harass by survey, locate and monitor nests.	Renew.
94719B	Richard Lis, Redding, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Survey, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
063230	Jim Rocks, San Diego, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Survey, pursue, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
43610A	Jessica Orsolini, Sacramento, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, release.	Renew.
99057B	Steve Howard, Ventura, California.	• Tidewater goby (*Eucyclogobius newberryi*). • Unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*).	CA	Survey, capture, handle, and release.	Renew.
105545	Wendy Knight, San Luis Obispo, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, release; collect tissue samples; remove and transport hybridized individuals from the wild; and conduct habitat restoration.	Renew.
93072A	Joel Mulder, Ventura, California.	• Tidewater goby (*Eucyclogobius newberryi*). • Unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*).	CA	Survey, capture, handle, and release.	Renew.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
92167B	San Francisco Zoological Society (Tanya Peterson), San Francisco, California.	• Sierra Nevada yellow-legged frog (*Rana sierrae*). • Mountain yellow-legged frog [northern Distinct Population Segment] (*Rana muscosa*). • Yosemite toad (*Anaxyrus canorus*) ..	CA, NV	Transport, captive-rear, provide veterinary treatment and husbandry, take skin swabs, clip toes or tails for genetic analysis, mark, provide disease treatment and immunization, perform behavioral and disease research, hold for educational display, release, sacrifice, and necropsy.	Renew.
118356	Olofson Environmental, Inc., Oakland, California.	• California Ridgway's rail (*Rallus* [*longirostris*] *obsoletus obsoletus*).	CA	Survey, play recorded vocalizations.	Renew.
836491	Michael Wilcox, Riverside, California.	• Delhi Sands flower-loving fly (*Rhaphiomidas terminatus abdominalis*). • Quino checkerspot butterfly (*Euphydryas editha quino*). • Casey's June Beetle (*Dinacoma caseyi*).	CA	Pursue, handle, and live-capture.	Renew.
840619	Jeff Priest, dba Priest Wildlife and Compliance Services, San Diego, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Survey, play recorded vocalizations.	Renew.
40087B	United States Department of Agriculture Forest Service, Cathy Brown, Sonora, California.	• Sierra Nevada yellow-legged frog (*Rana sierrae*). • Mountain yellow-legged frog [northern Distinct Population Segment] (*Rana muscosa*). • Yosemite toad (*Anaxyrus canorus*) ..	CA	Survey, capture, handle, measure, take skin swabs, clip toes, insert PIT (passive integrated transponder) tags, mark with VIE (visual implant elastomer), attach radio transmitters, transport, translocate, emergency salvage, and release.	Renew.
53825B	Zoological Society of San Diego (Ignacio Vilchis), San Diego, California.	• California least tern (*Sterna antillarum browni*).	CA	Survey, locate and monitor nests; mark and measure eggs; use decoys; utilize acoustic playback and recording devices in the colony; install and remove fence pens; radio tag (attach radio-transmitters to chicks) for the purposes of mark-recapture study; erect and use cameras to monitor nesting sites; use data loggers in nests; erect temporary hides inside the colony; deploy GPS loggers and nanotags, and remove geolocators from adults; collect blood and pull contour feathers from adults; collect or bury non-viable eggs; capture, handle, measure, band, color-band, and release.	Renew.
168924	Jeff Gurule, North Fork, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Survey, capture, handle, and release, collect adult vouchers, and collect branchiopod cysts.	Renew.
98997	Gregory Warrick, Tehachapi, California.	• Giant kangaroo-rat (*Dipodomys ingens*). • Tipton kangaroo-rat (*Dipodomys nitratoides nitratoides*).	CA	Capture, mark, handle, and release.	Renew.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
13632B	Elena Gregg, Chico, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Survey, capture, handle, and release; collect adult vouchers, and collect branchiopod cysts.	Renew.
026659	Ventana Wildlife Society, Monterey, California.	• California condor (*Gymnogyps californianus*).	CA	Capture, handle, and release; bring into and maintain in temporary captivity; collect biological samples; attach transmitters and wing tags; track; provide supplemental feed in the wild; transport; enter nests for management and monitoring purposes; collect and exchange wild and captive eggs; collect and transfer molted feathers; collect microtrash from nests; flush individuals at risk; and administer health and veterinary care.	Renew.
PER0046364	Geoff Hoetker, Atascadero, California.	• Fresno kangaroo-rat (*Dipodomys nitratoides exilis*). • Giant kangaroo-rat (*Dipodomys ingens*). • Tipton kangaroo-rat (*Dipodomys nitratoides nitratoides*). • Morro shoulderband snail (*Helminthoglypta walkeriana*).	CA	Survey, capture, handle, measure, relocate, and release.	New.
035336	Vollmar Natural Lands Consulting, Berkeley, California.	• Large-flowered fiddleneck (*Amsinckia grandiflora*). • Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Collect tissue, seeds, and whole plants; survey, capture, handle, measure, relocate, release, and conduct habitat restoration activities; collect adult vouchers, and collect branchiopod cysts.	Renew.
225974	Midpeninsula Regional Open Space District, Los Altos, California.	• San Francisco garter snake (*Thamnophis sirtalis tetrataenia*).	CA	Survey, capture, handle, transfer, mark, collect tissue, and release.	Renew.
815144	Rosemary Thompson, Loveland, Colorado.	• Tidewater goby (*Eucyclogobius newberryi*). • Unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*). • California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, release, collect voucher specimens, collect tail tissue, perform habitat restoration.	Renew.
PER0046365	Kimberly Feree, Encinitas, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*). • Least Bell's vireo (*Vireo bellii pusillus*).	CA	Play recorded vocalizations; locate and monitor nests.	New.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
063608	Brian Lohstroh, San Diego, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*). • Least Bell's vireo (*Vireo bellii pusillus*). • Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA, NV, AZ, NM, UT, TX, CO.	Play recorded vocalizations, survey, locate nests, monitor nests, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
PER0046366	Kristin E. Smith, Sacramento, California.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA, OR	Harass by survey, capture, handle, and release, collect adult vouchers, and collect branchiopod cysts.	New.
157291	National Park Service—Pinnacles National Park, Paicines, California.	• California condor (*Gymnogyps californianus*).	CA	Capture, maintain in temporary captivity, collect biological samples and feathers, attach transmitters and wing tags, track, provide supplemental feed in the wild, transport, enter nests for management and monitoring purposes, collect and exchange wild and captive eggs, collect microtrash from nests, flush individuals at risk, and administer health and veterinary care.	Renew.
027742	University of California, Davis—Fish Conservation and Culture Lab, Byron, California.	• Delta smelt (*Hypomesus transpacificus*).	CA	Capture, handle, collect, transport, hold in captivity, captive breed, captive rear, conduct captive research, and conduct research of contained specimens in the wild.	Renew.
94654B	Mesa Biological, LLC, Bakersfield, California.	• Fresno kangaroo-rat (*Dipodomys nitratoides exilis*). • Giant kangaroo-rat (*Dipodomys ingens*). • Tipton kangaroo-rat (*Dipodomys nitratoides nitratoides*). • Morro Bay kangaroo-rat (*Dipodomys heermanni morroensis*).	CA	Survey, capture, handle, and release.	Renew.
106908	Manna Warburton, San Diego, California.	• Mountain yellow-legged frog [southern Distinct Population Segment] (*Rana muscosa*). • Tidewater goby (*Eucyclogobius newberryi*). • Unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*).	CA	Survey, capture, handle, and release.	Renew.
758175	Griffith Wildlife Biology, Calumet, Michigan.	• Yuma Ridgway's rail (*Rallus obsoletus yumanensis*). • Light-footed Ridgway's rail (*Rallus obsoletus levipes*). • Southwestern willow flycatcher (*Empidonax traillii extimus*). • Least Bell's vireo (*Vireo bellii pusillus*).	CA, AZ, NM, NV	Survey using recorded vocalization, locate and monitor nests, remove brown-headed cowbird (*Molothrus ater*) eggs and chicks from parasitized nests, capture, handle, band, and release.	Renew.
98536C	Stillwater Sciences, Berkeley, California.	• Tidewater goby (*Eucyclogobius newberryi*). • California freshwater shrimp (*Syncaris pacifica*). • Sierra Nevada yellow-legged frog (*Rana sierrae*).	CA	Survey, capture, handle, and release.	Renew.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
166393	Peter Trenham, Philadelphia, Pennsylvania.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, release, apply artificial egg laying substrates, and conduct training workshops.	Renew.
097845	ManTech SRS Technologies, Inc., Lompoc, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*). • El Segundo blue butterfly (*Euphilotes battoides allyni*). • Unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*). • Tidewater goby (*Eucyclogobius newberryi*). • Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*.	CA	Survey using recorded vocalizations; survey by pursuit and incidentally handle and release larvae during host plant seed collection; survey, capture, handle, and release; capture, handle, release; and collect adult vouchers and/or branchiopod cysts.	Renew and Amend.
PER0038125	Carla Angulo, San Jose, California.	• Salt marsh harvest mouse (*Reithrodontomys raviventris*).	CA	Survey, capture, handle, and release.	New.
02971C	University of California, Irvine, Stephen G. Weller, Irvine, California.	• *Schiedea hawaiiensis* (ma' oli 'oli)	CA, HI	Collect tissue, seeds, and whole plants, transfer, conduct genetic research.	Renew.
144964	Derek S. Jansen, Brentwood, California.	• California tiger salamander (*Ambystoma californiense*), Sonoma County and Santa Barbara County distinct population segments.	CA	Survey, capture, handle, and release.	Renew.
823990	Wildwing, Atascadero, CA	• California least tern (*Sterna antillarum browni*).	CA	Survey, locate nests, monitor nests.	Renew.
793645	Donald W Alley, Brookdale, California.	• Tidewater goby (*Eucyclogobius newberryi*).	CA	Survey, capture, handle, release, and collect voucher specimens.	Renew.
832946	James E. Pike, Huntington Beach, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*). • Least Bell's vireo (*Vireo bellii pusillus*).	CA	Survey using recorded vocalization, locate and monitor nests, and remove brown-headed cowbird (*Molothrus ater*) eggs and chicks from parasitized nests.	Renew.
17841A	Tetra Tech, Inc., Santa Barbara, California.	• California least tern (*Sterna antillarum browni*).	CA	Survey, locate and monitor nests.	Renew.
069534	Victor Novik, San Diego, California.	• Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Survey, pursue, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
790167	United States Geological Survey—Santa Barbara Field Station, Santa Barbara, California.	• Tidewater goby (*Eucyclogobius newberryi*).	CA	Survey, capture, handle, release, and collect voucher specimens.	Renew.
58888A	Dale Ritenour, New Orleans, Louisiana.	• Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*). • Quino checkerspot butterfly (*Euphydryas editha quino*).	CA	Survey, pursue, capture, handle, release, collect adult vouchers, and collect branchiopod cysts.	Renew.
14532C	Hannah Donaghe, Carpinteria, California.	• Tidewater goby (*Eucyclogobius newberryi*).	CA	Survey, capture, handle, and release.	Renew.
31406A	California State Parks—Central Valley District, Ventura, California.	• California least tern (*Sterna antillarum browni*).	CA	Survey, locate and monitor nests, install symbolic fencing, and install and use remote cameras in nesting areas.	Renew.
068799	Mikael Romich, Redlands, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*). • San Bernardino Merriam's kangaroo-rat (*Dipodomys merriami parvus*). • Stephens' kangaroo-rat (*Dipodomys stephensi*).	CA, NV, AZ	Survey, capture, handle, and release.	Renew.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
PER0046430	Russell Sweet, Shafter, California.	• Giant kangaroo-rat (*Dipodomys ingens*). • Tipton kangaroo-rat (*Dipodomys nitratoides nitratoides*). • Fresno kangaroo-rat (*Dipodomys nitratoides exilis*).	CA	Survey, trap, capture, handle, and release.	Renew.
785148	Wood Environment & Infrastructure, San Diego, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*). • Stephens' kangaroo-rat (*Dipodomys stephensi*). • Pacific pocket mouse (*Perognathus longimembris pacificus*). • Quino checkerspot butterfly (*Euphydryas editha quino*). • Conservancy fairy shrimp (*Branchinecta conservatio*). • Longhorn fairy shrimp (*Branchinecta longiantenna*). • Vernal pool tadpole shrimp (*Lepidurus packardi*). • Riverside fairy shrimp (*Streptocephalus woottoni*). • San Diego fairy shrimp (*Branchinecta sandiegonensis*).	CA	Pursue, survey using recorded vocalization; capture, handle, measure, mark, and release; collect adult vouchers; and collect branchiopod cysts.	Renew.
76732A	Jennifer Kendrick, Encinitas, California.	• Southwestern willow flycatcher (*Empidonax traillii extimus*).	CA	Survey using recorded vocalization.	Renew.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Peter Erickson,

Acting Regional Endangered Species Program Manager, Pacific Southwest Region, Sacramento, California.

[FR Doc. 2022–16636 Filed 8–2–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA–9412, AA–9413, AA–9421, AA–9623, AA–9661, AA–9663, AA–9690, AA–9707, AA–9721, AA–9740, AA–9894; 22X.LLAK944000.L14100000.HY0000.P]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface estate in certain lands to Calista Corporation, an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA). The lands approved for conveyance lie entirely within Clarence Rhode National Wildlife Range now known as the Yukon Delta National Wildlife Refuge. As provided by ANCSA, ownership of the subsurface estate in the same lands will be retained by the United States.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513–7504.

FOR FURTHER INFORMATION CONTACT: Abby Muth, Land Law Examiner, BLM Alaska State Office, 907–271–3345 or *amuth@blm.gov.* 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. The relay service is available 24 hours a day, 7 days a week, to leave a message or question with the BLM. The BLM will reply during normal business hours.

SUPPLEMENTARY INFORMATION: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Calista Corporation. The decision approves conveyance of surface estate in certain lands pursuant to ANCSA (43 U.S.C. 1601, *et seq.*), as amended. Ownership of the subsurface estate will be retained by the United States.

The lands are located within the Yukon Delta National Wildlife Refuge, in the following townships, and aggregate 78.31 acres: T. 15 N, R. 86 W, Seward Meridian (SM); T. 10 N, R. 88 W, SM; T. 15 N, R. 88 W, SM; T. 17 N, R. 88 W, SM; T. 18 N, R. 88 W, SM; T. 10 N, R. 89 W, SM; and T. 12 N, R. 89 W, SM.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to Sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands approved for conveyance.

The BLM will also publish notice of the decision once a week for four consecutive weeks in ''The Delta Discovery'' newspaper.

Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail which is not certified, return receipt requested, shall have until September 2, 2022 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Abby Muth,

Land Law Examiner, Adjudication Section.

[FR Doc. 2022–16580 Filed 8–2–22; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA–9350, AA–9351, AA–9360, AA–9365, AA–9366, AA–9367, AA–9369, AA–9370, AA–9378, AA–9380, AA–9382, AA–9383, AA–9384, AA–9385, AA–9386, AA–9388, AA–11263, AA–11565, 22X.LLAK944000. L14100000.HY0000.P]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface and subsurface estates in certain lands to Calista Corporation, an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA), as amended.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513–7504.

FOR FURTHER INFORMATION CONTACT: Matthew R. Lux, Land Law Examiner, BLM Alaska State Office, 907–271–3176 or *mlux@blm.gov.* 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: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Calista Corporation. The decision approves conveyance of the surface and subsurface estates in certain lands pursuant to ANCSA (43 U.S.C. 1601, *et seq.*), as amended.

The lands are located within the Yukon Delta National Wildlife Refuge, in the following townships, and aggregate 224.53 acres: T. 30 N, R., 76 W, Seward Meridian (SM); T. 30 N, R., 78 W, SM; T. 23 N, R. 85 W, SM; T. 24 N, R. 85 W, SM; T. 25 N, R., 85 W, SM; T. 24 N, R., 86 W, SM; T. 25 N, R., 86 W, SM; and T. 24 N, R., 88 W, SM.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to Sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands described above. The BLM will also publish Notice of the decision once a week for four consecutive weeks in the ''The Delta Discovery'' newspaper. Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail not certified, return receipt requested, shall have until September 2, 2022 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Matthew R. Lux,

Land Law Examiner, Adjudication Section.

[FR Doc. 2022–16581 Filed 8–2–22; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA–9803, AA–9808, AA–9809, AA–9817, AA–9821, AA–9822, AA–9832, AA–10002, AA–10005, AA–10021, AA–10022, AA–11223, AA–11738; 22X.LLAK944000. L14100000.HY0000.P]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface estate in certain lands to Calista Corporation, an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA). The lands approved for conveyance lie entirely within Clarence Rhode National Wildlife Range, now known as the Yukon Delta National Wildlife Refuge. As provided by ANCSA, ownership of the subsurface estate in the same lands will be retained by the United States.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513–7504.

FOR FURTHER INFORMATION CONTACT: Rebecca Curtiss, Land Law Examiner, BLM Alaska State Office, 907–271–5066 or *rcurtiss@blm.gov.* 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: As required by 43 CFR 2650.7(d), notice is

hereby given that the BLM will issue an appealable decision to Calista Corporation. The decision approves conveyance of surface estate in certain lands pursuant to ANCSA (43 U.S.C. 1601, *et seq.*), as amended. Ownership of the subsurface estate will be retained by the United States.

The lands aggregate 85.14 acres and are located within the Yukon Delta National Wildlife Refuge in the following townships: T. 13 N, R. 83 W, Seward Meridian (SM); T. 3 N, R. 85 W, SM; T. 12 N, R. 85 W, SM; T. 13 N, R. 85 W, SM; T. 2 S, R. 86 W, SM; T. 15 N, R. 90 W, SM; T. 15 N, R. 92 W, SM.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to Sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands approved for conveyance.

The BLM will also publish notice of the decision once a week for four consecutive weeks in ''The Delta Discovery'' newspaper.

Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail, which is not certified, return receipt requested, shall have until September 2, 2022 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Rebecca Curtiss,

Land Law Examiner, Adjudication Section.

[FR Doc. 2022–16579 Filed 8–2–22; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA–9626, AA–9726, AA–9747, AA–9748, AA–9750, AA–9794, AA–9874, AA–9877, AA–9883, AA–9976, AA–10024, AA–10092, AA–11743; 22X.LLAK944000. L14100000.HY0000.P]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface and subsurface estates in certain lands to Calista Corporation, an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA), as amended.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513–7504.

FOR FURTHER INFORMATION CONTACT: Rolando R. Masvidal, Land Law Examiner, BLM Alaska State Office, 907–271–4687, or *rmasvidal@blm.gov.* 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: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Calista Corporation. The decision approves conveyance of the surface and subsurface estates in certain lands pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601, *et seq.*), as amended. The lands are located within the Yukon Delta National Wildlife Refuge, in the following townships, and aggregate 79.08 acres: T. 18 N, R. 71 W, Seward Meridian (SM); T. 19 N, R. 72 W, SM; T. 19 N, R. 73 W, SM; T. 5 N, R. 76 W, SM; T. 21 N, R. 77 W, SM; T. 20 N, R. 78 W, SM; T. 26 N, R. 82 W, SM; T. 21 N, R. 83 W, SM; T. 26 N, R. 84 W, SM; T. 16 N, R. 86 W, SM; T. 16 N, R. 87 W, SM; T. 20 N, R. 87 W, SM; T. 24 N, R. 87 W, SM.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to Sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands described above. The BLM will also publish notice of the decision once a week for four consecutive weeks in ''The Delta Discovery'' newspaper. Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail, which is not certified, return receipt requested, shall have until September 2, 2022 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Rolando R. Masvidal,

Land Law Examiner, Adjudication Section.

[FR Doc. 2022–16582 Filed 8–2–22; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034260; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Longyear Museum of Anthropology, Colgate University, Hamilton, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Longyear Museum of Anthropology, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Longyear Museum of Anthropology. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should

submit a written request with information in support of the claim to the Longyear Museum of Anthropology at the address in this notice by September 2, 2022.

FOR FURTHER INFORMATION CONTACT: Rebecca Mendelsohn, Curator of the Longyear Museum of Anthropology and Co-director of University Museums, Colgate University, 13 Oak Drive, Hamilton, NY 13346, telephone (315) 228–6643, email *rmendelsohn@colgate.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Longyear Museum of Anthropology, Colgate University, Hamilton, NY, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

Sometime between 1924 and 1957, two unassociated funerary objects were collected by Herbert Bigford Sr., during his excavations at the Beecher (a.k.a Blowers) (Ond-1) site in Stockbridge, New York. The site file documents the identification of two burial numbers (''Burial 07'' and ''Burial 12'') from Camp A. The two unassociated funerary objects are two ceramic pottery vessels.

Sometime between 1924 and 1957, one unassociated funerary object was collected by Herbert Bigford Sr., during his excavations at the Cameron (Ond-8) site in Vernon, New York. The site file documents the identification of an unnumbered burial. The one unassociated funerary object is a ceramic pot.

Sometime between 1924 and 1957, two unassociated funerary objects were collected by Herbert Bigford Sr., during his excavations from the Dungey (Msv-6) site in Stockbridge, New York. The site file documents the identification of one unnumbered burial. The two unassociated funerary objects are one metal kettle and one woven material, bark.

Sometime between 1924 and 1957, 94 unassociated funerary objects were collected by Herbert Bigford Sr., during his excavations from the Marshall (Msv-7) site in Stockbridge, New York. The site file documents the identification of four numbered burials (''Burial 02,'' ''Burial 03,'' ''Burial 08,'' ''Burial 11''). The 94 unassociated funerary objects are one horn figurine, one bone figurine, three ceramic pottery vessels, 65 shell and glass beads, one bone carving (faunal), one metal ax head, two glass beads, one metal turtle figurine, one perforated dog canine, and 18 elk teeth.

Sometime between 1924 and 1957, one unassociated funerary object was collected by Herbert Bigford Sr., during his excavations from the Stockbridge (possibly Cameron) (Ond-8) site, in Vernon, New York. The site file documents the identification of one unnumbered burial. The one unassociated funerary object is a bone and metal scraper.

Sometime between 1924 and 1957, 448 unassociated funerary objects were collected by Herbert Bigford Sr., during his excavations from Stone Quarry (a.k.a Quarry) (Msv-4) site in Stockbridge, New York. The site file documents the identification of four burial numbers (''Burial 03,'' ''Burial 05,'' ''Burial 07,'' and ''Burial 09''). The 448 unassociated funerary objects are three ceramic pottery vessels, one metal kettle, one horn figurine, and 443 glass beads.

Sometime between 1924 and 1957, 56 unassociated funerary objects were collected by Herbert Bigford Sr., during his excavations from the Sullivan (Ond-3) site in Stockbridge, New York. The site file documents the identification of one numbered (''Burial 03'' [South]) and one unnumbered burial (''Burial camp C''). The 56 unassociated funerary objects are four stone projectile points, one groundhog mandible, one carved mammal bone, one shell pendant, two turtle shell fragments, five shell beads, 40 glass and shell beads, one metal thimble, and one ceramic pottery vessel.

Sometime between 1924 and 1957, 916 unassociated funerary objects were collected by Herbert Bigford Sr., during his excavations from the Thurston (Msv-1) site in Stockbridge, New York. The site file documents the identification of twenty-four burial numbers (''Burial 04,'' ''Burial 06,'' ''Burial 08,'' ''Burial 14,'' ''Burial 15,'' ''Burial 16,'' ''Burial 17,'' ''Burial 18,'' ''Burial 19,'' ''Burial 26,'' ''Burial 28,'' ''Burial 29,'' ''Burial 30,'' ''Burial 31,'' ''Burial 32,'' '' Burial 33,'' ''Burial 36,'' ''Burial 37,'' ''Burial 38,'' ''Burial 40,'' ''Burial 41,'' ''Burial 49,'' ''Burial 50,'' ''Burial 58'') and one or more unnumbered burials. The 916 unassociated funerary objects are 14 ceramic pottery vessels, two ceramic pottery sherds, one stone pipe, one stone celt, two stone projectile points, 68 wolf teeth (six perforated), 13 bear teeth (two perforated, two canines), five bear phalanges, 11 moose teeth (seven perforated), eight elk teeth (two perforated), 26 rodent incisors, one deer tooth, two deer phalanges, one antler, five antler fragments, one antler object, nine antler tines, 15 teeth (one perforated) (faunal), two beaver incisors, one marten skull with jaw, nine marten teeth and bone fragments, one bone (faunal), two mammal bone fragments, two pieces of rodent bone, one bird beak fragment, two worked bone game discs, one bone figurine, one bone effigy comb, one bone comb, one bone pendant, one bone and metal cutting tool, one bone handle, two bone harpoons, four bone punches, two turtle shell rattles, six turtle shell fragments (three pieces along with three additional vials), one shell gorget, 49 shell discs, 286 Wampum, 106 shell beads, two shell crescent beads, 179 glass beads, one metal tube, one metal coach bell, three metal bells, two metal rolled pipes, one metal pipe bowl, five metal chisels, one metal harpoon, one metal spike, two metal awls, one metal kettle, six metal knives, five metal knives and chisels, one iron knife with bone handle, two metal projectile points, one projectile point with shaft fragment, one round metal object, one metal object, one scissors fragment, 31 metal fragments, and one fibrous material.

In 1959, Colgate University purchased the Bigford collection from Winona F. Bigford. Currently, this collection is housed in the Longyear Museum of Anthropology.

The information derived from Herbert Bigford's excavation records, Longyear Museum collection records, scholarly publications, and consultation shows that these cultural items were removed from eight sites within Oneida territory and are unassociated funerary objects. Accordingly, the 1,520 unassociated funerary objects are culturally affiliated with the present-day Oneida Indian Nation (*previously* listed as Oneida Nation of New York).

Determinations Made by the Longyear Museum of Anthropology

Officials of the Longyear Museum of Anthropology have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 1,520 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Oneida Indian Nation (*previously* listed as Oneida Nation of New York).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Rebecca Mendelsohn, Curator of the Longyear Museum of Anthropology and Co-director of University Museums, Colgate University, 13 Oak Drive, Hamilton, NY 13346, telephone (315) 228–6643, email *rmendelsohn@colgate.edu,* by September 2, 2022. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to the Oneida Indian Nation (*previously* listed as Oneida Nation of New York) may proceed.

The Longyear Museum of Anthropology is responsible for notifying the Oneida Indian Nation (*previously* listed as Oneida Nation of New York) that this notice has been published.

Dated: July 27, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–16568 Filed 8–2–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034261; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Valentine Museum, Richmond, VA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Valentine Museum, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Valentine Museum. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Valentine Museum at the address in this notice by September 2, 2022.

FOR FURTHER INFORMATION CONTACT: Alicia Starliper, Collection Project Manager/Registrar, Valentine Museum, 1015 E Clay Street, Richmond, VA 23219, telephone 804–649–0711 Ext. 329, email *astarliper@thevalentine.org.*

SUPPLEMENTARY INFORMATION: Notice is hereby given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Valentine Museum, Richmond, VA, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

At an unknown time, 711 cultural items were removed from multiple sites in Cabell County, West Virginia and the following locations in Virginia: Col. Cabell's Farm (Albemarle County), Halifax County, Amherst County, Buckingham County, Franklin County, Charlotte County, Mecklenburg County, Fluvanna County, Franklin County, Goochland County, Hanover County, Henrico County, Shenandoah, Louisa County, Nelson County, Patrick County, Pittsylvania County, Powhatan County, Roanoke County, Rockbridge County, and Smyth County. The 711 unassociated funerary objects are one adze, 126 axes, one bannerstone, two beaded objects, six stone blades, six bone tools, one bowl, 32 celts, 22 cores, two fish hooks, four pottery fragments, one gaming stone, one gorget, two hammerstones, one hand tool, one hatchet, one hoe, one shell disk, seven stone implements, three knives, one shell necklace, two pendants, three pestles, 11 pipe and pipe fragments, 17 projectile points, one ceramic pot, four potsherds, two pottery fragments, one set of strung shells, 289 sherds, one sinker, two stone samples, 85 worked stones, 69 tools, and two vessels.

As part of his interest in prehistoric culture, museum founder Mann S. Valentine II (1824–1892), together with his sons Benjamin B. Valentine (1862–1919) and Edward P. Valentine (1864–1908), initiated multiple amateur excavations of Native American burial sites predominantly located in Virginia and North Carolina. The Valentine family disturbed these burial sites and stole ancestral human remains and funerary objects to add to their private collection, which became the foundation of the Valentine Museum.

Determinations Made by the Valentine Museum

Officials of the Valentine Museum have determined that:

• Pursuant to 25 U.S.C. 3001(3)(B), the 711 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from specific burial sites of Native American individuals.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Monacan Indian Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Alicia Starliper, Collection Project Manager/Registrar, Valentine Museum, 1015 E Clay Street, Richmond, VA 23219, telephone 804–649–0711 Ext. 329, email *astarliper@thevalentine.org,* by September 2, 2022. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to the Monacan Indian Nation may proceed.

The Valentine Museum is responsible for notifying the Monacan Indian Nation that this notice has been published.

Dated: July 27, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–16567 Filed 8–2–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0034290; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: State University of New York at New Paltz, Department of Anthropology, New Paltz, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The State University of New York at New Paltz, Department of Anthropology (SUNY New Paltz) has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is a cultural affiliation between the human remains and a present-day Indian Tribe or Native Hawaiian organization. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to SUNY New Paltz. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to SUNY New Paltz at the address in this notice by September 2, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Joseph E. Diamond, Associate Professor of Anthropology, 325 Wooster Hall, State University of New York at New Paltz, 1 Hawk Drive, New Paltz, NY 12561, telephone (845) 257–2990, email *diamondj@newpaltz.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the State University of New York at New Paltz, Department of Anthropology, New Paltz, NY. The human remains were removed from several locations in Ulster County, NY, and one location in Dutchess County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the SUNY New Paltz professional staff in consultation with representatives of the Stockbridge Munsee Community, Wisconsin.

History and Description of the Remains

In 1985, human remains representing, at minimum, one individual were removed from the Hendrickson Site in Kingston, Ulster County, NY, by Dr. A. Leonard Eisenberg of SUNY New Paltz. The human remains—one complete skeleton belonging to a male 19–20 years old—were excavated from Feature #6. No known individual was identified. No associated funerary objects are present.

In 1973, human remains representing, at minimum, one individual were removed from Richmond Parkway in the Town of Ulster, Ulster County, NY. The human remains were found in a utility trench and were brought to SUNY New Paltz by Dr. Leonard Eisenberg at that time. The human remains belong to a female 10–14 years old. Although a 1973 newspaper article discussed the discovery of points and pottery at the site, these were not included with the human remains that were transferred to SUNY New Paltz. No known individual was identified. No associated funerary objects are present.

Sometime during the 1930s–1940s, human remains representing, at minimum, one individual were removed from River Road in the Town of Esopus, Ulster County, NY. The human remains were found by road workers. The human remains belong to a female 25–35 years old. The nearly complete skeleton is missing the mandible and cranium. No known individual was identified. No associated funerary objects are present.

At an unknown time, human remains representing, at minimum, three individuals were removed from an unknown location reasonably believed to be in NY. The human remains were assembled by or gifted to Dr. Leonard Eisenberg of SUNY New Paltz prior to his death in 1992. The comingled human remains include multiple skeletal elements belonging to three individuals. No known individuals were identified. No associated funerary objects are present.

Sometime in the 1930s, human remains representing, at minimum, two individuals were removed from Huyler Rockshelter in Hyde Park, Dutchess County, NY, by Alvin Wanzer and F. Lawrence Flewelling. The human remains belong to a subadult 14–23 years old and an adult 21–32 years old, both of unknown gender. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the State University of New York at New Paltz, Department of Anthropology

Officials of the State University of New York at New Paltz, Department of Anthropology have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of eight individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Stockbridge Munsee Community, Wisconsin.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Joseph E. Diamond, Associate Professor of Anthropology, 325 Wooster Hall, State University at New York at New Paltz, 1 Hawk Drive, New Paltz, NY 12561, telephone (845) 257–2990, email *diamondj@newpaltz.edu,* by September 2, 2022. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Stockbridge Munsee Community, Wisconsin may proceed.

The State University of New York at New Paltz, Department of Anthropology is responsible for notifying the Stockbridge Munsee Community, Wisconsin that this notice has been published.

Dated: July 27, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–16569 Filed 8–2–22; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1058 (Third Review)]

Wooden Bedroom Furniture From China; Scheduling of Expedited Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on wooden bedroom furniture from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: April 8, 2022

FOR FURTHER INFORMATION CONTACT: Julie Duffy (202–708–2579), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On April 8, 2022, the Commission determined that the domestic interested party group response to its notice of institution (87 FR 121, January 3, 2022) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the review has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for this review on July 28, 2022. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the review may file written comments with the Secretary on what determinations the Commission should reach in the review. Comments are due on or before August 4, 2022 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by August 4, 2022. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on Filing Procedures, available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings. In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.
Issued: July 29, 2022.

Katherine Hiner,
Acting Secretary to the Commission.

[FR Doc. 2022–16632 Filed 8–2–22; 8:45 am]

BILLING CODE 7020–02–P

[1] A record of the Commissioners' votes is available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the joint response to its notice of institution filed on behalf of the American Furniture Manufacturers Committee for Legal Trade (''Committee''), a U.S. trade association comprised of eight domestic producers of wooden bedroom furniture, and Vaughan-Bassett Furniture Company, Inc. (''Vaughan-Bassett''), a domestic producer of wooden bedroom furniture, to be individually adequate. The eight members of the Committee are: Caperton Furniture Works, LLC, d/b/a Gat Creek; Tom Seely Furniture; Carolina Furniture Works, Inc.; Century Furniture, LLC; Johnston-Tombigbee Furniture Manufacturing Company; L. & J.G. Stickley, Inc.; Perdues, Inc.; T. Copeland & Sons, Inc.; and Vaughan-Bassett. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–562 and 731–TA–1329 (Review)]

Ammonium Sulfate From China; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty and countervailing duty orders on ammonium sulfate from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: August 1, 2022.

FOR FURTHER INFORMATION CONTACT: Peter Stebbins ((202) 205–2039), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain

information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On May 9, 2022, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews should proceed (87 FR 29878, May 17, 2022); accordingly, full reviews are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website. Participation in the review and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of these reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to these reviews.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to these reviews. A party granted access to BPI following publication of the Commission's notice of institution of these reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in these reviews will be placed in the nonpublic record on November 18, 2022, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.— The Commission will hold a hearing in connection with the reviews beginning at 9:30 a.m. on December 6, 2022. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before November 29, 2022. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the investigation, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID–19 test result may be submitted by 3pm the business day prior to the hearing.

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on December 2, 2022. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony in camera no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to these reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is November 29, 2022. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is December 13, 2022. In addition, any person who has not entered an appearance as a party to these reviews may submit a written statement of information pertinent to the subject of these reviews on or before December 13, 2022. On January 13, 2023, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before January 18, 2023, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on Filing Procedures, available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to these reviews must be served on all other parties to these reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to

extend the review period by up to 90 days pursuant to 19 U.S.C.1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 29, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–16638 Filed 8–2–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0094]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Certification of Qualifying State Relief From Disabilities Program—ATF Form 3210.12

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 September 2, 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 without Change of a Currently Approved Collection.

(2) *The Title of the Form/Collection:* Certification of Qualifying State Relief from Disabilities Program.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 3210.12.

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: State, Local, or Tribal Government.

Other: None.

Abstract: The Certification of Qualifying State Relief from Disabilities Program—ATF Form 3210.12 is used by a State official to certify to the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) that it has established a qualifying mental health relief from firearms disabilities program that satisfies certain minimum criteria established by the NICS Improvement Amendment Act of 2007 (NIAA), Public Law 110–180.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 50 respondents will respond to this collection once annually, and it will take each respondent approximately 15 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 12.5 or 13 hours, which is equal to 50 (total respondents) * 1 (# of response per respondent) * .25 (15 minutes or the time taken to prepare each response).

If additional information is required contact: Robert Houser, Assistant Director, Policy and Planning Staff, Office of the Chief Information Officer, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, Mail Stop 3.E–206, Washington, DC 20530.

Dated: July 29, 2022.

Robert Houser,

Assistant Director, Policy and Planning Staff, Office of the Chief Information Officer, U.S. Department of Justice.

[FR Doc. 2022–16578 Filed 8–2–22; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–25]

Michael Simental, M.D.; Decision and Order

On January 24, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Michael Simental, M.D. (hereinafter, Applicant). OSC, at 1, 3. The OSC proposed the denial of Applicant's application for a Certificate of Registration No. W20129943C at the proposed registered address of 4201 Torrance Boulevard, Suite 590, Torrance, California 90503. *Id.* at 1. The OSC alleged that Applicant's application should be denied because Applicant is ''without authority to handle controlled substances in California, the state in which [he has] applied to be registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

By letter dated May 11, 2022,[1] Applicant requested a hearing. On May 12, 2022, Administrative Law Judge Teresa A. Wallbaum (hereinafter, the ALJ) issued an Order Directing Government to File Evidence of Service of the Order to Show Cause and Evidence of Lack of State Authority. On May 26, 2022, the Government filed its Notice of Filing of Evidence and Motion for Summary Disposition (hereinafter, Motion for Summary Disposition). On June 6, 2022, Applicant filed his Response to Government's Notice of Filing of Evidence and Motion for

[1] The record demonstrates that service was not accomplished until April 10, 2022 and the Government does not contest the timeliness of the request for a hearing. Motion for Summary Disposition, at n.2.

Summary Disposition (hereinafter, Response).[2]

On June 7, 2022, the ALJ granted the Government's Motion for Summary Disposition and recommended the denial of Applicant's application, finding that because Applicant lacks state authority to handle controlled substances, there is no genuine issue of material fact. Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD), at 6.[3]

The Agency issues this Decision and Order based on the entire record before it, 21 CFR 1301.43(e), and makes the following findings of fact.

Findings of Fact

On May 20, 2021, the Medical Board of California entered a Cease Practice Order against Applicant that prohibited him from engaging in the practice of medicine until ''a final Decision [had] been issued on an Accusation and/or a Petition to Revoke Probation filed pursuant to [the] [underlying] matter.'' Government Attachment 1, Exhibit A. According to California's online records, of which the Agency takes official notice, Applicant's state medical license was surrendered.[4] Medical Board of California License Verification, *https://www.mbc.ca.gov/License-Verification* (last visited date of signature of this Order). Accordingly, the Agency finds that Applicant is not licensed to engage in the practice of medicine in California, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).[5]

According to California statute, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery.'' Cal. Health & Safety Code § 11010 (West 2022). Further, a ''practitioner'' means a person ''licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in this state.'' *Id.* at § 11026(c).

Here, the undisputed evidence in the record is that Applicant lacks authority to practice medicine in California. As discussed above, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Applicant lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Applicant is not eligible to receive a DEA registration. Accordingly, the Agency will order that Applicant's application for a DEA registration be denied.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the pending application for a Certificate of Registration, Control Number W20129943C, submitted by Michael Simental, M.D., as well as any other pending application of Michael Simental, M.D., for additional registration in California. This Order is effective [insert Date Thirty Days From the Date of Publication in the **Federal Register**].

Signing Authority

This document of the Drug Enforcement Administration was signed on July 26, 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. 2022–16631 Filed 8–2–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Rebecca L. Adams, N.P.; Decision and Order

On March 10, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Rebecca L. Adams, N.P. (hereinafter, Registrant). OSC, at 1 and 3. The OSC proposed the revocation of Registrant's Certificate of Registration

[2] In his Response, Applicant did not dispute that he lacks state authority nor did he otherwise oppose the denial of his application, but rather, Applicant indicated that he had ''misguidedly applied for a DEA COR during the pendency of disciplinary proceedings before the Medical Board of California'' and had ''requested a hearing in the instant matter to see if the withdrawal of his application for a COR could be accomplished.'' Response, at 1.

[3] By letter dated July 5, 2022, the ALJ certified and transmitted the record to the Agency for final agency action and advised that neither party filed exceptions.

[4] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Applicant may dispute the Agency's finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[5] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

No. MA5778228 at the registered address of 1200 N. State St., Suite 420, Jackson, Mississippi, 39202. *Id.* at 1. The OSC alleged that Registrant's registration should be revoked because Registrant is ''without authority to handle controlled substances in the State of Mississippi, the state in which [she is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its Request for Final Agency Action (RFAA), submitted July 12, 2022.[1]

Findings of Fact

On April 15, 2021, the Mississippi Board of Nursing issued an Order revoking Registrant's license to practice medicine in Mississippi. RFAAX C (Final Order), at 3. According to Mississippi's online records, of which the Agency takes official notice, Registrant's license is still revoked. [2] Mississippi Board of Nursing License Verification, *https://gateway.licensure.msbn.ms.gov/verification/search.aspx* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not currently licensed to engage in the practice of medicine in Mississippi, the state in which she is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978). [3]

According to Mississippi statute, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.'' Miss. Code Ann. § 41–29–105(j) (2022). Further, a ''practitioner'' means a person ''licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.'' *Id.* at § 41–29–105(y)(i). Because Registrant is not currently licensed as a nurse practitioner, or otherwise licensed in Mississippi, she is not authorized to dispense controlled substances in Mississippi.

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in Mississippi. As already discussed, a person must be a licensed practitioner to dispense a controlled substance in Mississippi. Thus, because Registrant lacks authority to practice medicine in Mississippi and, therefore, is not authorized to handle controlled substances in Mississippi, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MA5778228 issued to Rebecca L. Adams, N.P. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending applications of Rebecca L. Adams, N.P., to renew or modify this registration, as well as any other pending application of Rebecca L. Adams, N.P., for additional registration in Mississippi. This Order is effective [insert Date Thirty Days From the Date of Publication in the **Federal Register**].

Signing Authority

This document of the Drug Enforcement Administration was signed on July 26, 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. 2022–16628 Filed 8–2–22; 8:45 am]

BILLING CODE 4410–09–P

[1] Based on the Declaration from a DEA Diversion Investigator that the Government submitted with its RFAA, the Agency finds that the Government's service of the OSC on Registrant was adequate. RFAA, Exhibit (hereinafter, RFAAX) B, at 2. Further, based on the Government's assertions in its RFAA, the Agency finds that more than thirty days have passed since Registrant was served with the OSC and Registrant has neither requested a hearing nor submitted a written statement or corrective action plan and therefore has waived any such rights. RFAA, at 2; *see also* 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C).

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[3] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Endre Kovacs, M.D.; Decision and Order

On April 12, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Endre Kovacs, M.D. (hereinafter, Registrant). OSC, at 1,

3. The OSC proposed the revocation of Registrant's Certificate of Registration No. BK5206695 at the registered address of 4476 Legendary Drive, Suite 100, Destin, Florida 32541. *Id.* at 1. The OSC alleged that Registrant's registration should be revoked because Registrant is ''without authority to handle controlled substances in the State of Florida, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its Request for Final Agency Action (RFAA), submitted July 7, 2022.[1]

Findings of Fact

On February 16, 2022, the Florida Board of Medicine issued a Final Order suspending Registrant's license to practice medicine in the State of Florida. RFAA, Declaration 1, Appendix C (Final Order), at 2; *see also id.* at 7 (Settlement Agreement). According to Florida's online records, of which the Agency takes official notice, Registrant's license is still suspended and Registrant is not authorized to practice medicine in Florida.[2] Florida Department of Health License Verification, *https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not currently licensed to engage in the practice of medicine in Florida, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).[3]

According to Florida statute, ''A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance.'' Fla. Stat. § 893.05(1)(a) (2022). Further, a ''practitioner'' as defined by Florida statute includes ''a physician licensed under chapter 458.[4]'' *Id.* at § 893.02(23).

Here, the undisputed evidence in the record is that Registrant currently is not a licensed practitioner in Florida, and a physician must be a licensed practitioner to dispense a controlled substance in Florida. Thus, Registrant is not eligible to maintain a DEA registration in Florida. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BK5206695 issued to Endre Kovacs, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending applications of Endre Kovacs, M.D. to renew or modify this registration, as well as any other pending application of Endre Kovacs, M.D. for additional registration in Florida.

This Order is effective September 2, 2022.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 26, 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. 2022–16630 Filed 8–2–22; 8:45 am]

BILLING CODE 4410–09–P

[1] Based on the Declarations from a DEA Diversion Investigator and a DEA Data Analyst that the Government submitted with its RFAA, the Agency finds that the Government's service of the OSC on Registrant was adequate. RFAA, Declaration 1, at 2; RFAA, Declaration 2, at 1. Further, based on the Government's assertions in its RFAA, the Agency finds that more than thirty days have passed since Registrant was served with the OSC and Registrant has neither requested a hearing nor submitted a written statement or corrective action plan and therefore has waived any such rights. RFAA, at 1–3; *see also* 21 CFR 1301.43(d)–(e) and 21 U.S.C. 824(c)(2)(C).

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[3] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

[4] Chapter 458 regulates medical practice.

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree under the Resource Conservation and Recovery Act

On July 27, 2022, the Department of Justice and the Oklahoma Department of Environmental Quality lodged a proposed Consent Decree with the United States District Court for the Western District of Oklahoma in the lawsuit entitled *United States of America and Oklahoma Department of Environmental Quality* v. *January Environmental Services, Inc., et al.,* Civil Action No. 5:20–cv–1205. The Complaint, which was docketed on December 1, 2020, alleges that the defendants, January Environmental Services, Inc., January Transport, Inc., and the president of both companies, Cris January, are civilly liable for

multiple violations of the Resource Conservation and Recovery Act (RCRA) and associated regulations at the defendants' used oil transportation and processing facility in Oklahoma City, Oklahoma. The violations were discovered in a series of inspections by the Oklahoma Department of Environmental Quality (ODEQ) and the United States Environmental Protection Agency (EPA).

Under the proposed Consent Decree, the companies and Cris January will pay $1,900,000 in civil penalties. The penalty payments will be split evenly between the United States and ODEQ. The Consent Decree also requires the defendants to perform corrective measures to bring the facility into compliance with RCRA and applicable regulations and to ensure compliance going forward. These measures include complying with all the regulations applicable to used oil transporters and processors, using proper methods to test for the potential presence of hazardous waste in used oil, characterizing wastes mixed with used oil filters prior to disposal or processing to determine whether the waste is hazardous, properly disposing of hazardous waste, hiring an independent engineer to evaluate the facility's spill prevention and containment preparedness, preparing and updating required reports and plans, training employees, and submitting periodic compliance reports to ODEQ and EPA.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America and Oklahoma Department of Environmental Quality* v. *January Environmental Services, Inc., et al.,* Civil Action No. 5:20–cv–1205, D.J. Ref. No. 90–7–1–12085. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted by either 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 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 Consent Decree 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 $12.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Thomas Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2022–16604 Filed 8–2–22; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Pattern of Violations

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before September 2, 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.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nora Hernandez by telephone at 202–693–8633, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Federal Mine Safety and Health Act of 1977 (Mine Act), as amended, places the ultimate responsibility on mine operators for ensuring the safety and health of miners. The legislative history of the Mine Act emphasizes that Congress included the pattern of violations (POV) provision for mine operators who demonstrated a disregard for the safety and health of miners through a recurring pattern of significant and substantial (S&S) violations. MSHA was to use the POV provision in situations where other enforcement actions had been ineffective at bringing the mines into compliance with safety and health standards.

Under section 104.2, at least once each year MSHA reviews the compliance and other records of mines to determine whether any mines meet the POV criteria. In determining whether to issue a POV notice, MSHA considers mitigating circumstances facing mine operators, in accordance with section 104.2(a)(8). Specifically, among the items MSHA could consider is any approved corrective action program (CAP) that the mine is implementing to reduce S&S violations, together with any improved results. This information collection is designed to encourage operators to take proactive measures to bring their mines into compliance. MSHA believes that operators who implement CAPs are thereby demonstrating a commitment to complying with MSHA's safety and health standards and to restoring safe and healthful working conditions for miners.

For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 22, 2022 (87 FR 16239).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not

display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Pattern of Violations.

OMB Control Number: 1219–0150.

Affected Public: Businesses or other for-profits institutions.

Total Estimated Number of Respondents: 6.

Total Estimated Number of Responses: 12.

Total Estimated Annual Time Burden: 304 hours.

Total Estimated Annual Other Costs Burden: $800.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nora Hernandez,

Departmental Clearance Officer.

[FR Doc. 2022–16586 Filed 8–2–22; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; The SUPPORT Act Grants Evaluation

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Chief Evaluation Office (CEO)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before September 2, 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.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: CEO, in partnership with the Employment and Training Administration (ETA), is sponsoring an implementation evaluation of grants awarded under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. CEO is seeking approval from OMB under the Paperwork Reduction Act for data collection instruments associated with the evaluation. With the goal of producing important information on innovative practices and implementation challenges in providing services that integrate employment services and substance use disorder (SUD) treatment services, DOL awarded nearly $20 million in SUPPORT Act grants to four state workforce agencies. Grantees may use these funds to provide a range of employment services for affected individuals. The grants can also be used to train and support two types of workers: workers personally affected by opioid misuse or other SUDs (including having a friend or family member with a substance use disorder), and workers who seek to transition to professions that address the opioid crisis (such as addiction and SUD treatment, mental health services, and pain management). Finally, grantees can use a portion of their funds for individual or group outpatient treatment and recovery services, in addition to using funds for employment services. DOL contracted with Abt Associates and its partner to conduct an implementation evaluation will inform program administrators and practitioners on providing services that address both employment and treatment needs for people with SUDs. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 13, 2022 (87 FR 21924).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–CEO.

Title of Collection: The SUPPORT Act Grants Evaluation.

OMB Control Number: 1290–0NEW.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 116.

Total Estimated Number of Responses: 116.

Total Estimated Annual Time Burden: 85 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior PRA Analyst.

[FR Doc. 2022–16584 Filed 8–2–22; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Surface Coal Mines Daily Inspection; Certified Person; Reports of Inspection

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before September 2, 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.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nora Hernandez by telephone at 202–693–8633, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 77.1713, Title 30 of the Code of Federal Regulations requires coal mine operators to conduct examinations of each active working area of surface mines, active surface installations at these mines, facilities and preparation plants not associated with underground coal mines for hazardous conditions during each shift. A report of hazardous conditions detected must be entered into a record book along with a description of any corrective actions taken. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 22, 2022 (87 FR 16240).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Surface Coal Mines Daily Inspection; Certified Person; Reports of Inspection.

OMB Control Number: 1219–0083.

Affected Public: Businesses or other for-profits institutions.

Total Estimated Number of Respondents: 796.

Total Estimated Number of Responses: 248,880.

Total Estimated Annual Time Burden: 373,320 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nora Hernandez,

Departmental Clearance Officer.

[FR Doc. 2022–16583 Filed 8–2–22; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection: IMLS Grants to States Program State Reporting System, Including Site Visit Checklist

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Submission for OMB Review, request for comments, collection of information.

SUMMARY: The Institute of Museum and Library Services announces the following information collection has been submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This program helps to ensure that 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 on respondents can be properly assessed. This Notice proposes the clearance of the IMLS Grants to States Program State Reporting System, Including Site Visit Checklist. A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before September 02, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this Notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Institute of Museum and Library Services'' under ''Currently Under Review;'' then check ''Only Show ICR for Public Comment'' checkbox. Once you have found this information collection request, select ''Comment,'' and enter or upload your comment and information. Alternatively, please mail your written comments to Office of Information and Regulatory Affairs, Attn.: OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, or call (202) 395–7316.

OMB is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

FOR FURTHER INFORMATION CONTACT: Teresa DeVoe, Associate Deputy Director of State Programs, Office of Library Services, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Ms. DeVoe can be reached by telephone at 202–653–4778, or by email at *tdevoe@imls.gov.* Persons who are deaf or hard of hearing (TTY users) may contact IMLS at 202–207–7858 via 711 for TTY-Based Telecommunications Relay Service.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant

making, research, and policy development. To learn more, visit *www.imls.gov.*

Current Actions: This notice proposes the clearance of the IMLS Grants to States Program State Reporting System, Including Site Visit Checklist. The Grants to States program is the largest source of Federal funding support for library services in the U.S. Using a population-based formula, more than $160 million is distributed among the State Library Administrative Agencies (SLAAs) every year. SLAAs are official agencies charged by the Library Services and Technology Act (20 U.S.C. 9121 and 20 U.S.C. 9141) with the extension and development of library services, and they are located in each of the 50 States of the United States, the District of Columbia, the five Territories of Guam, American Samoa, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands, and the three Freely Associated States of Federated States of Micronesia, Republic of Palau, and the Republic of the Marshall Islands.

Each State Library Administrative Agency (SLAA) is required, under 20 U.S.C. 9101 *et seq.* (in particular 20 U.S.C. 9134), to submit a plan that details library services goals for a five-year period, along with associated certifications. Pursuant to 20 U.S.C. 9134 (c), each SLAA that receives an IMLS grant under the Grants to States program is required to evaluate and report on all funded project activities to IMLS, prior to the end of the execution of its five-year plan. Each SLAA receives IMLS funding to support activities for the five-year period through a series of overlapping two-year grant awards. Each SLAA must file interim and final financial reports, and final performance reports for each of these two-year grants through IMLS's State Program Report (SPR) system. This action is to incorporate a Site Visit Checklist as a stand-alone form in the SPR system, which has an OMB Control Number of 3137–0071, expiring 8/31/2024. The 60-day Notice was published in the **Federal Register** on May 3, 2022 (87 FR 26231). The agency has taken into consideration the one comment that was received under this notice.

Agency: Institute of Museum and Library Services.

Title: IMLS Grants to States Program State Reporting System, Including Site Visit Checklist.

OMB Number: 3137–0071.

Agency Number: 3137.

Affected Public: State Library Administrative Agencies.

Total Number of Respondents: 59.

Frequency of Response: Annually for the State Program Report, once every five years for the Site Visit Checklist.

Average Hours per Response: 47.83 hours for the State Program Report (annually), 20 hours for the Site Visit Checklist (once every five years).

Total Burden Hours: 2,822.

Total Annualized capital/startup costs: n/a.

Total Annual Cost Burden: $87,086.

Total Annual Federal Costs: $40,377.

Dated: July 29, 2022.

Suzanne Mbollo,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2022–16621 Filed 8–2–22; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification request received and permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of a requested permit modification issued.

DATES: July 27, 2022 to September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Andrew Titmus, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–4479; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation (NSF), as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 671), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection.

Description of Permit Modification Requested: The Foundation issued a permit (ACA 2021–002) to Megan Cimino on August 12, 2020. The issued permit allows the permit holder and agents to enter Antarctic Specially Protected Areas (ASPAs), as well as engage in research activities that would result in Take, Harmful Interference, and Import into the USA. The permit holder and agents may conduct activities associated with long-term studies of seabird ecology including diets, breeding success, growth rates, survival, recruitment, behavior, population trends, foraging success, and seasonal dispersal. Study species include Adelie, Chinstrap, and Gentoo Penguins; Brown and South Polar Skua; Southern Giant Petrel; Blue-eyed Shag; Kelp Gull; and Snowy Sheathbill. Specimens from these and other species may be salvaged from birds that have died of natural causes.

A recent modification to this permit, dated April 21, 2021, permitted the permit holder to deploy three time-lapse cameras, two on Torgersen Island and one on Humble Island (Restricted Zones within ASMA 7, Southwest Anvers Island and Palmer Basin), to monitor Adelie penguin occupation patterns in relation to the Palmer Station pier construction. The two islands of interest are where Adelie penguin foraging behavior, diet, and phenology have been routinely studied and are the largest Adelie colonies near Palmer Station. The equipment consists of a small camera attached to a steel pole with a square base that is anchored under rocks. The cameras would be deployed at the end of May 2021 by permit agents (if there are any delays, the cameras would be installed during October 2021). The equipment would be hand carried in pieces to the sites of interest and assembled in the field. The cameras would remain in place for at least two years to obtain information during the pier construction and the year after construction.

Now the permit holder proposes a modification to deploy seven acoustic recorders, four on Humble Island and three on Torgersen Island (Restricted Zones within ASMA 7, Southwest Anvers Island and Palmer Basin), to record Adelie penguin vocalizations throughout the breeding season for assessing the validity of a new approach for high resolution population censusing and metapopulation modeling. The equipment consists of small battery powered acoustic recorders attached to a PVC pole with PVC pole bases that would be anchored under rocks. The recorders would be deployed in November 2022 by permit agents and retrieved in March 2023. Recorders will be visited weekly to replace batteries and memory cards.

The ACA Permit Officer has reviewed the modification request and has determined that the amendment is not a material change to the permit, and it

will have a less than a minor or transitory impact.

The permit modification was issued on July 27, 2022.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–16575 Filed 8–2–22; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by September 2, 2022. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314 or *ACApermits@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Andrew Titmus, ACA Permit Officer, at the above address, 703–292–4479.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 671) as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2023–006

1. *Applicant:* Lee Welhouse, University of Wisconsin-Madison Space Science and Engineering Center, Madison, WI 53706

Activity for Which Permit Is Requested

Enter Antarctic Specially Protected Area (ASPA). The applicant seeks an Antarctic Conservation Act permit authorizing entry into ASPA 106—Cape Hallett, Northern Victoria Land for a single period of 4–6 hours. The Antarctic Meteorological Research and Data Center has maintained a weather station in this ASPA since 2007. This entry would be to perform routine maintenance and upkeep that is necessary approximately every 3 years.

Location

ASPA 106—Cape Hallett, Northern Victoria Land.

Dates of Permitted Activities

November 1, 2022–December 1, 2022.

Permit Application: 2023–007

2. *Applicant:* Dr. Natasja van Gestel, Texas Tech University Biological Sciences Department, Lubbock, TX 79409

Activity for Which Permit Is Requested

Take, Enter Antarctic Specially Protected Area (ASPA), import into USA. The applicant seeks an Antarctic Conservation Act permit authorizing entry to ASPA 113—Litchfield Island, Arthur Harbor, to study Antarctic soils, microbial communities, and vegetation. The applicant would access the site weekly between the period of December 1–March 31 for four consecutive seasons between December 2022 and March 2026. The applicant proposes to conduct warming experiments on the soil and plants using five 1m^2 soil warming chambers that will also log soil moisture, temperature, and microclimate data. The applicant proposes to collect up to 100 small soil cores, 15 samples of plants of *Polytrichum* species, 15 samples of plants of *Chorisodontium* species, and 15 samples of various other moss species per year which would be brought back to Palmer Station for temperature incubation experiments. At the conclusion of the temperature experiments, the applicant would import all collected specimens back to the home institution for herbarium curation.

Location

ASPA 113, Litchfield Island, Arthur Harbor.

Dates of Permitted Activities

December 1, 2022–March 31, 2026.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–16576 Filed 8–2–22; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Andrew Titmus, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 603–292–4479; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On May 26, 2022, the National Science Foundation published a notice in the **Federal Register** of permit application received. The permit was issued on the following date:

1. Birgitte McDonald, Permit No. 2023–003, July 25, 2022

On June 24, 2022, the National Science Foundation published a notice in the **Federal Register** of permit application received. The permit was issued on the following date:

1. Steve Emslie, Permit No. 2023–004, July 26, 2022

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–16574 Filed 8–2–22; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Request for Information on the Federal Big Data Research and Development Strategic Plan Update

AGENCY: Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO), National Science Foundation (NSF).

ACTION: Request for Information (RFI); extension of comment period.

SUMMARY: On July 1, 2022, the NITRD NCO and NSF, as part of the NITRD Big Data interagency working group (BD IWG), published in the **Federal Register** a document entitled ''Request for

Information on the Federal Big Data Research and Development Strategic Plan Update''. Through this RFI, the NITRD NCO seeks input from the public, including academia, government, business, and industry groups of all sizes; those directly performing Big Data research and development (R&D); and those directly affected by such R&D, on ways in which the strategic plan should be revised and improved. The public input provided in response to this RFI will assist the NITRD BD IWG in updating the *Federal Big Data Research and Development Strategic Plan.* In response to requests by prospective commenters that they would benefit from additional time to adequately consider and respond to the RFI, the NITRD NCO and NSF have determined that an extension of the comment period until August 17, 2022, is appropriate.

DATES: The end of the comment period for the document entitled ''Request for Information on the Federal Big Data Research and Development Strategic Plan Update'', published on July 1, 2022 (87 FR 39567), is extended from July 29, 2022, until on or before 11:59 p.m. (ET) August 17, 2022.

ADDRESSES: Comments submitted in response to 87 FR 39567 may be sent by any of the following methods:

- *Email, BDStrategicPlan-RFI@nitrd.gov:* Email submissions should be machine-readable and not be copy-protected; submissions should include ''*RFI Response: Federal Big Data Research and Development Strategic Plan Update*'' in the subject line of the message.
- *Mail,* Attn: Ji Lee, NCO, 2415 Eisenhower Avenue, Alexandria, VA 22314, USA.

Instructions: Response to this RFI (87 FR 39567) is voluntary. Each participating individual or institution is asked to submit only one response. Submissions must not exceed 10 pages in 12-point or larger font, with a page number provided on each page [*optional*]. Include the name of the person(s) or organization(s) filing the comment in your response. Responses to this RFI (87 FR 39567) may be posted online at *https://www.nitrd.gov.* Therefore, we request that no business proprietary information, copyrighted information, or sensitive personally identifiable information be submitted as part of your response.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI (87 FR 39567).

FOR FURTHER INFORMATION CONTACT: Ji Lee at *BDStrategicPlan-RFI@nitrd.gov* or (202) 459–9679. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. (ET) Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background: On July 1, 2022, the NITRD NCO and NSF, as part of the NITRD Big Data interagency working group (BD IWG), published in the **Federal Register** a document requesting input on the work of the IWG to prepare updates to the Federal Big Data Research and Development Strategic Plan. The NITRD Subcommittee of the National Science and Technology Council coordinates multiagency R&D programs to help ensure continued U.S. leadership in networking and information technology, satisfy the needs of the Federal Government for advanced networking and information technology, and accelerate development and deployment of advanced networking and information technology. The RFI (87 FR 39567) was issued to seek input from the public, including academia, government, business, and industry groups of all sizes; those directly performing Big Data research and development (R&D); and those directly affected by such R&D, on ways in which the strategic plan should be revised and improved. The public input provided in response to this RFI (87 FR 39567) will assist the NITRD BD IWG in updating the Federal Big Data Research and Development Strategic Plan. The document stated that the comment period would close on July 29, 2022. The NITRD NCO and NSF have received requests to extend the comment period. An extension of the comment period will provide additional opportunity for the public to consider the RFI (87 FR 39567) and prepare comments to address the questions posed therein. Therefore, NITRD NCO and NSF are extending the end of the comment period for the RFI (87 FR 39567) from July 29, 2022, until August 17, 2022. Submitted by the National Science Foundation in support of the NITRD NCO on July 28, 2022.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2022–16560 Filed 8–2–22; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2022–91 and CP2022–95; MC2022–92 and CP2022–96]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 5, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance

with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2022–91 and CP2022–95; *Filing Title:* USPS Request to Add First-Class Package Service Contract 120 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 28, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* August 5, 2022.

2. *Docket No(s).:* MC2022–92 and CP2022–96; *Filing Title:* USPS Request to Add Priority Mail Express & Priority Mail Contract 134 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 28, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Katalin K. Clendenin; *Comments Due:* August 5, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–16624 Filed 8–2–22; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95381; File No. SR–BOX–2022–22]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend BOX Rule IM–5050–11

July 28, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 18, 2022, BOX Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BOX Rule IM–5050–11 to account for conflicts between different provisions within the Short Term Option Series Rules. 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 Rule IM–5050–11 to account for conflicts between different provisions within the Short Term Option Series Rules. The Exchange notes that this filing is based on a proposal recently submitted by Nasdaq ISE LLC (''Nasdaq ISE'') and approved by the Commission.[3]

In 2021, BOX amended Rule 5050 to limit the intervals between strikes in equity options listed as part of the Short Term Option Series Program, excluding Exchange-Traded Fund Shares and ETNs, that have an expiration date more than twenty-one days from the listing date (''Strike Interval Proposal'').[4] The Strike Interval Proposal adopted a new IM–5050–11 which included a table that intended to specify the applicable strike intervals that would supersede IM–5050–6(b)(5)[5] for Short Term Option Series in equity options, excluding Exchange-Traded Fund Shares and ETNs, which have an expiration date more than twenty-one days from the listing date. The Strike Interval Proposal was designed to reduce the density of strike intervals that would be listed in later weeks, within the Short Term Option Series Program, by utilizing limitations for intervals between strikes which have an expiration date more than twenty-one days from the listing date.

At this time, the Exchange proposes to amend the rule text within IM–5050–11 to clarify the current rule text and amend the application of the table to account for potential conflicts within the Short Term Option Series Rules. Currently, the table within IM–5050–11 is as follows:[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 95085 (June 10, 2022), 87 FR 36353 (June 16, 2022) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Amend ISE Options 4, Section 5, Series of Options Contracts Open for Trading) (SR–ISE–2022–10).

[4] *See* Securities Exchange Act Release No. 92072 (May 28, 2021), 86 FR 29856 (June 3, 2021) (SR–BOX–2021–12).

[5] The interval between strike prices on Short Term Option Series may be (i) $0.50 or greater where the strike price is less than $100, and $1 or greater where the strike price is between $100 and $150 for all option classes that participate in the Short Term Options Series Program; (ii) $0.50 for option classes that trade in one dollar increments in Related non-short Term Options and are in the Short Term Option Series Program; or (iii) $2.50 or greater where the strike price is above $150. During the month prior to expiration of an option class that is selected for the Short Term Option Series Program pursuant to this rule (Short Term Option), the strike price intervals for the related non-Short Term Option shall be the same as the strike price intervals for the Short Term Option. BOX Rule IM–5050–6(b)(5).

[6] The Share Price would be the closing price on the primary market on the last day of the calendar quarter and the Average Daily Volume would be the total number of options contracts traded in a given security for the applicable calendar quarter divided by the number of trading days in the applicable calendar quarter The Average Daily Volume would

Continued

Tier	Average daily volume	Share price				
		less than $25	$25 to less than $75	$75 to less than $150	$150 to less than $500	$500 or greater
1	Greater than 5,000	$0.50	$1.00	$1.00	$5.00	$5.00
2	Greater than 1,000 to 5,000	1.00	1.00	1.00	5.00	10.00
3	0 to 1,000	2.50	5.00	5.00	5.00	10.00

The first sentence of IM–5050–11 provides, ''With respect to listing Short Term Option Series in equity options, excluding Exchange-Traded Fund Shares and ETNs, which have an expiration date more than twenty-one days from the listing date, the strike interval for each option class will be based on the below table.''

First, the Exchange proposes to amend the first sentence of IM–5050–11 to instead provide, ''With respect to listing Short Term Option Series in equity options, excluding Exchange-Traded Fund Shares and ETNs, which have an expiration date more than twenty-one days from the listing date, the following table, which specifies the applicable interval for listing will apply. To the extent there is a conflict between applying IM–5050–6(b)(5) and the below table, the greater interval would apply.'' The table within IM–5050–11 provides for the listing of intervals based on certain parameters (average daily volume and share price). The Exchange proposes to amend the language in IM–5050–11 to make clear that the only permitted intervals are as specified in the table within IM–5050–11, except in the case where IM–5050–6(b)(5) provides for a greater interval as described in more detail below.

Today, there are instances where a conflict is presented as between the application of the table within IM–5050–11 and the rule text within IM–5050–6(b)(5) with respect to the correct interval. Adding the proposed language would make clear to Participants the applicable intervals where there is a conflict between the rule text within IM–5050–11 and the rule text within IM–5050–6(b)(5) thereby providing certainty as to the outcome. The Exchange proposes to insert the words ''greater interval'' because it proposes to permit IM–5050–6(b)(5) to govern only in the event that the interval would be greater. The same analysis would not be conducted where the result would be a lesser interval. By way of example,

Example 1: Assume a Tier 1 stock that closed on the last day of Q1 with a quarterly share price higher than $75 but less than $150. Therefore, utilizing the table within IM–5050–11, the interval would be $1.00 for strikes added during Q2 even for strikes above $150. Next, assume during Q2 the share price rises above $150. Utilizing only the table within IM–5050–11, the interval would be $1.00 even though the stock is now trading above $150 because the Share Price for purposes of IM–5050–11 was calculated utilizing data from the prior calendar quarter. However, a separate rule, IM–5050–6(b)(5), provides that the Exchange may list a Short Term Option Series at $2.50 intervals where the strike price is above $150. In other words, there is a potential conflict between the permitted strike intervals above $150. In this example, IM–5050–11 would specify a $1.00 interval whereas IM–5050–6(b)(5) would specify a $2.50 interval. As proposed, the Exchange proposes to apply the greater interval. The greater interval would then be $2.50 as per IM–5050–6(b)(5) in this scenario. Therefore, the following strikes would be eligible to list: $152.5 and $157.5. For strikes less than $150, the following strikes would be eligible to list: $149 and $148 because Short Term Option Series with expiration dates more than 21 days from the listing date as well as Short Term Option Series with expiration dates less than 21 days from the listing date would both be eligible to list $1 intervals pursuant to IM–5050–11 and IM–5050–6(b)(5).

Example 2: Assume a Tier 2 stock that closed on the last day of Q1 with a quarterly share price less than $25. Therefore, utilizing the table within IM–5050–11, the interval would be $1.00 for strikes added during Q2 even for strikes above $25. Next, assume during Q2 the share price rises above $100. Utilizing only the table within IM–5050–11, the interval would be $1.00 even though the stock is now trading above $100 because the Share Price for purposes of IM–5050–11 was calculated utilizing data from the prior calendar quarter. However, IM–5050–6(b)(5) provides that the Exchange may list a Short Term Option Series at $1.00 intervals where the strike price is above $100. As proposed, the Exchange would apply the greater interval, however, the $1.00 interval is the same in both cases in this scenario and, therefore, there is no conflict. Now, assume during Q2 the share price rises above $150. Utilizing only the table within IM–5050–11, the interval would continue to be $1.00 because the Share Price relied on data from the prior calendar quarter, however, pursuant to IM–5050–6(b)(5), the interval would be $2.50 for strike prices above $150. The greater interval would then be $2.50 as per IM–5050–6(b)(5) in this scenario.

Example 3: Assume a Tier 3 stock that closed on the last day of Q1 with a quarterly share price less than $25. Therefore, utilizing the table within IM–5050–11, the interval would be $2.50 for strikes added during Q2 even for strikes above $25. Next, assume during Q2 the share price rises above $100. Utilizing only the table within IM–5050–11, the interval would be $2.50 even though the stock was trading above $100 because the Share Price for purposes of IM–5050–11 was calculated utilizing data from the prior calendar quarter. However, IM–5050–6(b)(5) provides that the Exchange may list a Short Term Option Series at $1.00 intervals where the strike price is above $100. The greater interval would then be $2.50 as per the table in IM–5050–11 in this scenario.

The Exchange proposes to delete the last sentence of the first paragraph of IM–5050–11 which states, ''The below table indicates the applicable strike intervals and supersedes IM–5050–6(b)(4) above, which permits additional series to be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened.'' The table within IM–5050–11 impacts strike intervals, while IM–5050–6(b)(4) describes adding series of options. The table within IM–5050–11 supersedes other rules pertaining to

be the total number of options contracts traded in a given security for the applicable calendar quarter divided by the number of trading days in the applicable calendar quarter. Beginning on the second trading day in the first month of each calendar quarter, the Average Daily Volume shall be calculated by utilizing data from the prior calendar quarter based on Customer-cleared volume at The Options Clearing Corporation. For options listed on the first trading day of a given calendar quarter, the Average Daily Volume shall be calculated using the quarter prior to the last trading calendar quarter.

strike intervals, but the table does not supersede rules governing the addition of options series. Therefore, the table within IM–5050–11 and IM–5050–6(b)(4) do not conflict with each other. Deleting the reference to IM–5050–6(b)(4) will avoid confusion.

Finally, the Exchange provides within IM–5050–11(g), ''Notwithstanding the limitations imposed by IM–5050–11, this IM–5050–11 does not amend the range of strikes for Short Term Option Series that may be listed pursuant to IM–5050–6(b)(5) above.'' The Exchange proposes to remove this rule text. While the range limitations continue to be applicable to the table within IM–5050–11, the strike ranges do not conflict with strike intervals and therefore the sentence is not necessary. Removing IM–5050–11(g) will avoid confusion.

Implementation

The Exchange proposes to implement this rule on August 1, 2022. The Exchange will issue an Informational Circular to notify Participants of the implementation date.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[7] in general, and Section 6(b)(5) of the Act,[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Strike Proposal continues to limit the intervals between strikes listed in the Short Term Option Series Program that have an expiration date more than twenty-one days.

The Exchange's proposal to add clarifying language to IM–5050–11, is consistent with the Act because it will make clear that the only permitted intervals are as specified in the table within IM–5050–11, except in the case where IM–5050–6(b)(5) provides for a greater interval. This amendment will bring greater transparency to the rule.

Adopting new language within IM–5050–11 to address a potential conflict between the Short Term Option Series Program rules, specifically as between the application of the table within IM–5050–11 and the rule text within IM–5050–6(b)(5) with respect to the correct interval is consistent with the Act. This new rule text will make clear to Participants the applicable intervals when there is a conflict between the rule text within IM–5050–11 and the rule text within IM–5050–6(b)(5), thereby providing certainty as to the outcome. The proposed new rule text promotes just and equitable principles of trade by adding transparency to the manner in which BOX implements its listing rules, and protects investors and the general public by removing uncertainty.

Removing the last sentence of the first paragraph of IM–5050–11 is consistent with the Act because the table within IM–5050–11 impacts strike intervals, while IM–5050–6(b)(4) describes the addition of options series. The table within IM–5050–11 supersedes other rules pertaining to strike intervals, but the table does not supersede rules governing the addition of options series. Therefore, the table within IM–5050–11 and IM–5050–6(b)(4) do not conflict with each other. Deleting the reference to IM–5050–6(b)(4) will avoid confusion.

Removing IM–5050–11(g) is consistent with the Act because while the range limitations continue to be applicable, the strike ranges do not conflict with strike intervals, rendering the sentence unnecessary. Removing IM–5050–11(g) will avoid confusion.

The Strike Interval Proposal was designed to reduce the density of strike intervals that would be listed in later weeks, within the Short Term Option Series Program, by utilizing limitations for intervals between strikes which have an expiration date more than twenty-one days from the listing date. The Exchange's proposal intends to continue to remove certain strike intervals where there exist clusters of strikes whose characteristics closely resemble one another and, therefore, do not serve different trading needs,[9] rendering these strikes less useful. Also, the Strike Interval Proposal continues to reduce the number of strikes listed on BOX, allowing Market Makers to expend their capital in the options market in a more efficient manner, thereby improving overall market quality on BOX.

Additionally, by making clear that the greater interval would control as between the rule text within IM–5050–11 and the rule text within IM–5050–6(b)(5), the Exchange is reducing the number of strikes listed in a manner consistent with the intent of the Strike Interval Proposal, which was to reduce strikes which were farther out in time. The result of this clarification is to select wider strike intervals for Short Term Option Series in equity options which have an expiration date more than twenty-one days from the listing date. This rule change would harmonize strike intervals as between inner weeklies (those having less than twenty-one days from the listing date) and outer weeklies (those having more than twenty-one days from the listing date) so that strike intervals are not widening as the listing date approaches.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Strike Interval Proposal continues to limit the number of Short Term Option Series Program strike intervals available for quoting and trading on BOX for all BOX Participants.

Adding language to the first sentence of IM–5050–11 to make clear which parameter the table within IM–5050–11 amends within the Short Term Option Series Program will bring greater transparency to the rules. Adopting new language to address potential conflicts as between the rule text within IM–5050–11 and the rule text within IM–5050–6(b)(5), within the Short Term Option Series Program, will bring greater transparency to the manner in which BOX implements its listing rules. The table within IM–5050–11 impacts strike intervals, while IM–5050–6(b)(4), describes adding series of options. The table within IM–5050–11 supersedes other strike interval rules, but does not supersede the addition of series. Removing the last sentence of the first paragraph of IM–5050–11 does not impose an undue burden on competition because the table within IM–5050–11 supersedes other rules pertaining to strike intervals, but the table does not supersede rules governing the addition of options series. Also, deleting the reference to IM–5050–6(b)(4) will avoid confusion. Finally, deleting IM–5050–11(g) will remove any potential confusion. While the range limitations continue to be applicable, the strike ranges do not conflict with strike intervals and are not necessary.

While this proposal continues to limit the intervals of strikes listed on BOX, the Exchange continues to balance the needs of market participants by continuing to offer a number of strikes to meet a market participant's investment objective. The Exchange's

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] For example, two strikes that are densely clustered may have the same risk properties and may also be the same percentage out-of-the money.

Strike Interval Proposal does not impose an undue burden on inter-market competition as this Strike Interval Proposal does not impact the listings available at another self-regulatory organization.

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.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) [11] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange may implement the proposed rule change on August 1, 2022—the same time other exchanges are implementing an identical change.[14] The Exchange states that waiving the operative delay will allow the Exchange to harmonize its rules with other exchanges with similar rules. This, in turn, will reduce investor confusion and add transparency in the BOX rules. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–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–BOX–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. 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–2022–22 and should be submitted on or before August 24, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16548 Filed 8–2–22; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] *See* Securities Exchange Act Release No. 95085 (June 10, 2022), 87 FR 36353 (June 16, 2022) (SR–ISE–2022–10) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend ISE Options 4, Section 5, Series of Options Contracts Open for Trading).

[15] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95383; File No. SR–CboeBZX–2022–040]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Certain of Its Rules Related to Market-Makers

July 28, 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 July 14, 2022, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (''BZX Options'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to amend certain of its Rules related to Market Makers. The text of the proposed rule change is provided in Exhibit 5.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/BZX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend certain of its Rules related to Market Makers. Specifically, the Exchange proposes to amend its Rules to permit an Options Member to register separate Market Maker aggregation units as separate Market Makers, each of which would be subject to Market Maker obligations on an individual basis. Currently, the Exchange interprets the term ''Market Maker'' to apply at a firm level, including with respect to obligations. However, the Exchange understands Options Members have Market Maker units that are completely separate from each other for operational and profit/loss purposes, with appropriate information barriers between units.[3] Because of this operational separation, such organizations may prefer to have those units be treated as individual Market Makers under the Exchange's Rules consistent with those organizations' internal operations.

The proposed rule change amends certain Rules to provide Options Members with this flexibility:

- Rule 22.2 currently provides that Options Members registered as Market Makers have certain rights and bear certain responsibilities beyond those of other Options Members. The proposed rule change adds Interpretation and Policy .01 to provide that if an Options Member is comprised of multiple market making aggregation units and has in place appropriate information barriers or segregation requirements,[4] the Options Member may register each individual aggregation unit as a separate Market Maker.
- The proposed rule change adds Rule 22.3, Interpretation and Policy .01 to provide that Market Maker appointments would apply to each individual Market Maker aggregation unit and adds Rule 22.4, Interpretation and Policy .01 to provide that each Market Maker aggregation unit will be evaluated for good standing on an individual basis.
- The proposed rule change amends Rules 21.20, Interpretation and Policy .02 and adds Rule 22.5, Interpretation and Policy .01 and Rule 22.6, Interpretation and Policy .01 to provide that Market Maker obligations will apply to individual Market Maker aggregation units if an Options Member registers separate aggregation units as Market Makers.
- The proposed rule change adds Rule 22.5, Interpretation and Policy .01 and Rule 22.6, Interpretation and Policy .01 to provide that Market Maker obligations will apply to individual Market Maker aggregation units if an Options Member registers separate aggregation units as Market Makers.
- The proposed rule change adds Rule 2.4, Interpretation and Policy .02 to require any individual Market Maker aggregation unit within a single firm to connect to the Exchange's backup systems and participate in functional and performance testing announced by the Exchange if that unit satisfies the connection criteria set forth in Rule 2.4(b).

These proposed changes are consistent with the concept of treating individual Market Maker aggregation units within a single firm as separate Market Makers.

The proposed rule change states that an Options member may register separate aggregation units as individual Market Makers if the organization has in place appropriate information barriers or segregation units. The proposed language provides Options Members with flexibility to adapt their policies and procedures to reflect their business model and activities, including changes thereto. This flexibility is similar to other rules that require information barriers, such as Rule 18.4, which requires every Options Member to establish, maintain, and enforce written policies and procedures reasonably designed, taking into consideration the nature of the Options Members' business, to prevent the misuse of material nonpublic information by the Options Member or persons associated with such Options Member in violation of the federal securities laws or the Rules thereunder, and the Exchange Rules. In accordance with this proposed rule change, pursuant to Rule 18.4, an Options Member that registers separate business units as individual Market Makers would be obligated to ensure that its policies and procedures reflect the current state of its business and continue to be reasonably designed to prevent the misuse of material, nonpublic information. Separate market making units registered as individual Market Makers may dictate that an information barrier or functional separation be part of the appropriate set of policies and procedures that would be reasonably designed to achieve compliance with the proposed rule change. The proposed rule change has no pre-approval requirement; however, appropriate information barriers would be subject to review as part of the process to register the separate aggregation units as individual Market Makers with the Exchange.[5] Additionally, these policies and procedures would be subject to regular review by the Exchange's Regulation Division, such as part of the routine examination or testing process or as part of internal surveillances and investigations.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged

[3] Certain Exchange rules contemplate Options Members having separate business units and require information barriers in the form of appropriate policies and procedures that reflect the Options Member's business to establish those separate business units. *See, e.g.,* Rules 18.4 (prevention of the misuse of material, nonpublic information); and 18.7 (which applies Cboe Exchange, Inc. position limits to the Exchange).

[4] The Options Member will need to provide the Exchange with sufficient evidence of separation of these units.

[5] The Exchange's Regulatory Division intends to announce by Regulatory Circular a method by which an Options Member may seek pre-approval of the policies and procedures comprising the information barriers.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, because it will provide Options Members with flexibility to register its business units as Market-Makers with the Exchange, and have the Exchange regulate those Market-Maker business units, in a manner consistent with these organizations' internal business operations. The Exchange believes this will permit these organizations to manage the entirety of their Market-Maker operations—including Market-Maker registrations, appointments, and quoting—as they deem appropriate based on the nature of their businesses, which may ultimately benefit the efficiency of their Market-Maker businesses. The Exchange does not propose to modify any Market-Maker responsibilities or obligations. The Exchange does not believe the proposed rule change will reduce liquidity, as any individual Market-Maker aggregation unit (as opposed to the Options Member collectively) will need to satisfy all Market-Maker obligations, including continuous quoting obligations, on its own.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will not impose any burden on intramarket competition, because it will apply in the same manner to all Options Members that register with the Exchange as Market-Makers. Whether an Options Member registers separate business units as Market-Makers is within the sole discretion of that organization. With respect to Options Members that elect to register separate business units as Market-Makers, the proposed rule change will apply all applicable Market-Maker rules, including those regarding Market-Maker obligations and responsibilities, in the same manner to those units. The Exchange does not propose to modify any Market-Maker obligations or responsibilities, and thus does not believe the proposed rule change will diminish liquidity on the Exchange. The proposed rule change will not impose any burden on intermarket competition, because the proposed rule change applies only to how Options Members may register with the Exchange as a Market-Maker and how the Exchange will determine Market-Maker compliance with Exchange-imposed Market-Maker obligations and responsibilities.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The proposal provides flexibility to an Options Member to register separate market-maker aggregation units as separate Market-Makers, each of which would be subject to Market-Maker obligations on an individual basis, if appropriate information barriers or segregation requirements are in place. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any new or novel issues. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[12]

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.

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–CboeBZX–2022–040 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–CboeBZX–2022–040. 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

[8] *Id.*

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–CboeBZX–2022–040 and should be submitted on or before August 24, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16550 Filed 8–2–22; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–108, OMB Control No. 3235–0120]

Proposed Collection; Comment Request: Extension: Form 18–K

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form 18–K (17 CFR 249.318) is an annual report form used by foreign governments or political subdivisions of foreign governments that have securities listed on a United States exchange. The information to be collected is intended to ensure the adequacy and public availability of information available to investors. We estimate that Form 18–K takes approximately 8 hours to prepare and is filed by approximately 38 respondents for a total annual reporting burden of 304 hours (8 hours per response × 38 responses).

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication by October 3, 2022.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16554 Filed 8–2–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95387; File No. SR–NYSEAMER–2022–33]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 903

July 28, 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 July 21, 2022, NYSE American LLC (''NYSE American'' or 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 solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to to [sic] amend Rule 903 (Series of Options Open for Trading), Commentary .10 regarding the Short Term Option Series Program. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 903 (Series of Options Open for Trading). Specifically, the Exchange proposes to amend Commentary .10 to Rule 903 to account for conflicts between different provisions within the Short Term Option Series (''STOS'') rule. The Exchange notes that this proposal is substantively identical to the strike interval proposal recently submitted by Nasdaq ISE, LLC (''Nasdaq ISE'') and approved by the Securities and Exchange Commission (''Commission'').[4]

In 2021, the Exchange amended Rule 903, Commentary .10 (''Commentary .10'') to limit the intervals between strikes in equity options listed as part of the Short Term Option Series Program (the ''STOS Program''), excluding

[4] *See* Securities Exchange Act Release No. 95085 (June 10, 2022), 87 FR 36353 (June 16, 2022) (SR–ISE–2022–10) (approval order) (''ISE Strike Interval Clarification''). The Exchange notes that the rule change set forth in the ISE Strike Interval Clarification will be implemented on August 1, 2022.

Exchange-Traded Fund Shares[5] and Section 107 Securities,[6] that have an expiration date more than twenty-one days from the listing date (''Strike Interval Proposal'').[7] The Strike Interval Proposal adopted a new paragraph (e) to Commentary .10 that included a table intended to specify the applicable strike intervals for STOS in equity options, excluding Exchange-Traded Fund Shares and Section 107 Securities, which have an expiration date more than twenty-one days from the listing date. The newly adopted Commentary .10(e) was intended to establish strike intervals that would supersede those set forth in Commentary .10(d).[8] The Strike Interval Proposal was designed to reduce the density of strike intervals that would be listed in later weeks, within the STOS Program, by utilizing limitations for intervals between strikes which have an expiration date more than twenty-one days from the listing date.

At this time, the Exchange proposes to amend Commentary .10(e), and delete note 4 thereto, to alleviate any ambiguity regarding the appropriate strike interval per Commentary .10 (*i.e.,* whether to apply paragraph (d) or (e) of Commentary .10).

Currently, the table within Commentary .10(e) is as follows:[9]

* * * * *

Tier	Average daily volume	Share price				
		Less than $25	$25 to less than $75	$75 to less than $150	$150 to less than $500	$500 or greater
1	Greater than 5,000	$0.50	$1.00	$1.00	$5.00	$5.00
2	Greater than 1,000 to 5,000	1.00	1.00	1.00	5.00	10.00
3	0 to 1,000	2.50	5.00	5.00	5.00	10.00

The first sentence of Commentary .10(e) provides that ''[n]otwithstanding subparagraph (d) above, when Short Term Option Series in equity options (excluding options on Exchange-Traded Fund Shares and Section 107 Securities) have an expiration more than 21 days from the listing date, the strike interval for each option class will be based on the table below.''

To alleviate ambiguity, the Exchange proposes to delete the first clause of Commentary .10(e) (*i.e.,* to delete ''Notwithstanding subparagraph (d)''), and to add language specifying that the strike intervals in Commentary .10(e) would apply. Specifically, proposed Commentary .10(e) would provide that ''[w]hen Short Term Option Series in equity options (excluding options on Exchange-Traded Fund Shares and Section 107 Securities) have an expiration more than 21 days from the listing date, the table below, *which specifies the applicable interval for listing, will apply*'' (emphasis supplied). The Exchange proposes to add the phrase ''which specifies the applicable interval for listing'' to make clear that the table within Commentary .10(e), which provides for the listing of intervals based on certain parameters (*i.e.,* average daily volume and share price) dictates the permitted intervals, unless Commentary .10(d) specifically provides for a greater interval (as described below).

To add further clarity, the Exchange proposes to add a new sentence within Commentary .10(e), which would state that ''[t]o the extent there is a conflict between applying Commentary .10(d) and the below table, the greater interval would apply.'' Today, there are instances where a conflict is presented as between the application of the table within Commentary .10(e) and the rule text within Commentary .10(d) with respect to the correct interval. Adding the proposed sentence would make clear to ATP Holders the applicable intervals where there is a conflict between the rule text within subparagraph (e) and the rule text within subparagraph (d), thereby providing certainty as to the outcome. Specifically, subparagraph (d) would govern only in the event that the strike interval would be greater. Should subparagraph (d) provide for a lesser strike interval, it would not apply (and subparagraph (e) would apply). The following examples are designed to illustrate this point.

Example 1: Assume a Tier 1 stock that closed on the last day of Q1 with a quarterly share price higher than $75 but less than $150. Therefore, utilizing the table within Commentary .10(e), the interval would be $1.00 for strikes added during Q2 even for strikes above $150. Next, assume during Q2 the share price rises above $150. Utilizing only the table within Commentary .10(e), the interval would be $1.00 even though the stock is now trading above $150 because the Share Price for purposes of Commentary .10(e) was calculated utilizing data from the prior calendar quarter. However, a separate rule, Commentary .10(d), provides that the Exchange may list a STOS at $2.50 intervals where the strike price is above $150. In other words, there is a potential conflict between the permitted strike intervals above $150. In this example, Commentary .10(e) would specify a $1.00 interval whereas Commentary .10(d) would specify a $2.50 interval. As proposed, the Exchange proposes to apply the greater interval. The greater interval would then be $2.50 as per Commentary .10(d) in this scenario. Therefore, the following strikes would be eligible to list: $152.5 and $157.5. For strikes less than $150, the following strikes would be eligible to list: $149 and $148 because STOS with expiration dates more than 21 days from the listing date as well as STOS with expiration dates less than 21 days from the listing

[5] The term Exchange-Traded Fund Shares includes Exchange-listed securities representing interests in open-end unit investment trusts or open-end management investment companies that hold securities (including fixed income securities) based on an index or a portfolio of securities. *See* Rule 900.2NY(24).

[6] The term Section 107 Securities is the collective definition for the following securities: ''Index-Linked Securities'', ''Commodity-Linked Securities'', ''Currency-Linked Securities'', ''Fixed Income-Linked Securities'', ''Futures-Linked Securities'', and ''Combination-Linked Securities''. *See* Sections 107D, 107E, 107F, 107G, 107H and 107I of the Company Guide.

[7] *See* Securities Exchange Act Release No. 92336 (July 7, 2021) 86 FR 36827 (July 13, 2021) (SR–NYSEAMER–2021–32) (immediately effective Strike Interval Proposal to limit STOS Intervals between strikes).

[8] *See* Rule 903, Commentary .10(d) (providing in relevant part that ''[t]he strike price interval for Short Term Option Series may be $0.50 or greater for option classes that trade in $1 strike price intervals and are in the Short Term Option Series Program. If the class does not trade in $1 strike price intervals, the strike price interval for Short Term Option Series may be (i) $0.50 or greater where the strike price is less than $100; (ii) $1.00 or greater where the strike price is between $100 and $150; or (iii) $2.50 or greater for strike prices greater than $150.'').

[9] *See* Rule 903, Commentary .10(e), note 1 (describing the Share Price); note 2 (describing the Average Daily Volume or ''ADV''); and note 3 (providing that newly-listed options will not be subject to subparagraph (e) until after the end of the first full calendar quarter following the date the option class was first listed for trading on any options market).

date would both be eligible to list $1 intervals pursuant to paragraphs (d) and (e) to Commentary .10.

Example 2: Assume a Tier 2 stock that closed on the last day of Q1 with a quarterly share price less than $25. Therefore, utilizing the table within Commentary .10(e), the interval would be $1.00 for strikes added during Q2 even for strikes above $25. Next, assume during Q2 the share price rises above $100. Utilizing only the table within Commentary .10(e), the interval would be $1.00 even though the stock is now trading above $100 because the Share Price for purposes of Commentary .10(e), was calculated utilizing data from the prior calendar quarter. However, Commentary .10(d), provides that the Exchange may list a STOS at $1.00 intervals where the strike price is above $100. As proposed, the Exchange would apply the greater interval, however, the $1.00 interval is the same in both cases in this scenario and therefore there is no conflict. Now assume during the quarter the price rose above $150. Utilizing only the table within Commentary .10(e), the interval would continue to be $1.00 because the Share Price relied on data from the prior calendar quarter, however, pursuant to Commentary .10(d), the interval would be $2.50 for strike prices above $150. The greater interval would then be $2.50 as per Commentary .10(d) in this scenario.

Example 3: Assume a Tier 3 stock that closed on the last day of Q1 with a quarterly share price less than $25. Therefore, utilizing the table within Commentary .10(e), the interval would be $2.50 for strikes added during Q2 even for strikes above $25. Next, assume during Q2 the share price rises above $100. Utilizing only the table within Commentary .10(e), the interval would be $2.50 even though the stock was trading above $100 because the Share Price for purposes of Commentary .10(e), was calculated utilizing data from the prior calendar quarter. However, Commentary .10(d) provides that the Exchange may list a STOS at $1.00 intervals where the strike price is above $100. The greater interval would then be $2.50 as per the table in Commentary .10(e) in this scenario.

In addition, the Exchange proposes to delete the last sentence of the first paragraph of Commentary .10(e), which states that ''[t]he below table indicates the applicable strike intervals and supersedes subparagraph (d) above, which permits additional series to be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened.'' The Exchange believes the reference to Commentary .10(d) is an error as Commentary .10(c) (not subparagraph (d)) describes adding series of options in the STOS Program.[10] The table within Commentary .10(e) impacts permissible strike intervals. Because there should be no conflict between strike intervals set forth in Commentary .10(e) and details about adding option series set forth in Commentary .10(c) (albeit erroneously referred to as Commentary .10(d)), the Exchange believes that deleting this reference will avoid potential confusion.

Finally, consistent with the foregoing, the Exchange proposes to delete note 4 to the table in Commentary .10(e), which provides that ''[n]otwithstanding the limitations imposed by this subparagraph (e), this subparagraph (e) does not amend the range of strikes for Short Term Option Series that may be listed pursuant to subparagraph (d) above,'' which deletion would add clarity and consistency to Commentary .10 and limit the potential for confusion or ambiguity. In addition, the Exchange believes this sentence is unnecessary given the foregoing changes that propose to clarify the circumstances when either subparagraph (e) or subparagraph (d) applies to strike intervals.

Implementation

The Exchange proposes to implement this rule change on August 1, 2022, consistent with the date of ISE's rule change per the ISE Strike Interval Clarification.[11] The Exchange will issue a Trader Update to notify ATP Holders of the implementation date.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule maintains the goal of the Strike Interval Proposal and continues to limit the intervals between strikes listed in the STOS Program that have an expiration date more than twenty-one days.[14]

The Exchange's proposal to add clarifying language to the first sentence of Commentary .10(e), is consistent with the Act because it will make clear that the only permitted intervals are as specified in the table within Commentary .10(e), except in the case where Commentary .10(d) provides for a greater interval. This amendment will bring greater transparency to the rule.

Adopting a new sentence within Commentary .10(e) to address a potential conflict between provisions in the STOS rule, specifically as between the application of the table within Commentary .10(e) and the rule text within Commentary .10(d), with respect to the correct interval is consistent with the Act. Proposed Commentary .10(e) will make clear to ATP Holders the applicable intervals when there is a conflict between the rule text within Commentary .10(e) and the rule text within Commentary .10(d), thereby providing certainty as to the outcome. Further, the proposed new rule text promotes just and equitable principles of trade by adding transparency to the manner in which the Exchange implements its listing rules, and protects investors and the general public by removing uncertainty.

The Exchange believes that deleting the last sentence of the first paragraph of Commentary .10(e) is consistent with the Act. The table within Commentary

[10] As discussed herein, Commentary .10(d) relates to Strike Intervals, whereas Commentary .10(c), regarding ''Additional Series,'' provides that ''[i]f the Exchange opens less than thirty (30) Short Term Option Series for a Short Term Option Expiration Date, additional series may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened.'' The language of the filing indicates the intent to (correctly) refer to Commentary .10(c). *See* Strike Interval Proposal, 86 FR at 36829 (providing that the table in Commentary .10(e), ''indicates the applicable strike intervals and supersedes Rule 903, *Commentary .10(c),* which currently permits 10 additional series to be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened.'') (emphasis supplied).

[11] *See* ISE Strike Interval Clarification, *supra* note 4.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(5).

.10(e) supersedes other rules pertaining to strike intervals, but the table does [sic] is not intended to supersede (or conflict with) rules governing the addition of options series, per Commentary .10(c). Therefore, deleting the (erroneous) reference to Commentary .10(d) in proposed Commentary .10(e) will avoid confusion regarding the application of each paragraph, which clarity would protect investors and the general public.

Removing note 4 to the table in Commentary .10(e) is consistent with the Act because while the range limitations continue to be applicable, the strike ranges do not conflict with strike intervals, rendering the sentence unnecessary and potentially confusing. Also, the proposed rule text within Commentary .10(e) otherwise indicates when Commentary .10(d) would apply.

As noted here, the Strike Interval Proposal was designed to reduce the density of strike intervals that would be listed in later weeks, within the STOS Program, by utilizing limitations for intervals between strikes which have an expiration date more than twenty-one days from the listing date. The Exchange's proposal furthers this goal as it intends to continue to remove certain strike intervals where there exist clusters of strikes whose characteristics closely resemble one another and, therefore, do not serve different trading needs, rendering these strikes less useful.[15]

Also, the Strike Interval Proposal will continue to reduce the number of strikes listed on the Exchange, allowing Lead Market Makers and Market Makers to expend their capital in the options market in a more efficient manner, thereby improving overall market quality on the Exchange.

Additionally, by making clear that the greater interval would control as between the Commentary .10(e) and Commentary .10(d), the Exchange is reducing the number of strikes listed in a manner consistent with the intent of the Strike Interval Proposal (*i.e.,* to reduce strikes which were farther out in time). The result of this clarification is to select wider strike intervals for STOS in equity options that have an expiration date more than twenty-one days from the listing date. This proposed rule change would harmonize strike intervals as between inner weeklies (those having less than 21 days from the listing date) and outer weeklies (those having more than 21 days from the listing date) so that strike intervals are not widening as the listing date approaches.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to impact competition but rather is designed to clarify a potential ambiguity regarding strike intervals that exists in the current STOS rule.

The Exchange anticipates that this proposal, which is consistent with a Commission-approved rule of another options exchange, will be adopted by other option exchanges and therefore would have no impact on competition.[16]

In addition to alleviating potential ambiguity, the proposed rule will further the goal of limiting the number of STOS Program strike intervals available for quoting and trading on the Exchange for all ATP Holders. The Exchange continues to balance the needs of market participants by continuing to offer a number of strikes to meet a market participant's investment objective. The Exchange's Strike Interval Proposal does not impose an undue burden on inter-market competition as this Strike Interval Proposal does not impact the listings available at another self-regulatory organization.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[17] and Rule 19b–4(f)(6)[18] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[19] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[20] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange may implement the proposed rule change on August 1, 2022—the same time other exchanges are implementing an identical change.[21] The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any new or novel issues. Accordingly, the Commission hereby waives the operative delay.[22]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–

[15] For example, two strikes that are densely clustered may have the same risk properties and may also be the same percentage out-of-the money.

[16] *See* ISE Strike Interval Clarification, *supra* note 4.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

[21] *See* Securities Exchange Act Release No. 95085 (June 10, 2022), 87 FR 36353 (June 16, 2022) (SR–ISE–2022–10) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend ISE Options 4, Section 5, Series of Options Contracts Open for Trading).

[22] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

NYSEAMER–2022–33 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–NYSEAMER–2022–33. 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–NYSEAMER–2022–33 and should be submitted on or before August 24,2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16553 Filed 8–2–22; 8:45 am]

BILLING CODE 8011–01–P

[23] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95380; File No. SR–MSRB–2022–03]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Withdrawal of Proposed Rule Change To Amend Certain Rates of Assessment for Rate Card Fees Under MSRB Rules A–11 and A–13, Institute an Annual Rate Card Process for Future Rate Amendments, and Provide for Certain Technical Amendments to MSRB Rules A–11, A–12, and A–13

July 28, 2022.

On June 2, 2022, the Municipal Securities Rulemaking Board (''MSRB'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 [1] (''Exchange Act'') and Rule 19b–4 thereunder,[2] a proposed rule change to amend MSRB Rules A–11, A–12, and A–13. The proposed rule change was published for comment in the **Federal Register** on June 15, 2022.[3]

On July 21, 2022, MSRB withdrew the proposed rule change (SR–MSRB–2022–03).

For the Commission, pursuant to delegated authority.[4]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16547 Filed 8–2–22; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Release No. 95075 (June 9, 2022), 87 FR 36164 (June 15, 2022). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-msrb-2022-03/srmsrb202203.htm.*

[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95386; File No. SR–NYSEArca–2022–43]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 6.4–O

July 28, 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 July 21, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 6.4–O (Series of Options Open for Trading), Commentary .07 regarding the Short Term Option Series Program. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 6.4–O (Series of Options Open for Trading). Specifically, the Exchange proposes to amend Commentary .07 to Rule 6.4–O to account for conflicts between different provisions within the Short Term Option Series (''STOS'') rule. The Exchange notes that this proposal is substantively identical to the strike interval proposal recently submitted by Nasdaq ISE, LLC (''Nasdaq ISE'') and approved by the Securities and Exchange Commission (''Commission'').[4]

In 2021, the Exchange amended Rule 6.4–O, Commentary .07 (''Commentary .07'') to limit the intervals between strikes in equity options listed as part of

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 95085 (June 10, 2022), 87 FR 36353 (June 16, 2022) (SR–ISE–2022–10) (approval order) (''ISE Strike Interval Clarification''). The Exchange notes that the rule change set forth in the ISE Strike Interval Clarification will be implemented on August 1, 2022.

the Short Term Option Series Program (the ''STOS Program''), excluding Exchange-Traded Fund Shares [5] and Index-Linked Securities,[6] that have an expiration date more than twenty-one days from the listing date (''Strike Interval Proposal'').[7] The Strike Interval Proposal adopted a new paragraph (f) to Commentary .07 that included a table intended to specify the applicable strike intervals for STOS in equity options, excluding Exchange-Traded Fund Shares and Index-Linked Securities, which have an expiration date more than twenty-one days from the listing date. The newly adopted Commentary .07(f) was intended to establish strike intervals that would supersede those set forth in Commentary .07(e).[8] The Strike Interval Proposal was designed to reduce the density of strike intervals that would be listed in later weeks, within the STOS Program, by utilizing limitations for intervals between strikes which have an expiration date more than twenty-one days from the listing date.

At this time, the Exchange proposes to amend Commentary .07(f), and delete note 4 thereto, to alleviate any ambiguity regarding the appropriate strike interval per Commentary .07 (*i.e.,* whether to apply paragraph (e) or (f) of Commentary .07).

Currently, the table within Commentary .07(f) is as follows: [9]

* * * * *

Tier	Average daily volume	Share price				
		Less than $25	$25 to less than $75	$75 to less than $150	$150 to less than $500	$500 or greater
1	Greater than 5,000	$0.50	$1.00	$1.00	$5.00	$5.00
2	Greater than 1,000 to 5,000	1.00	1.00	1.00	5.00	10.00
3	0 to 1,000	2.50	5.00	5.00	5.00	10.00

The first sentence of Commentary .07(f) provides that ''[n]otwithstanding subparagraph (e) above, when Short Term Option Series in equity options (excluding options on Exchange-Traded Fund Shares and Index-Linked Securities) have an expiration more than 21 days from the listing date, the strike interval for each option class will be based on the table below.''

To alleviate ambiguity, the Exchange proposes to delete the first clause of Commentary .07(f) (*i.e.,* to delete ''Notwithstanding subparagraph (e)''), and to add language specifying that the strike intervals in Commentary .07(f) would apply. Specifically, proposed Commentary .07(f) would provide that ''[w]hen Short Term Option Series in equity options (excluding options on Exchange-Traded Fund Shares and Index-Linked Securities) have an expiration more than 21 days from the listing date, the table below, *which specifies the applicable interval for listing, will apply*'' (emphasis supplied). The Exchange proposes to add the phrase ''which specifies the applicable interval for listing'' to make clear that the table within Commentary .07(f), which provides for the listing of intervals based on certain parameters (*i.e.,* average daily volume and share price) dictates the permitted intervals, unless Commentary .07(e) specifically provides for a greater interval (as described below).

To add further clarity, the Exchange proposes to add a new sentence within Commentary .07(f), which would state that ''[t]o the extent there is a conflict between applying Commentary .07(e) and the below table, the greater interval would apply.'' Today, there are instances where a conflict is presented as between the application of the table within Commentary .07(f) and the rule text within Commentary .07(e) with respect to the correct interval. Adding the proposed sentence would make clear to OTP Holders and OTP Firms the applicable intervals where there is a conflict between the rule text within subparagraph (f) and the rule text within subparagraph (e), thereby providing certainty as to the outcome. Specifically, subparagraph (e) would govern only in the event that the strike interval would be greater. Should subparagraph (e) provide for a lesser strike interval, it would not apply (and subparagraph (f) would apply). The following examples are designed to illustrate this point.

Example 1: Assume a Tier 1 stock that closed on the last day of Q1 with a quarterly share price higher than $75 but less than $150. Therefore, utilizing the table within Commentary .07(f), the interval would be $1.00 for strikes added during Q2 even for strikes above $150. Next, assume during Q2 the share price rises above $150. Utilizing only the table within Commentary .07(f), the interval would be $1.00 even though the stock is now trading above $150 because the Share Price for purposes of Commentary .07(f) was calculated utilizing data from the prior calendar quarter. However, a separate rule, Commentary .07(e), provides that the Exchange may list a STOS at $2.50 intervals where the strike price is above $150. In other words, there is a potential conflict between the permitted strike intervals above $150. In this example, Commentary .07(f) would specify a $1.00 interval whereas Commentary .07(e) would specify a $2.50 interval. As proposed, the Exchange proposes to apply the greater interval. The greater interval would then be $2.50 as per Commentary .07(e) in this scenario. Therefore, the following strikes would be eligible to list: $152.5 and $157.5. For strikes less than $150, the following

[5] The term Exchange-Traded Fund Shares includes Exchange-listed securities representing interests in open-end unit investment trusts or open-end management investment companies that hold securities (including fixed income securities) based on an index or a portfolio of securities. *See* Rule 1.1.

[6] The term Index-Linked Securities is the collective definition for the following securities: ''Equity Index-Linked Securities'', ''Commodity-Linked Securities'', ''Currency-Linked Securities'', ''Fixed Income Index-Linked Securities'', ''Futures-Linked Securities'', and ''Multifactor Index-Linked Securities.'' *See* Rule 5.2–E(j)(6).

[7] *See* Securities Exchange Act Release No. 92335 (July 7, 2021), 86 FR 36844 (July 13, 2021) (SR–NYSEArca–2021–55) (immediately effective Strike Interval Proposal to limit STOS Intervals between strikes).

[8] *See* Rule 6.4–O, Commentary .07(e) (providing in relevant part that ''[t]he strike price interval for Short Term Option Series may be $0.50 or greater for option classes that trade in $1 strike price intervals and are in the Short Term Option Series Program. If the class does not trade in $1 strike price intervals, the strike price interval for Short Term Option Series may be (i) $0.50 or greater where the strike price is less than $100; (ii) $1.00 or greater where the strike price is between $100 and $150; or (iii) $2.50 or greater for strike prices greater than $150.'').

[9] *See* Rule 6.4–O, Commentary .07(f), note 1 (describing the Share Price); note 2 (describing the Average Daily Volume or ''ADV''); and note 3 (providing that newly-listed options will not be subject to subparagraph (f) until after the end of the first full calendar quarter following the date the option class was first listed for trading on any options market).

strikes would be eligible to list: $149 and $148 because STOS with expiration dates more than 21 days from the listing date as well as STOS with expiration dates less than 21 days from the listing date would both be eligible to list $1 intervals pursuant to paragraphs (e) and (f) to Commentary .07.

Example 2: Assume a Tier 2 stock that closed on the last day of Q1 with a quarterly share price less than $25. Therefore, utilizing the table within Commentary .07(f), the interval would be $1.00 for strikes added during Q2 even for strikes above $25. Next, assume during Q2 the share price rises above $100. Utilizing only the table within Commentary .07(f), the interval would be $1.00 even though the stock is now trading above $100 because the Share Price for purposes of Commentary .07(f), was calculated utilizing data from the prior calendar quarter. However, Commentary .07(e), provides that the Exchange may list a STOS at $1.00 intervals where the strike price is above $100. As proposed, the Exchange would apply the greater interval, however, the $1.00 interval is the same in both cases in this scenario and therefore there is no conflict. Now assume during the quarter the price rose above $150. Utilizing only the table within Commentary .07(f), the interval would continue to be $1.00 because the Share Price relied on data from the prior calendar quarter, however, pursuant to Commentary .07(e), the interval would be $2.50 for strike prices above $150. The greater interval would then be $2.50 as per Commentary .07(e) in this scenario.

Example 3: Assume a Tier 3 stock that closed on the last day of Q1 with a quarterly share price less than $25. Therefore, utilizing the table within Commentary .07(f), the interval would be $2.50 for strikes added during Q2 even for strikes above $25. Next, assume during Q2 the share price rises above $100. Utilizing only the table within Commentary .07(f), the interval would be $2.50 even though the stock was trading above $100 because the Share Price for purposes of Commentary .07(f), was calculated utilizing data from the prior calendar quarter. However, Commentary .07(e) provides that the Exchange may list a STOS at $1.00 intervals where the strike price is above $100. The greater interval would then be $2.50 as per the table in Commentary .07(f) in this scenario.

In addition, the Exchange proposes to delete the last sentence of the first paragraph of Commentary .07(f), which states that ''[t]he below table indicates the applicable strike intervals and supersedes subparagraph (d) above, which permits additional series to be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened.'' Commentary .07(d) describes adding series of options in the STOS Program.[10] The table within Commentary .07(f) impacts permissible strike intervals. Because there should be no conflict between strike intervals set forth in Commentary .07(f) and details about adding option series set forth in Commentary .07(d), the Exchange believes that deleting this reference will avoid potential confusion.

Finally, consistent with the foregoing, the Exchange proposes to delete note 4 to the table in Commentary .07(f), which provides that ''[n]otwithstanding the limitations imposed by this subparagraph (f), this subparagraph (f) does not amend the range of strikes for Short Term Option Series that may be listed pursuant to subparagraph (e) above,'' which deletion would add clarity and consistency to Commentary .07 and limit the potential for confusion or ambiguity. In addition, the Exchange believes this sentence is unnecessary given the foregoing changes that propose to clarify the circumstances when either subparagraph (f) or subparagraph (e) applies to strike intervals.

Implementation

The Exchange proposes to implement this rule change on August 1, 2022, consistent with the date of ISE's rule change per the ISE Strike Interval Clarification.[11] The Exchange will issue a Trader Update to notify OTP Holders and OTP Firms of the implementation date.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule maintains the goal of the Strike Interval Proposal and continues to limit the intervals between strikes listed in the STOS Program that have an expiration date more than twenty-one days.[14]

The Exchange's proposal to add clarifying language to the first sentence of Commentary .07(f), is consistent with the Act because it will make clear that the only permitted intervals are as specified in the table within Commentary .07(f), except in the case where Commentary .07(e) provides for a greater interval. This amendment will bring greater transparency to the rule.

Adopting a new sentence within Commentary .07(f) to address a potential conflict between provisions in the STOS rule, specifically as between the application of the table within Commentary .07(f) and the rule text within Commentary .07(e), with respect to the correct interval is consistent with the Act. Proposed Commentary .07(f) will make clear to OTP Holders and OTP Firms the applicable intervals when there is a conflict between the rule text within Commentary .07(f) and the rule text within Commentary .07(e), thereby providing certainty as to the outcome. Further, the proposed new rule text promotes just and equitable principles of trade by adding transparency to the manner in which the Exchange implements its listing rules, and protects investors and the general public by removing uncertainty.

The Exchange believes that deleting the last sentence of the first paragraph of Commentary .07(f) is consistent with the Act. The table within Commentary .07(f) supersedes other rules pertaining to strike intervals, but the table does [sic] is not intended to supersede (or conflict with) rules governing the addition of options series, per Commentary .07(d). Therefore, deleting the reference to Commentary .07(d) in proposed Commentary .07(f) will avoid confusion regarding the application of

[10] Commentary .07(d), regarding ''Additional Series,'' provides that ''[i]f the Exchange opens less than thirty (30) Short Term Option Series for a Short Term Option Expiration Date, additional series may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened.''

[11] *See* ISE Strike Interval Clarification, *supra* note 4.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78f(b)(5).

each paragraph, which clarity would protect investors and the general public.

Removing note 4 to the table in Commentary .07(f) is consistent with the Act because while the range limitations continue to be applicable, the strike ranges do not conflict with strike intervals, rendering the sentence unnecessary and potentially confusing. Also, the proposed rule text within Commentary .07(f) otherwise indicates when Commentary .07(e) would apply.

As noted here, the Strike Interval Proposal was designed to reduce the density of strike intervals that would be listed in later weeks, within the STOS Program, by utilizing limitations for intervals between strikes which have an expiration date more than twenty-one days from the listing date. The Exchange's proposal furthers this goal as it intends to continue to remove certain strike intervals where there exist clusters of strikes whose characteristics closely resemble one another and, therefore, do not serve different trading needs, rendering these strikes less useful.[15]

Also, the Strike Interval Proposal will continue to reduce the number of strikes listed on the Exchange, allowing Lead Market Makers and Market Makers to expend their capital in the options market in a more efficient manner, thereby improving overall market quality on the Exchange.

Additionally, by making clear that the greater interval would control as between the Commentary .07(f) and Commentary .07(e), the Exchange is reducing the number of strikes listed in a manner consistent with the intent of the Strike Interval Proposal (*i.e.,* to reduce strikes which were farther out in time). The result of this clarification is to select wider strike intervals for STOS in equity options that have an expiration date more than twenty-one days from the listing date. This proposed rule change would harmonize strike intervals as between inner weeklies (those having less than 21 days from the listing date) and outer weeklies (those having more than 21 days from the listing date) so that strike intervals are not widening as the listing date approaches.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to impact competition but rather is designed to clarify a potential ambiguity regarding strike intervals that exists in the current STOS rule.

The Exchange anticipates that this proposal, which is consistent with a Commission-approved rule of another options exchange, will be adopted by other option exchanges and therefore would have no impact on to competition.[16]

In addition to alleviating potential ambiguity, the proposed rule will further the goal of limiting the number of STOS Program strike intervals available for quoting and trading on the Exchange for all OTP Holders and OTP Firms. The Exchange continues to balance the needs of market participants by continuing to offer a number of strikes to meet a market participant's investment objective. The Exchange's Strike Interval Proposal does not impose an undue burden on inter-market competition as this Strike Interval Proposal does not impact the listings available at another self-regulatory organization.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[17] and Rule 19b–4(f)(6)[18] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[19] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[20] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange may implement the proposed rule change on August 1, 2022—the same time other exchanges are implementing an identical change.[21] The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any new or novel issues. Accordingly, the Commission hereby waives the operative delay.[22]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2022–43 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2022–43. This file number should be included on the

[15] For example, two strikes that are densely clustered may have the same risk properties and may also be the same percentage out-of-the money.

[16] *See* ISE Strike Interval Clarification, *supra* note 4.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

[21] *See* Securities Exchange Act Release No. 95085 (June 10, 2022), 87 FR 36353 (June 16, 2022) (SR–ISE–2022–10) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend ISE Options 4, Section 5, Series of Options Contracts Open for Trading).

[22] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2022–43 and should be submitted on or before August 24, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16552 Filed 8–2–22; 8:45 am]

BILLING CODE 8011–01–P

[23] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95382; File No. SR–CboeEDGX–2022–032]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Certain of Its Rules Related to Market-Makers

July 28, 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 July 14, 2022, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (''EDGX Options'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to amend certain of its Rules related to Market Makers. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

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 certain of its Rules related to Market Makers. Specifically, the Exchange proposes to amend its Rules to permit an Options Member to register separate Market Maker aggregation units as separate Market Makers, each of which would be subject to Market Maker obligations on an individual basis. Currently, the Exchange interprets the term ''Market Maker'' to apply at a firm level, including with respect to obligations. However, the Exchange understands Options Members have Market Maker units that are completely separate from each other for operational and profit/loss purposes, with appropriate information barriers between units.[3] Because of this operational separation, such organizations may prefer to have those units be treated as individual Market Makers under the Exchange's Rules consistent with those organizations' internal operations.

The proposed rule change amends certain Rules to provide Options Members with this flexibility:

- Rule 22.2 currently provides that Options Members registered as Market Makers have certain rights and bear certain responsibilities beyond those of other Options Members. The proposed rule change adds Interpretation and Policy .01 to provide that if an Options Member is comprised of multiple market making aggregation units and has in place appropriate information barriers or segregation requirements,[4] the Options Member may register each individual aggregation unit as a separate Market Maker. The proposed rule change also adds a similar interpretation and policy .02 regarding Designated Primary Market Makers (''DPMs'').
- The proposed rule change adds Rule 22.3, Interpretation and Policy .01 to provide that Market Maker appointments would apply to each individual Market Maker aggregation unit and adds Rule 22.4, Interpretation and Policy .01 to provide that each Market Maker aggregation unit will be evaluated for good standing on an individual basis.
- The proposed rule change amends Rules 21.20, Interpretation and Policy .02 and adds Rule 22.5, Interpretation and Policy .01 and Rule 22.6, Interpretation and Policy .01 to provide that Market Maker obligations will apply to individual Market Maker aggregation units if an Options Member registers separate aggregation units as Market Makers.
- The proposed rule change adds Rule 2.4, Interpretation and Policy .02 to require any individual Market Maker aggregation unit within a single firm to connect to the Exchange's backup systems and participate in functional and performance testing announced by the Exchange if that unit satisfies the connection criteria set forth in Rule 2.4(b).

[3] Certain Exchange rules contemplate Options Members having separate business units and require information barriers in the form of appropriate policies and procedures that reflect the Options Member's business to establish those separate business units. *See, e.g.,* Rules 18.4 (prevention of the misuse of material, nonpublic information); and 18.7 (which applies Cboe Exchange, Inc. position limits to the Exchange).

[4] The Options Member will need to provide the Exchange with sufficient evidence of separation of these units.

• The proposed rule change adds Rule 21.19, Interpretation and Policy .04 (related to the Automated Improvement Mechanism (''AIM'')) and Rule 21.21, Interpretation and Policy .04 (related to the Solicitation Auction Mechanism (''SAM'')) to provide that the restriction in the introductory paragraph of each Rule that prohibits a solicited order for the account of any Market Maker registered in the applicable series or with an appointment in the applicable class on the Exchange, respectively, applies to an individual Market Maker aggregation unit if an Options member has multiple aggregation units registered as separate Market Makers.[5]

These proposed changes are consistent with the concept of treating individual Market Maker aggregation units within a single firm as separate Market Makers.

The proposed rule change states that an Options member may register separate aggregation units as individual Market Makers if the organization has in place appropriate information barriers or segregation units. The proposed language provides Options Members with flexibility to adapt their policies and procedures to reflect their business model and activities, including changes thereto. This flexibility is similar to other rules that require information barriers, such as Rule 18.4, which requires every Options Member to establish, maintain, and enforce written policies and procedures reasonably designed, taking into consideration the nature of the Options Members' business, to prevent the misuse of material nonpublic information by the Options Member or persons associated with such Options Member in violation of the federal securities laws or the Rules thereunder, and the Exchange Rules. In accordance with this proposed rule change, pursuant to Rule 18.4, an Options Member that registers separate business units as individual Market Makers would be obligated to ensure that its policies and procedures reflect the current state of its business and continue to be reasonably designed to prevent the misuse of material, nonpublic information. Separate market making units registered as individual Market Makers may dictate that an information barrier or functional separation be part of the appropriate set of policies and procedures that would be reasonably designed to achieve compliance with the proposed rule change. The proposed rule change has no pre-approval requirement; however, appropriate information barriers would be subject to review as part of the process to register the separate aggregation units as individual Market Makers with the Exchange.[6] Additionally, these policies and procedures would be subject to regular review by the Exchange's Regulation Division, such as part of the routine examination or testing process or as part of internal surveillances and investigations.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, because it will provide Options Members with flexibility to register its business units as Market-Makers with the Exchange, and have the Exchange regulate those Market-Maker business units, in a manner consistent with these organizations' internal business operations. The Exchange believes this will permit these organizations to manage the entirety of their Market-Maker operations—including Market-Maker registrations, appointments, and quoting—as they deem appropriate based on the nature of their businesses, which may ultimately benefit the efficiency of their Market-Maker businesses. The Exchange does not propose to modify any Market-Maker responsibilities or obligations. The Exchange does not believe the proposed rule change will reduce liquidity, as any individual Market-Maker aggregation unit (as opposed to the Options Member collectively) will need to satisfy all Market-Maker obligations, including continuous quoting obligations, on its own.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will not impose any burden on intramarket competition, because it will apply in the same manner to all Options Members that register with the Exchange as Market-Makers. Whether an Options Member registers separate business units as Market-Makers is within the sole discretion of that organization. With respect to Options Members that elect to register separate business units as Market-Makers, the proposed rule change will apply all applicable Market-Maker rules, including those regarding Market-Maker obligations and responsibilities, in the same manner to those units. The Exchange does not propose to modify any Market-Maker obligations or responsibilities, and thus does not believe the proposed rule change will diminish liquidity on the Exchange. The proposed rule change will not impose any burden on intermarket competition, because the proposed rule change applies only to how Options Members may register with the Exchange as a Market-Maker and how the Exchange will determine Market-Maker compliance with Exchange-imposed Market-Maker obligations and responsibilities.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

[5] For example, if Firm ABC has aggregation units DEF and GHI each registered as separate Market Makers, if Market Maker DEF has an appointment in class XYZ but Market Maker GHI does not, Market Maker GHI could be solicited to be the contra-side order in an AIM or SAM auction in class XYZ, but Market Maker DEF could not.

[6] The Exchange's Regulatory Division intends to announce by Regulatory Circular a method by which an Options Member may seek pre-approval of the policies and procedures comprising the information barriers.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *Id.*

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 [10] and Rule 19b–4(f)(6) thereunder.[11]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The proposal provides flexibility to an Options Member to register separate market-maker aggregation units as separate Market-Makers, each of which would be subject to Market-Maker obligations on an individual basis, if appropriate information barriers or segregation requirements are in place. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any new or novel issues. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[13]

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.

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2022–032 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGX–2022–032. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change.

Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2022–032 and should be submitted on or before August 24, 2022.

[14] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16549 Filed 8–2–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95385; File No. SR–C2–2022–014]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Certain of Its Rules Related to Market-Makers

July 28, 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 July 14, 2022, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe C2 Exchange, Inc. (''C2'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to amend certain of its Rules related to Market-Makers. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/ctwo/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 certain of its Rules related to Market-Makers. Specifically, the Exchange proposes to amend its Rules to permit a Trading Permit Holder (''TPH'') to register separate market-maker aggregation units as separate Market-Makers, each of which would be subject to Market-Maker obligations on an individual basis. Currently, C2 interprets the term ''Market-Maker'' to apply at a firm level, including with respect to obligations. However, the Exchange understands TPHs have Market-Maker units that are completely separate from each other for operational and profit/loss purposes, with appropriate information barriers between units.[3] Because of this operational separation, such organizations may prefer to have those units be treated as individual Market-Makers under the Exchange's Rules consistent with those organizations' internal operations.

The proposed rule change amends certain Rules to provide TPH with this flexibility:

- Rule 3.52 currently provides that TPHs registered as Market-Makers have certain rights and bear certain responsibilities beyond those of other TPHs. The proposed rule change adds Interpretation and Policy .01 to provide that if a TPH is comprised of multiple market-making aggregation units and has in place appropriate information barriers or segregation requirements,[4] the TPH may register each individual aggregation unit as a separate Market-Maker.
- The proposed rule change adds Rule 5.50, Interpretation and Policy .01 to provide that Market-Maker appointments would apply to each individual Market-Maker aggregation unit and adds Rule 5.53, Interpretation and Policy .01 to provide that each Market-Maker aggregation unit will be evaluated for good standing on an individual basis.
- The proposed rule change amends Rules 5.33, Interpretation and Policy .02 and adds Rule 5.51, Interpretation and Policy .01; and Rule 5.52, Interpretation and Policy .01 to provide that Market-Maker obligations will apply to individual Market-Maker aggregation units if a TPH registers separate aggregation units as Market-Makers.
- The proposed rule change adds Rule 5.24, Interpretation and Policy .02 to require any individual Market-Maker aggregation unit within a single firm to connect to the Exchange's backup systems and participate in functional and performance testing announced by the Exchange if that unit satisfies the connection criteria set forth in Rule 5.24(b).

These proposed changes are consistent with the concept of treating individual Market-Maker aggregation units within a single firm as separate Market-Makers.

The proposed rule change states that a TPH may register separate aggregation units as individual Market-Makers if the TPH has in place appropriate information barriers or segregation units. The proposed language provides TPHs with flexibility to adapt their policies and procedures to reflect their business model and activities, including changes thereto. This flexibility is similar to other rules that require information barriers, such as Rule 8.10, which requires every TPH to establish, maintain, and enforce written policies and procedures reasonably designed, taking into consideration the nature of the TPH's business, to prevent the misuse, in violation of the Exchange Act and Exchange Rules, of material nonpublic information by the TPH or persons associated with the TPH. In accordance with this proposed rule change, pursuant to Rule 8.10, a TPH that registers separate business units as individual Market-Makers would be obligated to ensure that its policies and procedures reflect the current state of its business and continue to be reasonably designed to prevent the misuse of material, nonpublic information. Separate market-making units registered as individual Market-Makers may dictate that an information barrier or functional separation be part of the appropriate set of policies and procedures that would be reasonably designed to achieve compliance with the proposed rule change. The proposed rule change has no pre-approval requirement; however, appropriate information barriers would be subject to review as part of the process to register the separate aggregation units as individual Market-Makers with the Exchange.[5] Additionally, these policies and procedures would be subject to regular review by the Exchange's Regulation Division, such as part of the routine examination or testing process or as part of internal surveillances and investigations.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, because it will provide TPH organizations with flexibility to register its business units as Market-Makers with the Exchange, and have the Exchange regulate those Market-Maker business units, in a manner consistent with these organizations' internal business operations. The Exchange believes this will permit these organizations to manage the entirety of their Market-Maker operations—including Market-Maker registrations, appointments, and quoting—as they deem appropriate

[3] Certain C2 rules contemplate TPHs having separate business units and require information barriers in the form of appropriate policies and procedures that reflect the TPH's business to establish those separate business units. *See, e.g.,* Rules 8.10 (prevention of the misuse of material, nonpublic information); and 8.30, Interpretations and Policies .03 (position limits).

[4] The TPH will need to provide the Exchange with sufficient evidence of separation of these units.

[5] The Exchange's Regulatory Division intends to announce by Regulatory Circular a method by which a TPH may seek pre-approval of the policies and procedures comprising the information barriers.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

based on the nature of their businesses, which may ultimately benefit the efficiency of their Market-Maker businesses. The Exchange does not propose to modify any Market-Maker responsibilities or obligations. The Exchange does not believe the proposed rule change will reduce liquidity, as any individual Market-Maker aggregation unit (as opposed to the TPH organization collectively) will need to satisfy all Market-Maker obligations, including continuous quoting obligations, on its own.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will not impose any burden on intramarket competition, because it will apply in the same manner to all TPH organizations that register with the Exchange as Market-Makers. Whether a TPH organization registers separate business units as Market-Makers is within the sole discretion of that organization. With respect to TPH organizations that elect to register separate business units as Market-Makers, the proposed rule change will apply all applicable Market-Maker rules, including those regarding Market-Maker obligations and responsibilities, in the same manner to those units. The Exchange does not propose to modify any Market-Maker obligations or responsibilities, and thus does not believe the proposed rule change will diminish liquidity on the Exchange. The proposed rule change will not impose any burden on intermarket competition, because the proposed rule change applies only to how TPH organizations may register with the Exchange as a Market-Maker and how the Exchange will determine Market-Maker compliance with Exchange-imposed Market-Maker obligations and responsibilities.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The proposal provides flexibility to a TPH organization to register separate market-maker aggregation units as separate Market-Makers, each of which would be subject to Market-Maker obligations on an individual basis, if appropriate information barriers or segregation requirements are in place. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any new or novel issues. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[12]

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.

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–C2–2022–014 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–C2–2022–014. 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–C2–2022–014 and should be submitted on or before August 24, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–16551 Filed 8–2–22; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–1001]

Request for Comments in Minimum Seat Dimensions Necessary for Safety of Air Passengers (Emergency Evacuation)

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

ACTION: Request for comments.

SUMMARY: In 2018, Congress directed the FAA to, after notice and comment, issue such rules for minimum dimensions for passenger seats that are necessary for passenger safety. The FAA conducted simulated emergency evacuations, the results of which are in a publicly-available report. The FAA seeks public comment on the minimum seat dimensions that are necessary for passenger safety.

DATES: Written comments must be received on or before November 1, 2022.

ADDRESSES: Send comments identified by docket number FAA–2022–1001 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Facsimile:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For questions concerning this action, contact Mary Schooley, Aviation Safety, Federal Aviation Administration, 2200 S. 216th St, Des Moines, WA 98198, telephone: 206–231–3499, email: *AIR-seat-spacing-comments@faa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 577 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254, ''the Act'') directed the FAA to issue, after notice and comment, such rules as necessary for the safety of passengers with regard to the minimum dimensions, including seat pitch, width, and length, of passenger seats on aircraft operated by air carriers in interstate air transportation or intrastate air transportation. Section 577 recognizes the FAA's statutory mission of safety in air commerce. 49 U.S.C. 44701. To gather data in furtherance of the agency's implementation of Section 577 of the Act, the FAA conducted simulated emergency evacuations at the FAA's Civil Aerospace Medical Institute (CAMI) and produced a report.

Additionally, Section 337 of the Act directed the FAA to review, with stakeholders, the evacuation certification of transport-category aircraft used in air transportation, and report the results of the review to Congress. In support of the agency's compliance with Section 337 of the Act, the FAA chartered the Emergency Evacuation Standards Aviation Rulemaking Committee (ARC) to gather the stakeholders needed to perform the required review of evacuation issues. The ARC submitted a report to the FAA.[1] The FAA, in a report to Congress, submitted the ARC report along with the CAMI report on March 31, 2022.[2] These reports are available in the docket.

II. Request for Comments

In furtherance of the agency's implementation of Section 577 of the Act, the FAA invites public comments to assist the agency in determining what minimum dimensions (including pitch, width, and length) of passenger seats may be necessary for safety, including in particular airplane evacuation. The FAA has assessed what safety issues could be associated with seat dimensions and concluded that additional data regarding evacuations could be valuable.

The FAA invites comments on minimum seat dimensions necessary for passenger safety, especially during airplane evacuation, as the FAA examines whether new regulatory standards are necessary, in order to ensure such safety and comply with Section 577 of the Act. The FAA encourages commenters to review the CAMI report, and other materials in the docket, prior to commenting.

Comments should address whether, considering the existing regulatory requirements,[3] one or more of the following seat dimensions [4] have or demonstrably could adversely affect the safety of air passengers by delaying the group egress time [5] of an emergency evacuation:

a. Seat width;
b. Seat pitch;
c. Seat length; and
d. Other seat dimensions.

Further, commenters are asked to provide information regarding the minimum seat dimensions necessary to ensure safety during airplane evacuation of a broad range of passengers, including those who were not included in the CAMI study including children, people over 60, and individuals with disabilities.

The FAA emphasizes that comments that include technical data and information will be the most helpful. The FAA is not requesting comments regarding matters unrelated to the agency's determination under section 577, such as how the dimensions of passenger seats might relate to passenger comfort or convenience.

[1] *www.faa.gov/regulations_policies/rulemaking/committees/documents/media/Emergency%20Evac%20Standards%20ARC%20final%20report%20final%20(5–26–2020).pdf.*

[2] *www.faa.gov/data_research/research/med_humanfacs/oamtechreports/2020s/media/Effects_of_Airplane_Cabin_Interiors_on_Egress_I.pdf.*

[3] Under the relevant general performance standard provided by 14 CFR 25.803(a), transport category airplanes must have means to allow rapid evacuation under various conditions, including in the event of a fire. In § 25.803(c), the FAA mandates that the maximum seating capacity of the airplane can be evacuated to the ground under simulated emergency conditions within 90 seconds. However, the FAA established the 90-second requirement as a uniform, repeatable standard under specific conditions, not a standard that the FAA expects to be met in every actual emergency evacuation. In addition, 14 CFR 25.561(d) and 25.562(c)(8) require that seats having experienced static and dynamic emergency landing loads do not deform to the extent that they would impede rapid evacuation.

[4] For purposes of this request for comments, seat pitch is the distance between a fixed point on an airplane seat to the same fixed point on the seat directly in front of or behind that seat. Seat width is the distance between the armrests' inner faces directly above the bottom seat cushion. Seat length is the distance between the top aft edge of the bottom seat cushion to the top front edge. Also, CAMI discusses the terms it used for its study on pp. 21–22 of its report.

[5] For purposes of this request for comments, the group egress time is the time from when the aircraft comes to a rest after a crash or incident, to when the last passenger exits the aircraft.

Issued under authority provided by Public Law 115–254, 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on July 20, 2022.

Jodi L. Baker,

Deputy Associate Administrator for Aviation Safety.

[FR Doc. 2022–16565 Filed 8–2–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on a Land Release Request at Malden Regional Airport & Industrial Park (MAW), Malden, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release of airport land.

SUMMARY: The FAA proposes to rule and invites public comment on the request to release and sell a 4.81 acre parcel and a .016 acre parcel of federally obligated airport property at the Malden Regional Airport & Industrial Park (MAW), Malden, Missouri, under the provisions agency regulations.

DATES: Comments must be received on or before September 2, 2022.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Amy J. Walter, Airports Land Specialist, Federal Aviation Administration, Airports Division, ACE–620G, 901 Locust, Room 364, Kansas City, MO 64106. In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: David Blalock, Airport Manager, City of Malden Regional Airport & Industrial Park, 3077 Mitchell Drive, P.O. Box 411, Malden, MO 63863–0411, (573) 276–2279.

FOR FURTHER INFORMATION CONTACT: Amy J. Walter, Airports Land Specialist, Federal Aviation Administration, Airports Division, ACE–620G, 901 Locust, Room 364, Kansas City, MO 64106, (816) 329–2603, *amy.walter@faa.gov.* The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release a 4.81 acre parcel and a 0.16 acre parcel of airport property at the Malden Regional Airport & Industrial Park (MAW) under the provisions of 49 U.S.C. 47107(h)(2). This is a Surplus Property Airport. The City of Malden requested a release from the FAA to sell a 4.81 acre parcel to Aycorp, LLC for residential development, and a 0.16 acre parcel to Jerry Smith for future development. The FAA determined this request to release and sell property at the Malden Regional Airport & Industrial Park (MAW) submitted by the Sponsor meets the procedural requirements of the FAA and the release and sale of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The following is a brief overview of the request:

The Malden Regional Airport & Industrial Park (MAW) is proposing the release and sale of a 4.81 acre parcel and a 0.16 acre parcel of airport property. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at the Malden Regional Airport & Industrial Park (MAW) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances in order to sell the land. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in another eligible airport improvement project for general aviation use.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**. In addition, any person may request an appointment to inspect the application, notice and other documents determined by the FAA to be related to the application in person at the Malden City Hall.

Issued in Kansas City, MO, on July 28, 2022.

James A. Johnson,

Director, FAA Central Region, Airports Division.

[FR Doc. 2022–16540 Filed 8–2–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0029]

National Railroad Passenger Corporation—Amtrak's Request To Amend Its Positive Train Control Safety Plan and Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on July 26, 2022, the National Railroad Passenger Corporation (Amtrak) submitted a request for amendment (RFA) to its FRA-approved Positive Train Control Safety Plan (PTCSP). As this RFA may involve a request for FRA's approval of proposed material modifications to an FRA-certified positive train control (PTC) system, FRA is publishing this notice and inviting public comment on the railroad's RFA to its PTCSP.

DATES: FRA will consider comments received by August 23, 2022. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0029. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/train-control/ptc/ptc-annual-and-quarterly-reports.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, Title 49 United States Code (U.S.C.) Section 20157(h) requires FRA to certify that a host railroad's PTC system complies with Title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated

in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal and train control system. Accordingly, this notice informs the public that, on July 26, 2022, Amtrak submitted an RFA to its PTCSP for its Advanced Civil Speed Enforcement System II (ACSES II) and that RFA is available in Docket No. FRA–2010–0029.

Interested parties are invited to comment on Amtrak's RFA to its PTCSP by submitting written comments or data. During FRA's review of this railroad's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA to its PTCSP at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://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.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.* To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2022–16595 Filed 8–2–22; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number MARAD–2019–0109]

Port of Long Beach (POLB or Port) Pier B On-Dock Rail Support Facility Project; Combined Final Environmental Impact Statement/Record of Decision and Final Section 4(f) Evaluation Notice of Availability

AGENCY: Maritime Administration, Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The U.S. Department of Transportation (DOT), Maritime Administration (MARAD) announces the availability of the Combined Final Environmental Impact Statement/Record of Decision and Final Section 4(f) Evaluation, (FEIS/ROD) for the Port of Long Beach (POLB or Port) Pier B On-Dock Rail Support Facility Project (Project) to support an application to DOT for Railroad Rehabilitation & Improvement Financing (RRIF) and potentially other federal funding programs. MARAD has issued a single document that consists of a FEIS/ROD. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

ADDRESSES: The FEIS/ROD, supporting information, and comments are available for viewing and download at *https://www.regulations.gov* under docket number MARAD–2019–0109.

FOR FURTHER INFORMATION CONTACT: Alan Finio, Office of Environmental Compliance, at telephone number: 202–503–6643 or by email at *Alan.Finio@dot.gov.* 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 business hours. The FIRS is available twenty-four hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours. Additionally, if you go to the online docket and sign up for email alerts, you will be notified if other Project documents are posted.

SUPPLEMENTARY INFORMATION: The Project is designed to address current traffic and cargo distribution bottlenecks into, out of, and within the POLB. The Project also includes consideration for: anticipated future demand for cargo movement via on-dock rail; maximization of on-dock intermodal operations to reach the long-term goal of 30 to 35 percent of cargo containers to be handled by on-dock rail; provision of a facility that can accept and handle longer container trains; and provision of a rail yard that is cost effective and fiscally prudent. The Port is applying to the RRIF Program, and potentially other federal funding programs, to support the Project.

Summary of the Project

The City of Long Beach (COLB), acting by and through its Board of Harbor Commissioners (BHC), is proposing to construct the 12th Street Alternative in the POLB. The purposes of the proposed reconfiguration and expansion Project are to: (a) provide a sufficient facility to accommodate the expected demand of cargo to be moved via on-dock rail into the foreseeable future; (b) maximize on-dock intermodal operations to reach the long-term goal of 30 to 35 percent of cargo containers to be handled by on-dock rail (c) provide a facility that can accept and handle longer container trains; and (d) provide a rail yard that is cost effective and fiscally prudent.

The proposed Project would be constructed in three phases over an estimated seven years and has an estimated opening year of 2025. Components of the proposed Project would include:

- Adding 31 yard tracks and five arrival/departure tracks, thereby expanding the yard from an existing 12 tracks (2 main line tracks, 10-yard tracks, and no arrival/departure tracks) to a total of 48 tracks (2 main tracks, 41 yard tracks, and five arrival/departure tracks);
- Providing for up to 10,000-foot long receiving/departure tracks;
- Widening the existing rail bridge over Dominguez Channel to accommodate one additional track; and
- Constructing an area for locomotive refueling within the yard.

Realignments and closures of some roadways would be required. Pier B Street would be realigned to the south, its geometrics would be improved, and two lanes of traffic in each direction would be provided.

- The realignment of Pier B Street would require the reconstruction of two intersections, at Anaheim Way and Edison Avenue.
- The existing at-grade 9th Street railroad grade crossing would be closed, and the Shoemaker ramps removed.
- Pico Avenue would be realigned to the west beginning at the I–710 ramps south to approximately Pier D Street, allowing space for four additional tracks between Pico Avenue and the I–710 freeway.
- Areas needed for new rail tracks would require the closure of portions of

9th, 10th, 11th, and 12th streets and Edison, Jackson, Santa Fe, Canal, Caspian, Harbor, and Fashion avenues between Anaheim Street and Pier B Street, in the City of Long Beach.

• Portions of Farragut, Foote, Cushing, Macdonough, and Schley avenues would be closed in the vicinity of existing railroad right-of-way (ROW) in the City of Long Beach.

The proposed Project would be located in two POLB Planning Districts (the Northeast Harbor and North Harbor); the site also includes the Wilmington-Harbor City Community Plan Area of the City of Los Angeles. The Project site is generally situated between Dominguez Channel to the west, Interstate 710 (I–710) to the east, Ocean Boulevard to the south, and Anaheim Street to the north. The proposed Project area includes rail tracks that extend west beyond the Terminal Island Freeway (State Route 103) to just west of Dominguez Channel, where they connect with the Alameda Corridor, and also south as far as Ocean Boulevard. In addition to privately owned property, a variety of public agencies own property within the Project site and in its vicinity, including the POLB, COLB, City of Los Angeles, Port of Los Angeles, Union Pacific, and Burlington Northern Santa Fe railroads; Alameda Corridor Transportation Authority; Los Angeles County Flood Control District; and Southern California Edison.

(Authority: 49 CFR 1.93)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–16585 Filed 8–2–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

[OMB Control No. 2105–0573; Docket No. DOT–OST–2022–0085]

Notice and Request for Comments on Revision of a Previously Approved Information Collection Request

AGENCY: Department of Transportation.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Department of Transportation's (DOT) Office of the Secretary (OST) announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. The Executive Order, ''Setting Customer Service Standards,'' directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers' needs, the Department of Transportation (DOT) seeks a renewal without revision to a fast track generic clearance information collection request already approved by OMB. OST requests renewal without revision of ICR with OMB Control Number: 2105–0573 as described below. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on May 24, 2022. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before: September 2, 2022.

ADDRESSES: Submit comments identified by Information Collection 2105–0573, Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, by any of the following methods:

• *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.

• *Mail:* U.S. Department of Transportation, Office of the Chief Information Officer, 1200 New Jersey Avenue SE, Washington, DC 20590. ATTN: Chief Data Officer/IC 2105–0573, Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Instructions: Please submit comments only and cite Information Collection 2105–0573, Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery in all correspondence related to this collection. To confirm receipt of your comment(s), please check *regulations.gov,* approximately two-to-three business days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Daniel Morgan, Assistant Chief Information Officer for Data Services/Chief Data Officer, or via email to *daniel.morgan@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Department's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insight into customer or stakeholder perceptions, opinions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Department of Transportation and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. Feedback or information collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population.

The U.S. Department of Transportation will only submit collections if they meet the following criteria.

• The collections are voluntary.

• The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government.

• The collections are noncontroversial and do not raise issues of concern to other Federal agencies.

• Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future.

• Personally identifiable information (PII) is collected only to the extent necessary and is not retained.

• Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the Department (if released, the Department must indicate the qualitative nature of the information).

This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which

generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Type of Review: Renewal without revision of a previously approved Information Collection Request.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Estimated Number of Respondents: 240,000.

Estimated Annual Responses: 80,000.

Estimated Annual Burden Hours: 20,000 hours.

Frequency: One-time requirement.

Annual burden hours = (80,000 responses) × (15 minutes) = 1,200,000 min = 20,000 hours.

Total burden hours for 3 years = 20,000 × 3 = 60,000 hours.

Total respondents = 80,000 (each year) × 3 = 240,000.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. 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.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection *Regulations.gov.*

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 Office of Management and Budget control number.

Dated: July 28, 2022.

Michael Howell,

Paperwork Reduction Act, Information Collection Officer.

[FR Doc. 2022–16539 Filed 8–2–22; 8:45 am]

BILLING CODE 4910–9X–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meeting

TIME AND DATE: August 8, 2022, 11:00 a.m. to 1:00 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll) or (ii) 1–877–853–5247 (US Toll Free) or 1–888–788–0099 (US Toll Free), Meeting ID: 979 8108 2545, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/tJMkf-iopjkvHtGOJrP4ApjM8gz7AhNEux2d.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Industry Advisory Subcommittee (the ''Subcommittee'') will conduct a meeting to continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Agenda

I. Call to Order—UCR Industry Advisory Subcommittee Chair

The Industry Advisory Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Industry Advisory Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda—UCR Industry Advisory Subcommittee Chair

For Discussion and Possible Board Action

The proposed Agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

➢ Subcommittee action only to be taken in designated areas on agenda.

IV. Review and Approval of Minutes From the May 19, 2022 Meeting—UCR Industry Advisory Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the May 19, 2022 Industry Advisory Subcommittee meeting via teleconference will be reviewed. The UCR Industry Advisory Subcommittee will consider action to approve.

V. Review of the Full UCR Board Agenda—UCR Industry Advisory Subcommittee Chair

For Discussion and Possible Subcommittee Action

The UCR Industry Advisory Subcommittee Chair will discuss the full UCR Board agenda for the Board's August 11, 2022 Board meeting. The Subcommittee may take action to recommend or oppose to the UCR Board any action items listed on that Board agenda.

VI. Truck Parking Initiative—UCR Industry Advisory Subcommittee Chair

For Discussion and Possible Subcommittee Action

The UCR Industry Advisory Subcommittee Chair will discuss the truck parking initiative with Subcommittee. The Subcommittee may take action to recommend to the UCR Board that the Board authorize the UCR Board Chair to draft, sign, and send a letter to Congress recommending approval of such legislation.

VII. Compliance With Bracket 1 Fees—Tamara Young, Member, Industry Advisory Subcommittee

Tamara Young will lead a general discussion on the issue of compliance for entities required to pay UCR Bracket 1 fees.

VIII. Discussion on New Roles on Subcommittees—UCR Industry Advisory Subcommittee Chair

The UCR Industry Advisory Subcommittee Chair will discuss the new roles with Subcommittee.

IX. Other Items—UCR Industry Advisory Subcommittee Chair

The UCR Industry Advisory Subcommittee Chair will call for any other business, old or new, that Subcommittee members would like to discuss.

X. Adjournment—UCR Industry Advisory Subcommittee Chair

The UCR Industry Advisory Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, July 29, 2022 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2022–16714 Filed 8–1–22; 4:15 pm]

BILLING CODE 4910–YL–P

FEDERAL REGISTER

Vol. 87 Wednesday,

No. 148 August 3, 2022

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 483

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2023; Changes to the Requirements for the Director of Food and Nutrition Services and Physical Environment Requirements in Long-Term Care Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 483

[CMS–1765–F and CMS–3347–F]

RIN 0938–AU76 and 0938–AT36

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2023; Changes to the Requirements for the Director of Food and Nutrition Services and Physical Environment Requirements in Long-Term Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates payment rates; forecast error adjustments; diagnosis code mappings; the Patient Driven Payment Model (PDPM) parity adjustment; the SNF Quality Reporting Program (QRP); and the SNF Value-Based Purchasing (VBP) Program. It also establishes a permanent cap policy to smooth the impact of year-to-year changes in SNF payments related to changes in the SNF wage index. We also announce the application of a risk adjustment for the SNF Readmission Measure for COVID–19 beginning in FY 2023. We are finalizing changes to the long-term care facility fire safety provisions referencing the National Fire Protection Association (NFPA)® Life Safety Code, and Director of Food and Nutrition Services requirements.

DATES: These regulations are effective on October 1, 2022.

FOR FURTHER INFORMATION CONTACT: *PDPM@cms.hhs.gov* for issues related to the SNF PPS.

Heidi Magladry, (410) 786–6034, for information related to the skilled nursing facility quality reporting program.

Alexandre Laberge, (410) 786–8625, for information related to the skilled nursing facility value-based purchasing program.

Kristin Shifflett, *Kristin.shifflett@cms.hhs.gov,* and Cameron Ingram, *Cameron.ingram@cms.hhs.gov,* for information related to the LTC requirements for participation.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the internet on the CMS website. The wage index tables for this final rule can be accessed on the SNF PPS Wage Index home page, at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Burwell at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

I. Executive Summary
- A. Purpose
- B. Summary of Major Provisions
- C. Summary of Cost and Benefits
- D. Advancing Health Information Exchange

II. Background on SNF PPS
- A. Statutory Basis and Scope
- B. Initial Transition for the SNF PPS
- C. Required Annual Rate Updates

III. Analysis and Responses to Public Comments on the FY 2023 SNF PPS Proposed Rule
- A. General Comments on the FY 2023 SNF PPS Proposed Rule

IV. SNF PPS Rate Setting Methodology and FY 2023 Update
- A. Federal Base Rates
- B. SNF Market Basket Update
- C. Case-Mix Adjustment
- D. Wage Index Adjustment
- E. SNF Value-Based Purchasing Program
- F. Adjusted Rate Computation Example

V. Additional Aspects of the SNF PPS
- A. SNF Level of Care—Administrative Presumption
- B. Consolidated Billing
- C. Payment for SNF-Level Swing-Bed Services
- D. Revisions to the Regulation Text

VI. Other SNF PPS Issues
- A. Permanent Cap on Wage Index Decreases
- B. Technical Updates to PDPM ICD–10 Mappings
- C. Recalibrating the PDPM Parity Adjustment
- D. Request for Information: Infection Isolation

VII. Skilled Nursing Facility Quality Reporting Program (SNF QRP)
- A. Background and Statutory Authority
- B. General Considerations Used for the Selection of Measures for the SNF QRP
- C. SNF QRP Quality Measure Beginning With the FY 2025 SNF QRP
- D. SNF QRP Quality Measures Under Consideration for Future Years: Request for Information (RFI)
- E. Overarching Principles for Measuring Equity and Healthcare Quality Disparities across CMS Quality Programs—Request for Information (RFI)
- F. Inclusion of the CoreQ: Short Stay Discharge Measure in a Future SNF QRP Program Year—Request for Information (RFI)
- G. Form, Manner, and Timing of Data Submission Under the SNF QRP
- H. Policies Regarding Public Display of Measure Data for the SNF QRP

VIII. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)
- A. Statutory Background
- B. SNF VBP Program Measures
- C. SNF VBP Performance Period and Baseline Period
- D. Performance Standards
- E. SNF VBP Performance Scoring
- F. Adoption of a Validation Process for the SNF VBP Program Beginning With the FY 2023 Program Year
- G. SNF Value-Based Incentive Payments for FY 2023
- H. Public Reporting on the Provider Data Catalog website
- I. Requests for Comment Related to Future SNF VBP Program Expansion Policies

IX. Changes to the Requirements for the Director of Food and Nutrition Services and Physical Environment Requirements in Long-Term (LTC) Facilities and Summary of Public Comments and Responses to the Request for Information on Revising the Requirements for Long-Term Care Facilities to Establish Mandatory Minimum Staffing Levels

X. Collection of Information Requirements

XI. Economic Analyses
- A. Regulatory Impact Analysis
- B. Regulatory Flexibility Act Analysis
- C. Unfunded Mandates Reform Act Analysis
- D. Federalism Analysis
- E. Regulatory Review Costs

I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for fiscal year (FY) 2023, as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication of certain specified information relating to the payment update (see section II.C. of this final rule) in the **Federal Register**, before the August 1 that precedes the start of each FY. In addition, this final rule includes requirements for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) and the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP), including adopting new quality measures for the SNF VBP Program and finalizing several updates to the Program's scoring methodology.

The SNF QRP adopts one new measure to promote patient safety, begins collection of information which will improve the quality of care for all SNF patients, and revises associated regulation text. We are revising the qualification requirements for the Director of Food and Nutrition Services and revising requirements for life safety from fire for long-term care facilities that previously used the Fire Safety Evaluation System (FSES) to demonstrate compliance with provisions of the Life Safety Code (LSC).

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5) of the Act, the Federal rates in this final rule will reflect an update to the rates that we published in the SNF PPS final rule for FY 2022 (86 FR 42424, August 4, 2021). In addition, the final rule includes a forecast error adjustment for FY 2023, updates to the diagnosis code mappings used under the Patient Driven Payment Model (PDPM), and includes a recalibration of the PDPM parity adjustment. This final rule also establishes a permanent cap policy to smooth the impact of year-to-year changes in SNF payments related to changes in the SNF wage index.

This final rule finalizes requirements for the SNF QRP, including the adoption of one new measure beginning with the FY 2024 SNF QRP: the Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431) measure. We are also revising the compliance date for the Transfer of Health Information measures and certain standardized patient assessment data elements. In addition, we are revising regulation text that pertains to data submission requirements for the SNF QRP.

We are also finalizing several updates for the SNF VBP Program, including a policy to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for the FY 2023 SNF VBP Program Year for scoring and payment adjustment purposes. We are also adding two new measures to the SNF VBP Program beginning with the FY 2026 SNF VBP program year and one new measure beginning with the FY 2027 program year. We are also finalizing several updates to the scoring methodology beginning with the FY 2026 program year. We are also revising our regulation text in accordance with our proposals.

In addition, we are finalizing LTC facilities LSC changes in § 483.90(a) to allow older exiting facilities to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment, and people movement requirements as set out in the LSC. Older facilities who may not meet the FSES requirements previously used the 2000 LSC FSES will be allowed to remain in compliance with the older FSES without incurring substantial expenses to change their construction types, while maintaining resident and staff safety.

Additionally, we are finalizing changes to the requirements for the Director of Food and Nutrition Services in LTC facilities in § 483.60. We are revising the required qualifications for a director of food and nutrition services to provide that those with several years of experience performing as the director of food and nutrition services in a facility can continue to do so. Specifically, we have added to the current requirements that individuals with 2 or more years of experience in the position of a director of food and nutrition services and who have also completed a minimum course of study in food safety that includes topics integral to managing dietary operations (such as, but not limited to: foodborne illness, sanitation procedures, food purchasing/receiving, etc.) can continue to qualify as a director of food and nutrition services. This will help address concerns related to costs associated with training for existing staff and the potential need to hire new staff.

C. Summary of Cost and Benefits

TABLE 1: Cost and Benefits

Provision Description	Total Transfers/Costs
FY 2023 SNF PPS payment rate update	The overall economic impact of this final rule is an estimated increase of $904 million in aggregate payments to SNFs during FY 2023.
FY 2023 SNF QRP changes	The overall economic impact of this final rule is an estimated increase in aggregate cost to SNFs of $30,949,079.36.
FY 2023 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $185.55 million in aggregate payments to SNFs during FY 2023.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their digital health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) to facilitate collaboration with interested parties to develop Health Level Seven International® (HL7) Fast Healthcare Interoperability Resource® (FHIR) standards. These standards could support the exchange and reuse of patient assessment data derived from the post-acute care (PAC) setting assessment tools, such as the minimum data set (MDS), inpatient rehabilitation facility -patient assessment instrument (IRF–PAI), Long-Term Care Hospital (LTCH) continuity assessment record and evaluation (CARE) Data Set (LCDS), outcome and assessment information set (OASIS), and other sources.[1] [2] The PACIO Project has focused on HL7 FHIR implementation guides for: functional status, cognitive status and new use cases on advance directives, re-assessment timepoints, and Speech, language, swallowing, cognitive communication and hearing (SPLASCH) pathology.[3] We encourage PAC provider

[1] HL7 FHIR Release 4. Available at *https://www.hl7.org/fhir/.*

[2] HL7 FHIR. PACIO Functional Status Implementation Guide. Available at *https://paciowg.github.io/functional-status-ig/.*

[3] PACIO Project. Available at *http://pacioproject.org/about/.*

and health IT vendor participation as the efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as a resource for PAC assessment data elements and their associated mappings to health IT standards such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED).[4] The DEL furthers CMS' goal of data standardization and interoperability. Standards in the DEL can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2022 ISA is available at *https://www.healthit.gov/isa/sites/isa/files/inline-files/2022-ISA-Reference-Edition.pdf.*

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) required HHS and ONC to take steps to promote adoption and use of electronic health record (EHR) technology.[5] Specifically, section 4003(b) of the Cures Act required ONC to take steps to advance interoperability through the development of a Trusted Exchange Framework and Common Agreement aimed at establishing full network-to network exchange of health information nationally. On January 18, 2022, ONC announced a significant milestone by releasing the Trusted Exchange Framework[6] and Common Agreement Version 1.[7] The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement is a contract that advances those principles. The Common Agreement and the Qualified Health Information Network Technical Framework Version 1 (incorporated by reference into the Common Agreement) establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other, all under commonly agreed to terms. The technical and policy architecture of how exchange occurs under the Common Agreement follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, healthcare practices, hospitals, public health agencies, and Individual Access Services (IAS) Providers.[8] For more information, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

We invited providers to learn more about these important developments and how they are likely to affect SNFs.

Comment: We received one comment on the information provided in this section. The commenter expressed support for efforts across HHS to advance health information technology exchange and encouraged use of a standard set of data by providers and health IT vendors, including efforts through the PACIO project. The commenter also noted a recent National Academies report describing technology barriers for PAC settings due to not being eligible for previous incentives to purchase technology certified under the ONC Health IT Certification Program. The commenter supported recommendations in the report for HHS to pursue financial incentives for post-acute care settings to adopt certified health information technology in order to enable health information exchange.

Response: We will take this comment into consideration as we coordinate with Federal partners, including ONC, on interoperability initiatives, and to inform future rulemaking.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33, enacted August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physicians' services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.*

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(c)(4) of the IMPACT Act amended section 1888(e)(6) of the Act, which requires the Secretary to implement a QRP for SNFs under which SNFs report data on measures and resident assessment data. Finally, section 111 of the Consolidated Appropriations Act, 2021 (CAA) updated section 1888(h) of the Act, authorizing the Secretary to apply up to nine additional measures to the VBP program for SNFs.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and (e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the Federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods

[4] Centers for Medicare & Medicaid Services. Newsroom. Fact sheet: CMS Data Element Library Fact Sheet. June 21, 2018. Available at *https://www.cms.gov/newsroom/fact-sheets/cms-data-element-library-fact-sheet.*

[5] Sections 4001 through 4008 of Public Law 114–255. Available at *https://www.govinfo.gov/content/pkg/PLAW-114publ255/html/PLAW-114publ255.htm.*

[6] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange (Jan. 2022). Available at *https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.*

[7] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022). Available at *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[8] The Common Agreement defines Individual Access Services (IAS) as ''with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.'' The Common Agreement defines ''IAS Provider'' as: ''Each QHIN, Participant, and Subparticipant that offers Individual Access Services.'' *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full Federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted Federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2022 (86 FR 42424, August 4, 2021).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** the following:

- The unadjusted Federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this final rule provides the required annual updates to the per diem payment rates for SNFs for FY 2023.

III. Analysis and Responses to Public Comments on the FY 2023 SNF PPS Proposed Rule

In response to the publication of the FY 2023 SNF PPS proposed rule, we received 6,970 public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2023 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the following, more general, observations on the SNF PPS and SNF care generally. A discussion of these comments, along with our responses, appears below.

Comment: Commenters submitted comments and recommendations that are outside the scope of the proposed rule addressing a number of different policies, including the Coronavirus disease 2019 (COVID–19) pandemic. This included comments on the flexibilities provided to SNFs during the PHE, specifically through the waivers issued under sections 1135 of the Act and coverage flexibility provided under section 1812(f) of the Act. Commenters also expressed concerns about the substantial additional costs due to the PHE that they were concerned would be permanent due to changes in patient care, infection control staff and equipment, personal protective equipment (PPE), reporting requirements, increased wages, increased food prices, and other necessary costs. Some commenters who received CARES Act Provider Relief funds indicated that those funds were not enough to cover these costs. Additionally, a few commenters from rural areas stated that their facilities were heavily impacted from the additional costs, particularly the need to raise wages, and that this could affect patients' access to care.

Response: Because these comments are outside the scope of the current rulemaking, we are not addressing them in this final rule. We may take them under consideration in future rulemaking.

Comment: We received a number of comments related to monitoring Medicare Advantage Organizations (MAOs). These commenters referred to a recent OIG report, which discussed how some MAOs have reportedly denied or delayed beneficiary access to SNF services. These commenters encouraged CMS to review the requirements and policies surrounding the payment and practices of MAOs.

Response: Because these comments are outside the scope of the current rulemaking, we are not addressing them in this final rule. We may take them under consideration in future rulemaking.

Comment: One commenter requested that we consider including recreational therapy time provided to SNF residents by recreational therapists as part of the calculation of the resident's RUG–IV therapy classification or as part of determining the number of restorative nursing services provided to the resident.

Response: We appreciate the commenter raising this issue, but we do not believe there is sufficient evidence at this time regarding the efficacy of recreational therapy interventions or, more notably, data which would substantiate a determination of the effect on payment of such interventions, as such services were not considered separately, as were physical, occupational and speech-language pathology services, when RUG–IV was being developed. That is, we note that Medicare Part A originally paid for institutional care in various provider settings, including SNF, on a reasonable cost basis, but now makes payment using PPS methodologies, such as the SNF PPS. To the extent that one of these SNFs furnished recreational therapy to its inpatients under the previous, reasonable cost methodology, the cost of the services would have been included in the base payments when SNF PPS payment rates were derived. Under the PPS methodology, Part A makes a comprehensive payment for the bundled package of items and services that the facility furnishes during the course of a Medicare-covered stay. This package encompasses nearly all services that the beneficiary receives during the course of the stay—including any medically necessary recreational therapy—and payment for such services is included within the facility's comprehensive SNF PPS payment for the covered Part A stay itself.

Comment: One commenter encouraged CMS to monitor the use of concurrent and group therapy under PDPM and identify any facilities that are consistently exceeding the established group and concurrent therapy limit. This commenter referred to reports by their members to disregard the established limit on these therapy modalities, as well as the impact of the PHE on the provision of group and concurrent therapy.

Response: We continue to monitor all aspects of payment and service provision under PDPM. Should we discover any outliers in the provision of group and concurrent therapy that consistently exceed the established limit on these therapy modalities, we will refer such outliers for administrative action.

IV. SNF PPS Rate Setting Methodology and FY 2023 Update

A. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem Federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the Federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the Federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to

the SNF PPS, would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case-mix. In compiling the database used to compute the Federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA 1997 prescribed, we set the Federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the Federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

B. SNF Market Basket Update

1. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we rebased and revised the market basket index, which included updating the base year from FY 2010 to 2014. In the SNF PPS final rule for FY 2022 (86 FR 42444 through 42463), we rebased and revised the market basket index, which included updating the base year from 2014 to 2018.

The SNF market basket index is used to compute the market basket percentage change that is used to update the SNF Federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section IV.B.4. of this final rule.

As outlined in the proposed rule, we proposed a FY 2023 SNF market basket percentage of 2.8 percent based on IHS Global Inc.'s (IGI's) fourth quarter 2021 forecast of the 2018-based SNF market basket (before application of the forecast error adjustment and productivity adjustment). We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket and/or the productivity adjustment), we would use such data, if appropriate, to determine the FY 2023 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or productivity adjustment in the SNF PPS final rule.

Since the proposed rule, we have updated the FY 2023 market basket percentage increase based on IGI's second quarter 2022 forecast with historical data through the first quarter of 2022. The FY 2023 growth rate of the 2018-based SNF market basket is estimated to be 3.9 percent.

In section IV.B.5. of this final rule, we discussed the 2 percent reduction applied to the market basket update for those SNFs that fail to submit measures data as required by section 1888(e)(6)(A) of the Act.

2. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the Federal rates outlined in this final rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2023. This factor is based on the FY 2023 percentage increase in the 2018-based SNF market basket index reflecting routine, ancillary, and capital-related expenses. As stated previously, in the proposed rule, the SNF market basket percentage update was estimated to be 2.8 percent for FY 2023 based on IGI's fourth quarter 2021 forecast. For this final rule, based on IGI's second quarter 2022 forecast with historical data through the first quarter of 2022, the FY 2023 growth rate of the 2018-based SNF market basket is estimated to be 3.9 percent.

3. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004 and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2021 (the most recently available FY for which there is final data), the forecasted or estimated increase in the SNF market basket index was 2.2 percent, and the actual increase for FY 2021 is 3.7 percent, resulting in the actual increase being 1.5 percentage point higher than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index exceeds the 0.5 percentage point threshold, under the policy previously described (comparing the forecasted and actual increase in the market basket), the FY 2023 market basket percentage change of 3.9 percent would be adjusted upward to account for the forecast error correction of 1.5 percentage point, resulting in a SNF market basket percentage change of 5.1 percent after reducing the market basket update by the productivity adjustment of 0.3 percentage point, discussed later in this section of the preamble.

Table 2 shows the forecasted and actual market basket increases for FY 2021.

TABLE 2: Difference Between the Actual and Forecasted Market Basket Increases for FY 2021

Index	Forecasted FY 2021 Increase*	Actual FY 2021 Increase**	FY 2021 Difference
SNF	2.2	3.7	1.5

*Published in **Federal Register**; based on second quarter 2020 IGI forecast (2014-based index).
** Based on the second quarter 2022 IGI forecast.

4. Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF payment system (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measure of productivity for the U.S. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned previously in this section, the data and methods are unchanged. We refer readers to the BLS website at *www.bls.gov* for the BLS historical published TFP data.

A complete description of the TFP projection methodology is available on our website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.* In addition, in the FY 2022 SNF final rule (86 FR 42429) we noted that, effective with FY 2022 and forward, we are changing the name of this adjustment to refer to it as the ''productivity adjustment,'' rather than the ''MFP adjustment.''

a. Incorporating the Productivity Adjustment Into the Market Basket Update

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the productivity adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act being less than such payment rates for the preceding fiscal year. Thus, if the application of the productivity adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in a productivity-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted Federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

Based on the data available for the FY 2023 SNF PPS proposed rule, the proposed productivity adjustment (the 10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending September 30, 2023) was projected to be 0.4 percentage point. However, for this final rule, based on IGI's second quarter 2022 forecast, the estimated 10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending September 30, 2023 is 0.3 percentage point.

Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), as discussed previously, the market basket percentage for FY 2023 for the SNF PPS is based on IGI's second quarter 2022 forecast of the SNF market basket percentage, which is estimated to be 3.9 percent. This market basket percentage is then increased by 1.5 percentage point, due to application of the forecast error adjustment discussed earlier in this section of the preamble. Finally, as discussed earlier in this section of the preamble, we are applying a 0.3 percentage point productivity adjustment to the FY 2023 SNF market basket percentage. The resulting productivity-adjusted FY 2023 SNF market basket update is, therefore, equal to 5.1 percent, or 3.9 percent plus 1.5 percentage point to account for forecast error and less 0.3 percentage point to account for the productivity adjustment.

5. Market Basket Update Factor for FY 2023

Sections 1888(e)(4)(E)(ii)(IV) and (e)(5)(i) of the Act require that the update factor used to establish the FY 2023 unadjusted Federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2021 through September 30, 2022 to the average market basket level for the period of October 1, 2022 through September 30, 2023. This process yields a percentage change in the 2018-based SNF market basket of 3.9 percent.

As further explained in section IV.B.3. of this final rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold in absolute terms. Since the actual FY 2021 SNF market basket percentage change exceeded the forecasted FY 2021 SNF market basket percentage change (FY 2021 is the most recently available FY for which there is historical data) by

more than the 0.5 percentage point threshold, we are adjusting the FY 2023 market basket percentage change upward by the forecast error correction. Applying the 1.5 percentage point forecast error correction results in an adjusted FY 2023 SNF market basket percentage change of 5.4 percent (3.9 percent market basket update plus 1.5 percentage point forecast error adjustment).

Section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the productivity adjustment (10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending September 30, 2023) which is estimated to be 0.3 percentage point, as described in section IV.B.4. of this final rule. Thus, we apply a net SNF market basket update factor of 5.1 percent in our determination of the FY 2023 SNF PPS unadjusted Federal per diem rates, which reflects a market basket increase factor of 3.9 percent, plus the 1.5 percentage point forecast error correction and less the 0.3 percentage point productivity adjustment.

As outlined in the proposed rule, we noted that if more recent data became available (for example, a more recent estimate of the SNF market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the FY 2023 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or productivity adjustment in the FY 2023 SNF PPS final rule. Since more recent data did become available since the proposed rule, as outlined above, we have updated the various adjustment factors described through this section accordingly.

We also noted that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the productivity adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket index percentage change being less than zero for a fiscal year, and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

A discussion of the public comments received on the FY 2023 SNF market basket percentage increase to the SNF PPS rates, along with our responses, may be found below.

Comment: One commenter supported and appreciated the proposed increase in Medicare rates as a result of the market basket and forecast error adjustment. Several commenters supported the increase and urged CMS to use the most recent economic data as it becomes available in finalizing the payment update to capture the significant cost increases and inflation being felt by the long-term care sector and across the economy. However, multiple commenters raised concerns about whether rising costs, and costs of labor, in particular, are being sufficiently accounted for in the SNF market basket. One commenter urged CMS to discuss in the final rule how the agency will account for these increased costs. One commenter shared that their State wage survey of nursing facilities, which is used to inform their Medicaid inflation adjustment each year, indicates a 14.8 percent increase in nursing compensation (a composite of employee and agency staff) from 2022 to 2023, along with non-nursing compensation growth of 7.3 percent.

Commenters were concerned that CMS' use of the historical Employment Cost Index (ECI) for Wages and Salaries for Private Industry Workers in Nursing Care Facilities to measure the price growth of wages and salaries may not be accurately capturing employment costs in nursing homes, or otherwise not in a timely manner. They stated that the quarterly updates of the price proxies do not address changes in staffing levels, changes in the occupational mix, increases in the use of contract labor or travel nurses, or other drivers of wage rate growth such as labor market tightness and consumer inflation.

One commenter calculated notable differences in Medicare Cost Report Direct Care Wage Data and the labor component of market basket updates, which they estimated to be about 6 percent between 1998 and 2021. The commenter suggested spreading an adjustment for this difference into the update equally over a 2 to 3-year period. In addition, they requested that CMS develop a methodology to account for rapidly escalating labor costs in a more timely fashion than the current price proxy calculation method captures. The commenter also noted faster growth of the BLS Current Employment Statistics (CES) average hourly earnings (AHE) series for Production and Non-Supervisory Nursing care facility employees (without seasonality adjustment), compared to the ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities.

One commenter requested that CMS provide a labor-related market basket price add-on due to workforce shortages and other challenges not addressed by the current market basket methodology.

Response: We recognize the challenges facing SNFs in operating during a high inflationary environment. Due to SNF payments under PPS being set prospectively, we rely on a projection of the SNF market basket that reflects both recent historical trends, as well as forecast expectations over the next roughly 18 months. The forecast error for a market basket update is calculated as the actual market basket increase for a given year, less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. We are confident that the forecast error adjustments built into the SNF market basket update factor will account for these discrepancies over time.

In the FY 2023 SNF PPS proposed rule, we proposed a 2018-based SNF market basket increase of 2.8 percent based on IGI's fourth quarter 2021 forecast with historical data through third quarter 2021. For this final rule, based on IGI's second quarter 2022 forecast with historical data through first quarter 2022 we are finalizing a 2018-based SNF market basket increase of 3.9 percent, which is the highest market basket update we have implemented in a final rule since the beginning of the SNF PPS. The 3.9-percent increase reflects forecasted compensation price growth of 4.2 percent (which is approximately 2 percentage points higher than the 10-year historical average price growth for compensation), reflecting increased wage pressures due to various economic and industry-specific factors. Additionally, the FY 2023 productivity-adjusted SNF market basket update of 3.6 percent (3.9 percent less 0.3 percentage point) will be increased by the FY 2021 forecast error adjustment of 1.5 percentage point for a total FY 2023 update of 5.1 percent (3.6 percent plus 1.5 percentage points). A forecast error

for FY 2022 cannot be calculated until historical data through third quarter 2022 are available; if there is a FY 2022 forecast error and a similar update approach is used for FY 2024, then a forecast error adjustment would be applied to the FY 2024 SNF PPS payment update.

Section 1888(e)(5)(A) of the Act states the Secretary shall establish a skilled nursing facility market basket index that reflects changes over time in the *prices* of an appropriate mix of goods and services included in covered skilled nursing facility services. The 2018-based SNF market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured. For the compensation cost weight in the 2018-based SNF market basket (which includes salaried and contract labor employees), we use the ECI for wages and salaries and benefits for nursing care facilities to proxy the price increase of SNF labor. The ECI (published by the BLS) measures the change in the hourly labor cost to employers, independent of the influence of employment shifts among occupations and industry categories. Therefore, we believe the ECI for nursing care facilities, which only reflects the price change associated with the labor used to provide SNF care and appropriately does not reflect other factors that might affect labor costs, is an appropriate measure to use in the SNF market basket.

We acknowledge the commenters' concerns regarding the ECI being based on 2012 occupational distribution. Our analysis of the 2021 BLS Occupational Employment Statistics data, the most recent data available (published at *https://www.bls.gov/oes/*), shows that the salary (estimated as the product of employment and average annual salary) distribution by occupation for skilled nursing care facilities (NAICS 6231) is similar to the BLS OES data for 2012. Specifically, we found that the healthcare occupational distribution among the major occupations—registered nurses (16 percent in 2021), licensed practical and vocational nurses (16 percent), nursing assistants (25 percent), and therapists (4 percent)—were notably similar between 2012 and 2021. Additionally, we found the split between healthcare (70 percent in 2021) and nonhealthcare (30 percent) salaries by occupation to be virtually unchanged.

We also recognize the commenters' concerns regarding the need for increased reliance on the use of contract labor and travel nurses due to the overall tightness in the labor market and the more specific labor constraints of healthcare staff in particular. The compensation cost weight of the SNF market basket includes expenses for wages and salaries, employee benefits, and contract labor, with the contract labor expenses apportioned to the Wages and Salaries and Employee Benefits cost category weights. We analyzed the 2020 Medicare Cost Report (MCR) data and found the Compensation cost weight decreased slightly from 60.2 percent in 2018 to 59.8 percent in 2020. This was due to a decrease in the Contract Labor cost weight from 7.5 percent in 2018 to 6.8 percent in 2020 offset by a 0.3 percentage point increase in employed wages and salaries and benefits combined. Our analysis found that while there was an increase in the contract nursing staff hours, there was an offsetting decrease in the use of contract therapy staff hours. We will continue to analyze the MCR data, including the 2021 data when available, and assess the appropriateness of rebasing and revising the SNF market basket. Any rebasing or revising of the SNF market basket, if deemed necessary, would be proposed in future rulemaking and subject to public comments.

Regarding commenters' request that CMS consider other methods and data sources to calculate the final rule market basket update by exercising administrative authority, we note that we did not propose to use other methods or data sources to calculate the final market basket update for FY 2023, and therefore, we are not finalizing such an approach for this final rule. Further, while the Secretary has the discretion under the statute to establish the methodology for determining the appropriate mix of goods and services that comprise the SNF market basket, the statute requires the SNF PPS payment rates to be annually updated by the SNF market basket percentage change. As discussed in section IV.B.1. of this final rule, the market basket used to update SNF PPS payments has been rebased and revised over the history of the SNF PPS to reflect more recent data on SNF cost structures, and we believe it continues to appropriately reflect SNF cost structures. Consistent with our proposal, we have used more recent data to calculate a final SNF market basket update of 5.1 percent for FY 2023. Additionally, MedPAC did a full analysis of payment adequacy for SNF providers in its March 2022 Report to Congress (*https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch7_SEC.pdf*) and determined that, even considering the cost increases that have occurred as a result of the PHE associated with the COVID–19 pandemic, payments to SNFs continue to be adequate.

Comment: One commenter recommended that CMS convene a technical expert panel to discuss a more long-range approach to collecting and imputing appropriate and timely data for market basket labor update calculations, in an attempt to encompass factors not captured by currently available price proxies.

Response: We are open to hearing from interested parties about any data or analyses available to achieve the shared goal of ensuring that the SNF market basket price proxies are technically appropriate. As required by statute, any proposed changes to improve and/or update the SNF market basket occur through the rulemaking process and interested parties have an opportunity to publicly comment and make recommendations regarding the appropriateness of proposed changes.

Comment: One commenter stated that CMS should update the SNF market basket more frequently than every 4 to 5 years. The commenter noted that the SNF market basket uses a 2018 base year to measure the labor vs. non-labor cost inputs of 2018, which was prior to the pandemic and related significant labor cost increases.

Response: We note that while there is no official schedule for updating the market baskets, we typically attempt to rebase a market basket every 4 to 5 years since we have found that the cost weights are relatively stable over time. As the commenter acknowledged, the SNF market basket was last rebased in the FY 2022 SNF final rule using 2018 Medicare cost reports (86 FR 42444 through 42463), the most recent year of complete data available at the time of the rebasing. As described in that final rule, the primary data source for the major cost weights (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceutical, Malpractice, Capital-related, and Home Office) for the 2018-based SNF market basket are the MCRs for freestanding SNFs (CMS Form 2540–10, OMB NO. 0938–0463). We also indicated in the FY 2022 SNF final rule that we planned to review the 2020 MCR data as soon as complete information was available, to ensure the market basket relative cost shares are still appropriate.

Our analysis of the MCR data for 2019 and 2020 showed little change in the reported cost weights with the exception of the Pharmaceuticals cost weight in 2020. The Pharmaceuticals cost weight (including the adjustment for Medicaid dual-eligible drug costs) decreased approximately one percentage point from 7.5 percent in 2018 to 6.4 percent in 2020. The decrease in the Pharmaceuticals cost weight is stemming from the estimated Part D drug costs per day for dual-eligible Medicare beneficiaries, which decreased in 2020 as a result of an increase in the proportion of generic drugs. More detail regarding this adjustment is described in the FY 2022 SNF PPS rule (86 FR 42447). The 2020 Medicare cost report data also indicates that the Compensation cost weight is slightly lower at 59.8 percent, compared to the 2018-based SNF market basket with 60.2 percent. MCR data for 2021 are incomplete at this time. Given that the changes to the Compensation cost weight for 2020 are minimal and it is unclear whether changes in the cost weights are temporary as a result of the PHE, we continue to believe it is premature at this time to use more recent MCR data to derive a rebased and revised SNF market basket. We will continue to monitor these data, and any necessary changes to the SNF market basket will be proposed in future rulemaking.

Comment: One commenter expressed concern about the proposed 0.4 percent reduction for productivity and asked CMS in the final rule to further elaborate on the specific productivity gains that are the basis for this proposed market basket offset. The commenter stated that the productivity adjustment contradicts their members' PHE experiences of actual losses in productivity during the pandemic.

Response: Section 1888(e)(5)(B)(ii) of the Act requires the application of a productivity adjustment to the SNF market basket update. As required by statute, the FY 2023 productivity adjustment is derived based on the 10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending FY 2023, which is currently projected to be 0.3 percent.

Comment: One commenter stated that they do not support the triggering of automatic forecast error adjustments. They expressed concern that automatic forecast corrections would, in some years, result in making payment increases on top of the statutory increases to the payment rates, despite the industry having sizeable average Medicare margins. The commenter also noted that eliminating the automatic adjustments would result in more stable updates and consistency across settings because CMS does not apply automatic forecast error adjustments to any other market baskets. They noted that although CMS is required by statute to update the payment rates each year by the estimated change in the market basket index, it is not required to make automatic forecast error corrections.

Response: When forecast error adjustments for the SNF market basket were introduced in the FY 2004 SNF PPS final rule (68 FR 46035), we indicated the goal was ''to pay the appropriate amount, to the correct provider, for the proper service, at the right time''. We note that since implementation, forecast errors have generally been relatively small and clustered near zero and that for FY 2008 and subsequent years, we increased the threshold at which adjustments are triggered from 0.25 to 0.5 percentage point. Our intent in raising the threshold was to distinguish typical statistical variances from more major unanticipated impacts, such as unforeseen disruptions of the economy (such as occurred during the recent PHE) or unexpected inflationary patterns (either at lower or higher than anticipated rates).

Comment: One commenter stated that the market basket update reflects the actual cost of delivering services and it should not be used to justify the severity of the parity adjustment.

Response: We are required to update SNF PPS payments annually by the market basket update as required under section 1888(e)(4)(E)(ii)(IV) and (e)(5)(B) of the Act, as amended by section 53111 of the BBA 2018. We refer readers to section VI.C for a full discussion of the need for and the implementation of the parity adjustment.

6. Unadjusted Federal Per Diem Rates for FY 2023

As discussed in the FY 2019 SNF PPS final rule (83 FR 39162), in FY 2020 we implemented a new case-mix classification system to classify SNF patients under the SNF PPS, the PDPM. As discussed in section V.B.1. of that final rule (83 FR 39189), under PDPM, the unadjusted Federal per diem rates are divided into six components, five of which are case-mix adjusted components (Physical Therapy (PT), Occupational Therapy (OT), Speech-Language Pathology (SLP), Nursing, and Non-Therapy Ancillaries (NTA)), and one of which is a non-case-mix component, as existed under the previous RUG–IV model. We proposed to use the SNF market basket, adjusted as described previously, to adjust each per diem component of the Federal rates forward to reflect the change in the average prices for FY 2023 from the average prices for FY 2022. We proposed to further adjust the rates by a wage index budget neutrality factor, described later in this section. Further, in the past, we used the revised Office of Management and Budget (OMB) delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS proposed and final rules, we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021.

Tables 3 and 4 reflect the updated unadjusted Federal rates for FY 2023, prior to adjustment for case-mix.

TABLE 3: FY 2023 Unadjusted Federal Rate Per Diem—URBAN

Rate Component	PT	OT	SLP	Nursing	NTA	Non-Case-Mix
Per Diem Amount	$66.06	$61.49	$24.66	$115.15	$86.88	$103.12

TABLE 4: FY 2023 Unadjusted Federal Rate Per Diem—RURAL

Rate Component	PT	OT	SLP	Nursing	NTA	Non-Case-Mix
Per Diem Amount	$75.30	$69.16	$31.07	$110.02	$83.00	$105.03

Commenters submitted the following comments related to the proposed unadjusted federal per diem rates for FY 2021. A discussion of these comments, along with our responses, appears below.

Comment: One commenter stated that the case mix adjusted rates shown in Tables 5 and 6 for PT, OT, SLP and nursing rates are higher in urban areas than rural areas and noted this may be driving inequities and labor shortages between rural and urban nursing homes.

Response: We disagree with the commenter's statement that the case-mix adjusted rates for the PT, OT and SLP components are higher in urban than rural areas as shown in Tables 5 and 6. Additionally, the Federal per diem rates were established separately for urban and rural areas using allowable costs from FY 1995 cost reports, and therefore, account for and reflect the relative costs differences between urban and rural facilities. We note that the SNF PPS payment rates are updated annually by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered SNF services and a portion of these rates are further adjusted by a wage index to reflect geographic variations in wages. We will continue to monitor our SNF payment policies to ensure they reflect as accurately as possible the current costs of care in the SNF setting.

Accordingly, after considering the comments received, for the reasons specified in this final rule and in the FY 2023 SNF PPS proposed rule, we are finalizing the unadjusted federal per diem rates set forth in Tables 3 and 4.

C. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the Federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the FY 2019 final rule (83 FR 39162, August 8, 2018), we finalized a new case-mix classification model, the PDPM, which took effect beginning October 1, 2019. The previous RUG–IV model classified most patients into a therapy payment group and primarily used the volume of therapy services provided to the patient as the basis for payment classification, thus creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs. PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs.

The PDPM uses clinical data from the MDS to assign case-mix classifiers to each patient that are then used to calculate a per diem payment under the SNF PPS, consistent with the provisions of section 1888(e)(4)(G)(i) of the Act. As discussed in section IV.A. of this final rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. As we have stated in prior rules, for an MDS to be considered valid for use in determining payment, the MDS assessment should be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.*

Under section 1888(e)(4)(H) of the Act, each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The FY 2023 payment rates set forth in this proposed rule reflect the use of the PDPM case-mix classification system from October 1, 2022, through September 30, 2023. The case-mix adjusted PDPM payment rates for FY 2023 are listed separately for urban and rural SNFs, in Tables 5 and 6 with corresponding case-mix values.

Given the differences between the previous RUG–IV model and PDPM in terms of patient classification and billing, it was important that the format of Tables 5 and 6 reflect these differences. More specifically, under both RUG–IV and PDPM, providers use a Health Insurance Prospective Payment System (HIPPS) code on a claim to bill for covered SNF services. Under RUG–IV, the HIPPS code included the three-character RUG–IV group into which the patient classified as well as a two-character assessment indicator code that represented the assessment used to generate this code. Under PDPM, while providers still use a HIPPS code, the characters in that code represent different things. For example, the first character represents the PT and OT group into which the patient classifies. If the patient is classified into the PT and OT group ''TA'', then the first character in the patient's HIPPS code would be an A. Similarly, if the patient is classified into the SLP group ''SB'', then the second character in the patient's HIPPS code would be a B. The third character represents the Nursing group into which the patient classifies. The fourth character represents the NTA group into which the patient classifies. Finally, the fifth character represents the assessment used to generate the HIPPS code.

Tables 5 and 6 reflect the PDPM's structure. Accordingly, Column 1 of Tables 5 and 6 represents the character in the HIPPS code associated with a given PDPM component. Columns 2 and 3 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant PT group. Columns 4 and 5 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant OT group. Columns 6 and 7 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant SLP group. Column 8 provides the nursing case-mix group (CMG) that is connected

with a given PDPM HIPPS character. For example, if the patient qualified for the nursing group CBC1, then the third character in the patient's HIPPS code would be a ''P.'' Columns 9 and 10 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant nursing group. Finally, columns 11 and 12 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant NTA group.

Tables 5 and 6 do not reflect adjustments which may be made to the SNF PPS rates as a result of the SNF VBP Program, discussed in section VII. of this final rule, or other adjustments, such as the variable per diem adjustment. Further, in the past, we used the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos, 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021.

As we noted in the FY 2022 SNF PPS final rule (86 FR 42434), we continue to monitor the impact of PDPM implementation on patient outcomes and program outlays. Because of this analysis, in section V.C. of the proposed rule, we proposed to recalibrate the PDPM parity adjustment discussed in the FY 2020 SNF PPS final rule (84 FR 38734). Following the methodology of this proposed change, Tables 5 and 6 incorporate the recalibration of the PDPM parity adjustment.

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TABLE 5: PDPM Case-Mix Adjusted Federal Rates and Associated Indexes—URBAN (Including the Parity Adjustment Recalibration)

PDPM Group	PT CMI	PT Rate	OT CMI	OT Rate	SLP CMI	SLP Rate	Nursing CMG	Nursing CMI	Nursing Rate	NTA CMI	NTA Rate
A	1.49	$98.43	1.45	$89.16	0.66	$16.28	ES3	3.95	$454.84	3.15	$273.67
B	1.65	$109.00	1.59	$97.77	1.77	$43.65	ES2	2.99	$344.30	2.46	$213.72
C	1.83	$120.89	1.64	$100.84	2.60	$64.12	ES1	2.85	$328.18	1.79	$155.52
D	1.87	$123.53	1.49	$91.62	1.42	$35.02	HDE2	2.33	$268.30	1.29	$112.08
E	1.38	$91.16	1.37	$84.24	2.28	$56.22	HDE1	1.94	$223.39	0.93	$80.80
F	1.57	$103.71	1.56	$95.92	2.90	$71.51	HBC2	2.18	$251.03	0.70	$60.82
G	1.62	$107.02	1.60	$98.38	1.98	$48.83	HBC1	1.81	$208.42	-	-
H	1.13	$74.65	1.12	$68.87	2.78	$68.55	LDE2	2.02	$232.60	-	-
I	1.10	$72.67	1.15	$70.71	3.43	$84.58	LDE1	1.68	$193.45	-	-
J	1.38	$91.16	1.41	$86.70	2.91	$71.76	LBC2	1.67	$192.30	-	-
K	1.48	$97.77	1.50	$92.24	3.60	$88.78	LBC1	1.39	$160.06	-	-
L	1.06	$70.02	1.08	$66.41	4.10	$101.11	CDE2	1.82	$209.57	-	-
M	1.24	$81.91	1.26	$77.48	-	-	CDE1	1.58	$181.94	-	-
N	1.44	$95.13	1.46	$89.78	-	-	CBC2	1.51	$173.88	-	-
O	1.51	$99.75	1.51	$92.85	-	-	CA2	1.06	$122.06	-	-
P	1.05	$69.36	1.06	$65.18	-	-	CBC1	1.30	$149.70	-	-
Q	-	-	-	-	-	-	CA1	0.91	$104.79	-	-
R	-	-	-	-	-	-	BAB2	1.01	$116.30	-	-
S	-	-	-	-	-	-	BAB1	0.96	$110.54	-	-
T	-	-	-	-	-	-	PDE2	1.53	$176.18	-	-
U	-	-	-	-	-	-	PDE1	1.43	$164.66	-	-
V	-	-	-	-	-	-	PBC2	1.19	$137.03	-	-
W	-	-	-	-	-	-	PA2	0.69	$79.45	-	-
X	-	-	-	-	-	-	PBC1	1.10	$126.67	-	-
Y	-	-	-	-	-	-	PA1	0.64	$73.70	-	-

TABLE 6: PDPM Case-Mix Adjusted Federal Rates and Associated Indexes—RURAL (Including the Parity Adjustment Recalibration)

PDPM Group	PT CMI	PT Rate	OT CMI	OT Rate	SLP CMI	SLP Rate	Nursing CMG	Nursing CMI	Nursing Rate	NTA CMI	NTA Rate
A	1.49	$112.20	1.45	$100.28	0.66	$20.51	ES3	3.95	$434.58	3.15	$261.45
B	1.65	$124.25	1.59	$109.96	1.77	$54.99	ES2	2.99	$328.96	2.46	$204.18
C	1.83	$137.80	1.64	$113.42	2.60	$80.78	ES1	2.85	$313.56	1.79	$148.57
D	1.87	$140.81	1.49	$103.05	1.42	$44.12	HDE2	2.33	$256.35	1.29	$107.07
E	1.38	$103.91	1.37	$94.75	2.28	$70.84	HDE1	1.94	$213.44	0.93	$77.19
F	1.57	$118.22	1.56	$107.89	2.90	$90.10	HBC2	2.18	$239.84	0.70	$58.10
G	1.62	$121.99	1.60	$110.66	1.98	$61.52	HBC1	1.81	$199.14	-	-
H	1.13	$85.09	1.12	$77.46	2.78	$86.37	LDE2	2.02	$222.24	-	-
I	1.10	$82.83	1.15	$79.53	3.43	$106.57	LDE1	1.68	$184.83	-	-
J	1.38	$103.91	1.41	$97.52	2.91	$90.41	LBC2	1.67	$183.73	-	-
K	1.48	$111.44	1.50	$103.74	3.60	$111.85	LBC1	1.39	$152.93	-	-
L	1.06	$79.82	1.08	$74.69	4.10	$127.39	CDE2	1.82	$200.24	-	-
M	1.24	$93.37	1.26	$87.14	-	-	CDE1	1.58	$173.83	-	-
N	1.44	$108.43	1.46	$100.97	-	-	CBC2	1.51	$166.13	-	-
O	1.51	$113.70	1.51	$104.43	-	-	CA2	1.06	$116.62	-	-
P	1.05	$79.07	1.06	$73.31	-	-	CBC1	1.30	$143.03	-	-
Q	-	-	-	-	-	-	CA1	0.91	$100.12	-	-
R	-	-	-	-	-	-	BAB2	1.01	$111.12	-	-
S	-	-	-	-	-	-	BAB1	0.96	$105.62	-	-
T	-	-	-	-	-	-	PDE2	1.53	$168.33	-	-
U	-	-	-	-	-	-	PDE1	1.43	$157.33	-	-
V	-	-	-	-	-	-	PBC2	1.19	$130.92	-	-
W	-	-	-	-	-	-	PA2	0.69	$75.91	-	-
X	-	-	-	-	-	-	PBC1	1.10	$121.02	-	-
Y	-	-	-	-	-	-	PA1	0.64	$70.41	-	-

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D. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the Federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We proposed to continue this practice for FY 2023, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data under the inpatient prospective payment system (IPPS) also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. As in previous years, we would continue to use the pre-reclassified IPPS hospital wage data, without applying the occupational mix, rural floor, or outmigration adjustment, as the basis for the SNF PPS wage index. For FY 2023, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2018 and before October 1, 2019 (FY 2019 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of the data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. In addition, adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS, given that there are nearly five times as many SNFs as there are inpatient hospitals. While we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not believe this undertaking is feasible at this time. Therefore, as discussed in the proposed rule, in the absence of a SNF-specific wage index, we believe the use of the pre-reclassified and pre-floor hospital wage data (without the occupational mix adjustment) continue to be an appropriate and reasonable proxy for the SNF PPS.

In addition, we proposed to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2022 SNF PPS wage index. For rural geographic areas that do not have hospitals and, therefore, lack hospital wage data on which to base an area wage adjustment, we proposed to continue using the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2023, there are no rural geographic areas that do not have hospitals, and thus, this methodology will not be applied. For rural Puerto Rico, we proposed not to apply this methodology due to the distinct economic circumstances there (for example, due to the close proximity of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we would continue using the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we proposed that we would use the average wage indexes of all urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2023, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA.

The wage index applicable to FY 2023 is set forth in Tables A and B available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), after the expiration of this 1-year transition on September 30, 2006, we used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided minor updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013 and were adopted under the SNF PPS in the FY 2017 SNF PPS final rule (81 FR 51983, August 5, 2016). In addition, on August 15, 2017, OMB issued Bulletin No. 17–01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300) which was adopted in the SNF PPS final rule for FY 2019 (83 FR 39173, August 8, 2018).

As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) beginning October 1, 2020, including a 1-year transition for FY 2021 under which we applied a 5 percent cap on any decrease in a hospital's wage index compared to its wage index for the prior fiscal year (FY 2020). The updated OMB delineations more accurately reflect the contemporary urban and rural nature of areas across the country, and the use of such delineations allows us to determine more accurately the appropriate wage index and rate tables to apply under the SNF PPS. For FY 2023 and subsequent years, we proposed to apply a permanent 5 percent cap on any decreases to a provider's wage index from its wage index in the prior year, regardless of the circumstances causing the decline, which was further discussed in section V.A. of the proposed rule.

As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index. We note that on March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the updates (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In the FY 2021 SNF PPS final rule (85 FR 47611), we stated that we intended to propose any updates from OMB Bulletin No. 20–01 in the FY 2022 SNF PPS proposed rule. After reviewing OMB Bulletin No. 20–01, we have determined that the changes in OMB Bulletin 20–01 encompassed delineation changes that do not impact the CBSA-based labor market area delineations adopted in FY 2021. Therefore, while we proposed to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we noted that specific wage index updates would not be necessary for FY 2022 as a result of adopting these OMB updates and for these reasons we did not make such a proposal for FY 2023.

The wage index applicable to FY 2023 is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Once calculated, we would apply the wage index adjustment to the labor-related portion of the Federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and

Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. Effective beginning FY 2022 (86 FR 42437), we rebased and revised the labor-related share to reflect the relative importance of the 2018-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. The methodology for calculating the labor-related portion beginning in FY 2022 is discussed in detail in the FY 2022 SNF PPS final rule (86 FR 42424).

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2023. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2023 than the base year weights from the SNF market basket. We calculate the labor-related relative importance for FY 2023 in four steps. First, we compute the FY 2023 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2023 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2023 relative importance for each cost category by multiplying this ratio by the base year (2018) weight. Finally, we add the FY 2023 relative importance for each of the labor-related cost categories (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of Capital-Related expenses) to produce the FY 2023 labor-related relative importance.

For the proposed rule, the labor-related share for FY 2023 was based on IGI's fourth quarter 2021 forecast of the 2018-based SNF market basket with historical data through third quarter 2021. As outlined in the proposed rule, we noted that if more recent data became available (for example, a more recent estimate of the labor-related share relative importance) we would use such data if appropriate for the SNF final rule. For this final rule, we base the labor-related share for FY 2023 on IGI's second quarter 2022 forecast, with historical data through the first quarter 2022. Table 7 summarizes the labor-related share for FY 2023, based on IGI's second quarter 2022 forecast of the 2018-based SNF market basket, compared to the labor-related share that was used for the FY 2022 SNF PPS final rule.

TABLE 7: Labor-Related Share, FY 2022 and FY 2023

	Relative importance, labor-related share, FY 2022 21:2 forecast[1]	Relative importance, labor-related share, FY 2023 22:2 forecast[2]
Wages and salaries	51.4	51.9
Employee benefits	9.5	9.5
Professional fees: Labor-related	3.5	3.5
Administrative & facilities support services	0.6	0.6
Installation, maintenance & repair services	0.4	0.4
All other: Labor-related services	2.0	2.0
Capital-related (.391)	3.0	2.9
Total	70.4	70.8

1. Published in the **Federal Register**; Based on the second quarter 2021 IHS Global Inc. forecast of the 2018-based SNF market basket.

2. Based on the second quarter 2022 IHS Global Inc. forecast of the 2018-based SNF market basket.

To calculate the labor portion of the case-mix adjusted per diem rate, we would multiply the total case-mix adjusted per diem rate, which is the sum of all five case-mix adjusted components into which a patient classifies, and the non-case-mix component rate, by the FY 2023 labor-related share percentage provided in Table 7. The remaining portion of the rate would be the non-labor portion. Under the previous RUG–IV model, we included tables which provided the case-mix adjusted RUG–IV rates, by RUG–IV group, broken out by total rate, labor portion and non-labor portion, such as Table 9 of the FY 2019 SNF PPS final rule (83 FR 39175). However, as we discussed in the FY 2020 final rule (84 FR 38738), under PDPM, as the total rate is calculated as a combination of six different component rates, five of which are case-mix adjusted, and given the sheer volume of possible combinations of these five case-mix adjusted components, it is not feasible to provide tables similar to those that existed in the prior rulemaking.

Therefore, to aid interested parties in understanding the effect of the wage index on the calculation of the SNF per diem rate, we have included a hypothetical rate calculation in Table 9.

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2023 (Federal rates effective October 1, 2022), we apply an adjustment to fulfill the budget neutrality requirement. We meet this requirement by multiplying each of the components of the

unadjusted Federal rates by a budget neutrality factor, equal to the ratio of the weighted average wage adjustment factor for FY 2022 to the weighted average wage adjustment factor for FY 2023. For this calculation, we would use the same FY 2021 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor portion of the rate component multiplied by the wage index plus the non-labor portion of the rate component. The proposed budget neutrality factor for FY 2023 set forth in the proposed rule was 1.0011.

We noted that if more recent data became available (for example, revised wage data), we would use such data, as appropriate, to determine the wage index budget neutrality factor in the SNF PPS final rule. Since the proposed rule, we have updated the wage adjustment factor for FY 2023. Based on this updated information, the budget neutrality factor for FY 2023 is 1.0005.

The following is a summary of the public comments we received on the proposed revisions to the Wage Index Adjustment and our responses.

Comment: Several commenters recommended that CMS develop a SNF-specific wage index utilizing SNF wage data rather than relying on hospital wage data. Most of these commenters recommended CMS utilize BLS data, while one commenter recommended CMS focus on Payroll-Based Journaling (PBJ) data.

Response: We appreciate the commenters' suggestion that we develop a SNF-specific wage index utilizing SNF wage data instead of hospital wage data while considering the use of BLS and PBJ data. We note that, consistent with the discussion published most recently in the FY 2021 SNF PPS final rule (86 FR 42436 through 42439), and in further detail in the FY 2019 SNF PPS final rule (83 FR 39172 through 39178) to these recurring comments, developing such a wage index would require a resource-intensive audit process similar to that used for IPPS hospital data, to improve the quality of the SNF cost report data in order for it to be used as part of this analysis. We also discussed in the FY 2019 SNF PPS why utilizing concepts such as BLS data and PBJ are unfeasible or not applicable to SNF policy.

We continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified, pre-rural floor hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS.

Comment: Several comments suggested that CMS revise the SNF wage index to adopt the same geographic reclassification and rural floor polices that are used to adjust the IPPS wage index.

Response: We note that until the development of a SNF-specific wage index, the SNF PPS does not account for geographic reclassification under section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted December 21, 2000).

With regard to implementing a rural floor under the SNF PPS, we do not believe it would be prudent at this time to adopt such a policy, particularly because MedPAC has repeatedly recommended eliminating the rural floor policy from the calculation of the IPPS wage index. For example, Chapter 3 of MedPAC's March 2013 Report to Congress on Medicare Payment Policy, available at *http://www.medpac.gov/docs/default-source/reports/mar13_ch03.pdf,* notes on page 65 that, in 2007, MedPAC had recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies (Medicare Payment Advisory Commission 2007b)). If we adopted the rural floor policy at this time, the SNF PPS wage index could become vulnerable to problems similar to those MedPAC identified in its March 2013 Report to Congress.

Furthermore, as we do not have an SNF-specific wage index, we are unable to determine the degree, if any, to which a geographic reclassification adjustment or a rural floor policy under the SNF PPS would be appropriate. The rationale for our current wage index policies was most recently published in the FY 2022 SNF PPS final rule (86 FR 42436) and previously described in the FY 2016 SNF PPS final rule (80 FR 45401 through 46402).

After consideration of public comments, we are finalizing our proposal to continue to use the updated pre-reclassification and pre-floor IPPS wage index data to develop the FY 2023 SNF PPS wage index.

E. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we finalized in the FY 2019 SNF PPS final rule the addition of § 413.337(f) to our regulations (83 FR 39178).

Please see section VIII. of this final rule for further discussion of our policies for the SNF VBP Program.

F. Adjusted Rate Computation Example

Tables 8 through 10 provide examples generally illustrating payment calculations during FY 2023 under PDPM for a hypothetical 30-day SNF stay, involving the hypothetical SNF XYZ, located in Frederick, MD (Urban CBSA 23224), for a hypothetical patient who is classified into such groups that the patient's HIPPS code is NHNC1. Table 8 shows the adjustments made to the Federal per diem rates (prior to application of any adjustments under the SNF VBP Program as discussed previously and taking into account the proposed parity adjustment discussed in section VI.C. of this final rule) to compute the provider's case-mix adjusted per diem rate for FY 2023, based on the patient's PDPM classification, as well as how the variable per diem (VPD) adjustment factor affects calculation of the per diem rate for a given day of the stay. Table 9 shows the adjustments made to the case-mix adjusted per diem rate from Table 8 to account for the provider's wage index. The wage index used in this example is based on the FY 2023 SNF PPS wage index that appears in Table A available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.* Finally, Table 10 provides the case-mix and wage index adjusted per-diem rate for this patient for each day of the 30-day stay, as well as the total payment for this stay. Table 10 also includes the VPD adjustment factors for each day of the patient's stay, to clarify why the patient's per diem rate changes for certain days of the stay. As illustrated in Table 8, SNF XYZ's total PPS payment for this particular patient's stay would equal $20,821.69.

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TABLE 8: PDPM Case-Mix Adjusted Rate Computation Example

Per Diem Rate Calculation				
Component	**Component Group**	**Component Rate**	**VPD Adjustment Factor**	**VPD Adj. Rate**
PT	N	$95.13	1.00	$95.13
OT	N	$89.78	1.00	$89.78
SLP	H	$68.55	1.00	$68.55
Nursing	N	$173.88	1.00	$173.88
NTA	C	$155.52	3.00	$466.56
Non-Case-Mix	-	$103.12	-	$103.12
Total PDPM Case-Mix Adj. Per Diem				$997.02

TABLE 9: Wage Index Adjusted Rate Computation Example

PDPM Wage Index Adjustment Calculation						
HIPPS Code	**PDPM Case-Mix Adjusted Per Diem**	**Labor Portion**	**Wage Index**	**Wage Index Adjusted Rate**	**Non-Labor Portion**	**Total Case Mix and Wage Index Adj. Rate**
NHNC1	$997.02	$705.89	0.9577	$676.03	$291.13	$967.16

TABLE 10: Adjusted Rate Computation Example

Day of Stay	NTA VPD Adjustment Factor	PT/OT VPD Adjustment Factor	Case Mix and Wage Index Adjusted Per Diem Rate
1	3.0	1.0	$967.16
2	3.0	1.0	$967.16
3	3.0	1.0	$967.16
4	1.0	1.0	$665.44
5	1.0	1.0	$665.44
6	1.0	1.0	$665.44
7	1.0	1.0	$665.44
8	1.0	1.0	$665.44
9	1.0	1.0	$665.44
10	1.0	1.0	$665.44
11	1.0	1.0	$665.44
12	1.0	1.0	$665.44
13	1.0	1.0	$665.44
14	1.0	1.0	$665.44
15	1.0	1.0	$665.44
16	1.0	1.0	$665.44
17	1.0	1.0	$665.44
18	1.0	1.0	$665.44
19	1.0	1.0	$665.44
20	1.0	1.0	$665.44
21	1.0	0.98	$661.85
22	1.0	0.98	$661.85
23	1.0	0.98	$661.85
24	1.0	0.98	$661.85
25	1.0	0.98	$661.85
26	1.0	0.98	$661.85
27	1.0	0.98	$661.85
28	1.0	0.96	$658.26
29	1.0	0.96	$658.26
30	1.0	0.96	$658.26
Total Payment			$20,821.69

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V. Additional Aspects of the SNF PPS

A. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section IV.C. of this final rule. This approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the SNF stay, of one of the case-mix classifiers designated for this purpose to assist in making certain SNF level of care determinations.

In accordance with § 413.345, we include in each update of the Federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. We also designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in 42 CFR 409.30. This designation reflects an administrative presumption that those beneficiaries who are correctly assigned one of the designated case-mix classifiers on the initial Medicare assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) for that assessment.

A beneficiary who does not qualify for the presumption is not automatically classified as either meeting or not meeting the level of care definition, but instead receives an individual determination on this point using the existing administrative criteria. This presumption recognizes the strong likelihood that those beneficiaries who are correctly assigned one of the designated case-mix classifiers during the immediate post-hospital period would require a covered level of care, which would be less likely for other beneficiaries.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/*

index.html (where such designations appear in the paragraph entitled ''Case Mix Adjustment''), and would publish such designations in rulemaking only to the extent that we actually intend to propose changes in them. Under that approach, the set of case-mix classifiers designated for this purpose under PDPM was finalized in the FY 2019 SNF PPS final rule (83 FR 39253) and is posted on the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*), in the paragraph entitled ''Case Mix Adjustment.''

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that any services prompting the assignment of one of the designated case-mix classifiers (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations where the sole classifier that triggers the presumption is itself assigned through the receipt of services that are subsequently determined to be not reasonable and necessary. Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the initial Medicare assessment.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.* In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA 1999) (Pub. L. 106–113, enacted November 29, 1999) amended section 1888(e)(2)(A)(iii) of the Act by further excluding a number of individual high-cost, low probability services, identified by HCPCS codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA 1999 amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf.*

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA 1999 not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of these four specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA 1999 Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA 1999 is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, the amendments enacted in section 103 of the BBRA 1999 do not designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as is consistent with our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA 1999: they must fall within one of the four service categories specified in the BBRA 1999; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA 1999 Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791).

Effective with items and services furnished on or after October 1, 2021, section 134 in Division CC of the CAA established an additional category of excluded codes in section 1888(e)(2)(A)(iii)(VI) of the Act, for certain blood clotting factors for the treatment of patients with hemophilia and other bleeding disorders along with items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act. Like the provisions enacted in the BBRA 1999, new section 1888(e)(2)(A)(iii)(VI) of the Act gives the Secretary the authority to designate additional items and services for exclusion within the category of items and services described in that section.

In the proposed rule, we specifically solicited public comments identifying HCPCS codes in any of these five service categories (chemotherapy items, chemotherapy administration services, radioisotope services, customized prosthetic devices, and blood clotting factors) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. In the proposed rule, we noted that we may consider excluding a particular service if it meets our criteria for exclusion as specified previously. We requested that commenters identify in their comments the specific HCPCS code that is associated with the service

in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

In the proposed rule, we noted that the original BBRA amendment and the CAA identified a set of excluded items and services by means of specifying individual HCPCS codes within the designated categories that were in effect as of a particular date (in the case of the BBRA 1999, July 1, 1999, and in the case of the CAA, July 1, 2020), as subsequently modified by the Secretary. In addition, as noted in this section of the preamble, the statute (sections 1888(e)(2)(A)(iii)(II) through (VI) of the Act) gives the Secretary authority to identify additional items and services for exclusion within the categories of items and services described in the statute, which are also designated by HCPCS code. Designating the excluded services in this manner makes it possible for us to utilize program issuances as the vehicle for accomplishing routine updates to the excluded codes to reflect any minor revisions that might subsequently occur in the coding system itself, such as the assignment of a different code number to a service already designated as excluded, or the creation of a new code for a type of service that falls within one of the established exclusion categories and meets our criteria for exclusion.

Accordingly, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, October 1, 2022). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions. The latest list of excluded codes can be found on the SNF Consolidated Billing website at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling.*

The following is a summary of the public comments we received on the proposed revisions to Consolidated Billing and our responses.

Comment: One commenter stated that consolidated billing exclusions remain inadequate and should be revised. The commenter stated that there continue to be outlier drug costs that need to be considered for exclusion from consolidated billing. The commenter stated that certain classes of drugs considered ''Specialty'' drugs are the largest exposure items for SNFs and need to be evaluated by CMS. The commenter further stated that many pharmaceutical therapies in use today were not in existence at the time that consolidated billing PPDs were created. Therefore, they cannot be considered ''included'' within the Medicare A FFS rate.

Response: As we noted in the proposed rule, sections 1888(e)(2)(A)(iii)(II) through (VI) of the Act give the Secretary authority to identify additional items and services for exclusion only within the categories of items and services described in the statute. Accordingly, it is beyond the statutory authority of CMS to exclude services that do not fit these categories, or to create additional categories of excluded services. Such changes would require Congressional action.

Comment: A commenter requested that CMS to consider agents that have evolving indications for use for different malignancies. In particular, the commenter requested consideration for both Leuprolide Acetate (HCPCS J9217) as well as Denosumab (HCPCS J0897) which previously was indicated as an osteoporosis medication but now has broader uses. The commenter also requested continued consideration of covering expensive antibiotics in Skilled Nursing Facilities as part of a Part A covered stay. The commenter stated that use of antibiotics such as ceftolozane 50 mg and tazobactam 25 mg (HCPCS J0695) are prohibitively expensive for facilities to cover outside of SNF consolidated billing and limit beneficiaries' abilities to access these skilled rehab services.

Response: For the reasons discussed previously in prior rulemaking, the particular drugs cited in these comments remain subject to consolidated billing. In the case of leuprolide acetate, we have addressed this when suggested in past rulemaking cycles, most recently in the SNF PPS final rules for FY 2019 (83 FR 39162, August 8, 2018) and FY 2015 (79 FR 45642, August 5, 2014). In those rules, we explained that this drug is unlikely to meet the criterion of ''low probability'' specified in the BBRA. With regard to denosumab, it would similarly be unlikely to meet the criterion of ''low probability.'' One of the indications for treatment is for bone metastases from solid tumors such as bone or prostate cancer. This can occur in up to 70 to 90 percent of patients with breast or prostate cancer.

With regard to the suggestion that CMS should exclude antibiotics, we note again that it is beyond the statutory authority of CMS to exclude services that do not fit the categories for exclusion defined by statute, or to create additional categories of excluded services. Such changes would require Congressional action.

C. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, SNF-level services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this final rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. As discussed in the FY 2019 SNF PPS final rule (83 FR 39235), revisions were made to the swing bed assessment to support implementation of PDPM, effective October 1, 2019. A discussion of the assessment schedule and the MDS effective beginning FY 2020 appears in the FY 2019 SNF PPS final rule (83 FR 39229 through 39237). The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html.*

D. Revisions to the Regulation Text

We proposed to make certain revisions in the regulation text itself. Specifically, we proposed to revise § 413.337(b)(4) and add new paragraphs (b)(4)(i) through (iii). These proposed revisions reflect that the application of the wage index would be made on the basis of the location of the facility in an urban or rural area as defined in § 413.333, and that starting on October 1, 2022, we would apply a cap on decreases to the wage index such that

the wage index applied to a SNF is not less than 95 percent of the wage index applied to that SNF in the prior FY, as discussed in section VI.A. of this final rule.

We did not receive public comments specific to the proposed revisions to the regulation text, and therefore, we are finalizing as proposed. We discuss comments received on the wage index cap policy itself in section VI.A. of this final rule.

VI. Other SNF PPS Issues

A. Permanent Cap on Wage Index Decreases

As outlined in section III.D. of the proposed rule, we proposed and finalized temporary transition policies in the past to mitigate significant changes to payments due to changes to the SNF PPS wage index. Specifically, for FY 2015 (79 FR 45644 through 45646), we implemented a 50/50 blend for all geographic areas consisting of the wage index values computed using the then-current OMB area delineations and the wage index values computed using new area delineations based on OMB Bulletin No. 13–01. In FY 2021 (85 FR 47594, 47617), we implemented a 1-year transition to mitigate any negative effects of wage index changes by applying a 5 percent cap on any decrease in a SNF's wage index from the final wage index from FY 2020. We explained that we believed the 5-percent cap would provide greater transparency and would be administratively less complex than the prior methodology of applying a 50/50 blended wage index. We indicated that no cap would be applied to the reduction in the wage index for FY 2022, and we noted that this transition approach struck an appropriate balance by providing a transition period to mitigate the resulting short-term instability and negative impacts on providers and time for them to adjust to their new labor market area delineations and wage index values.

In the FY 2022 final rule (86 FR 42424, 42439), commenters recommended that CMS extend the transition period adopted in the FY 2021 SNF PPS final rule so that SNFs could offset the cuts scheduled for FY 2022. Although, we acknowledged that certain changes to wage index policy could affect Medicare payment. In addition, we reiterated that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios around SNF payment volatility, in notice and comment rulemaking. We did not propose to modify the transition policy that was finalized in the FY 2021 SNF PPS final rule, and therefore, did not extend the transition period for FY 2022. With these policy principles in mind for this FY 2023 proposed rule, we considered how best to address commenters' concerns discussed in the FY 2022 final rule around SNF payment volatility; that is, scenarios in which changes to wage index policy may significantly affect Medicare payments.

In the past, we have established transition policies of limited duration to phase in significant changes to labor market. In taking this approach in the past, we have sought to strike an appropriate balance between maintaining the accuracy of the overall labor market area wage index system and mitigating short-term instability and negative impacts on providers due to wage index changes. In accordance with the requirements of the SNF PPS wage index regulations at § 413.337(a)(1), we use an appropriate wage index based on the best available data, including the best available labor market area delineations, to adjust SNF PPS payments for wage differences. We have previously stated that, because the wage index is a relative measure of the value of labor in prescribed labor market areas, we believe it is important to implement new labor market area delineations with as minimal a transition as is reasonably possible. However, we recognize that changes to the wage index have the potential to create instability and significant negative impacts on certain providers even when labor market areas do not change. In addition, year-to-year fluctuations in an area's wage index can occur due to external factors beyond a provider's control, such as the COVID–19 public health emergency (PHE). For an individual provider, these fluctuations can be difficult to predict. So, we also recognize that predictability in Medicare payments is important to enable providers to budget and plan their operations.

In light of these considerations, we proposed a permanent approach to smooth year-to-year changes in providers' wage indexes. We proposed a policy that we believe increases the predictability of SNF PPS payments for providers, and mitigates instability and significant negative impacts to providers resulting from changes to the wage index.

As previously discussed, we believed applying a 5-percent cap on wage index decreases for FY 2021 provided greater transparency and was administratively less complex than prior transition methodologies. In addition, we believed this methodology mitigated short-term instability and fluctuations that can negatively impact providers due to wage index changes. Lastly, we have noted that we believed the 5-percent cap we applied to all wage index decreases for FY 2021 provided an adequate safeguard against significant payment reductions related to the adoption of the revised CBSAs. However, we recognize there are circumstances that a 1-year mitigation policy, like the one adopted for FY 2021, would not effectively address future years where providers continue to be negatively affected by significant wage index decreases.

Typical year-to-year variation in the SNF PPS wage index has historically been within 5 percent, and we expect this will continue to be the case in future years. For FY 2023, the provider level impact analysis indicates that approximately 97 percent of SNFs will experience a wage index change within 5 percent. Because providers are usually experienced with this level of wage index fluctuation, we believe applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability in SNF PPS payments due to any significant wage index decreases that may affect providers in any year. We believe this approach would address concerns about instability that commenters raised in the FY 2022 SNF PPS rule. Additionally, as noted in the proposed rule, we believe that applying a 5-percent cap on all wage index decreases would support increased predictability about SNF PPS payments for providers, enabling them to more effectively budget and plan their operations. Lastly, because applying a 5-percent cap on all wage index decreases would represent a small overall impact on the labor market area wage index system we believe it would ensure the wage index is a relative measure of the value of labor in prescribed labor market wage areas. As outlined in detail in section XI.A.4. of the proposed rule, we estimated that applying a 5-percent cap on all wage index decreases will have a very small effect on the wage index budget neutrality factor for FY 2023. Because the wage index is a measure of the value of labor (wage and wage-related costs) in a prescribed labor market area relative to the national average, we anticipate that in the absence of proposed policy changes most providers will not experience year-to-year wage index

declines greater than 5 percent in any given year. As noted in the proposed rule, we also believe that when the 5-percent cap would be applied under this proposal, it is likely that it would be applied similarly to all SNFs in the same labor market area, as the hospital average hourly wage data in the CBSA (and any relative decreases compared to the national average hourly wage) would be similar. While this policy may result in SNFs in a CBSA receiving a higher wage index than others in the same area (such as situations when delineations change), we believe the impact would be temporary. Therefore, we anticipate that the impact to the wage index budget neutrality factor in future years would continue to be minimal.

The Secretary has broad authority to establish appropriate payment adjustments under the SNF PPS, including the wage index adjustment. As discussed earlier in this section, the SNF PPS regulations require us to use an appropriate wage index based on the best available data. For the reasons discussed earlier in this section, we believe that a 5-percent cap on wage index decreases would be appropriate for the SNF PPS. Therefore, for FY 2023 and subsequent years, we proposed to apply a permanent 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we proposed that SNF's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, regardless of whether the SNF is part of an updated CBSA, and that for subsequent years, a provider's wage index would not be less than 95 percent of its wage index calculated in the prior FY. This means, if a SNF's prior FY wage index is calculated with the application of the 5-percent cap, then the following year's wage index would not be less than 95 percent of the SNF's capped wage index in the prior FY. For example, if a SNF's wage index for FY 2023 is calculated with the application of the 5-percent cap, then its wage index for FY 2024 would not be less than 95 percent of its capped wage index in FY 2023. Lastly, we proposed that a new SNF would be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied, because a new SNF would not have a wage index in the prior FY. As we outlined in the proposed rule, we believe this proposed methodology would maintain the SNF PPS wage index as a relative measure of the value of labor in prescribed labor market areas, increase the predictability of SNF PPS payments for providers, and mitigate instability and significant negative impacts to providers resulting from significant changes to the wage index. In section XI. of the proposed rule, we estimated the impact to payments for providers in FY 2023 based on this proposed policy. We also noted that we would examine the effects of this policy on an ongoing basis in the future in order to assess its continued appropriateness.

Subject to the aforementioned proposal becoming final, we also proposed to revise the regulation text at § 413.337(a)(1) to provide that starting October 1, 2022, we would apply a cap on decreases to the wage index such that the wage index applied is not less than 95 percent of the wage index applied to that SNF in the prior year.

We invited public comments on this proposal. The following is a summary of the comments we received on the proposed permanent cap on wage index decreases and our responses.

Comment: MedPAC expressed support for the 5-percent permanent cap on wage index decreases policy, but recommended that the 5-percent cap limit should apply to both increases and decreases in the wage index because they stated that no provider should have its wage index value increase or decrease by more than 5 percent.

Response: We appreciate MedPAC's suggestion that the cap on wage index changes of more than 5 percent should also be applied to increases in the wage index. However, as we discussed in the FY 2023 SNF PPS proposed rule (87 FR 22735), one purpose of the proposed policy is to help mitigate the significant negative impacts of certain wage index changes. Likewise, we explained that we believe that applying a 5-percent cap on all wage index decreases would support increased predictability about SNF PPS payments for providers, enabling them to more effectively budget and plan their operations. That is, we proposed to cap decreases because we believe that a provider would be able to more effectively budget and plan when there is predictability about its expected minimum level of SNF PPS payments in the upcoming fiscal year. We did not propose to limit wage index increases, because we do not believe such a policy would enable SNFs to more effectively budget and plan their operations. So, we believe it is appropriate for providers that experience an increase in their wage index value to receive the full benefit of their increased wage index value.

Comment: A few commenters requested that CMS retroactively apply the 5 percent cap policy to the FY 2022 wage index.

Response: In the FY 2021 SNF PPS rulemaking cycle, CMS proposed and finalized a one-time, 1-year transition policy to mitigate the effects of adopting OMB delineations updated in OMB Bulletin 18–04. In the FY 2023 SNF PPS proposed rule we did not propose to modify the one-time transition policy that was finalized in the FY 2021 SNF PPS final rule, nor did we propose to extend the transition period for FY 2022. We have historically implemented 1-year transitions, as discussed in the FY 2006 (70 FR 45026) and FY 2015 (79 FR 45644) final rules, to address CBSA changes due to substantial updates to OMB delineations. Our policy principles, as noted in the FY 2022 final rule (86 FR 42439), with regard to the wage index are to use the most updated data and information available. Therefore, the FY 2023 wage index policy proposal is prospective and is designed to mitigate any significant decreases beginning in FY 2023, not retroactively.

Comment: A number of commenters suggested the 5-percent cap be applied in a non-budget neutral manner.

Response: The statute at section 1888(e)(4)(G)(ii) of the Act requires that adjustments for geographic variations in labor costs for a FY are made in a budget-neutral. We are required to apply the permanent 5-percent cap policy in a budget-neutral manner.

Comment: A commenter recommended the percentage cap be lower than the proposed 5-percent stating they found that most wage indices do not swing by 5-percent.

Response: We appreciate the commenter's suggestion that the permanent cap percentage should be lower than 5-percent. However, as we discussed in the proposed rule, for FY 2023, the provider level impact analysis indicates that approximately 97 percent of SNFs will experience a wage index change within 5 percent. Because providers are usually experienced with this level of wage index fluctuation, we believe applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability in SNF PPS payments due to any significant wage index decreases that may affect providers in any year.

Comment: One commenter was opposed to the implementation of the permanent 5-percent cap on wage index decreases at this time, stating that the industry struggled prior to the PHE.

Response: We appreciate the concern with implementing the permanent 5-percent cap on wage index decreases.

However, as we discussed in the proposed rule, we believe moving forward with the permanent cap on wage index decreases would effectively mitigate instability in SNF PPS payments due to any significant wage index decreases that may affect providers in any year.

After consideration of the comments we received, we are finalizing the proposed permanent 5-percent cap on wage index decreases for the SNF PPS, beginning in FY 2023.

B. Technical Updates to PDPM ICD–10 Mappings

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of the Patient Driven Payment Model (PDPM), effective October 1, 2019. The PDPM utilizes International Classification of Diseases, Version 10 (ICD–10) codes in several ways, including to assign patients to clinical categories under several PDPM components, specifically the PT, OT, SLP and NTA components. The ICD–10 code mappings and lists used under PDPM are available on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.*

Each year, the ICD–10 Coordination and Maintenance Committee, a Federal interdepartmental committee that is chaired by representatives from the National Center for Health Statistics (NCHS) and by representatives from CMS, meets biannually and publishes updates to the ICD–10 medical code data sets in June of each year. These changes become effective October 1 of the year in which these updates are issued by the committee. The ICD–10 Coordination and Maintenance Committee also can make changes to the ICD–10 medical code data sets effective on April 1 of each year.

In the FY 2020 SNF PPS final rule (84 FR 38750), we outlined the process by which we maintain and update the ICD–10 code mappings and lists associated with the PDPM, as well as the SNF Grouper software and other such products related to patient classification and billing, to ensure that they reflect the most up to date codes possible. Beginning with the updates for FY 2020, we apply nonsubstantive changes to the ICD–10 codes included on the PDPM code mappings and lists through a subregulatory process consisting of posting updated code mappings and lists on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.* Such nonsubstantive changes are limited to those specific changes that are necessary to maintain consistency with the most current ICD–10 medical code data set. On the other hand, substantive changes, or those that go beyond the intention of maintaining consistency with the most current ICD–10 medical code data set, will be proposed through notice and comment rulemaking. For instance, changes to the assignment of a code to a comorbidity list or other changes that amount to changes in policy are considered substantive changes for which we would undergo notice and comment rulemaking.

We proposed several changes to the PDPM ICD–10 code mappings and lists. We note that, in the case of any diagnoses that are either currently mapped to ''Return to Provider'' or that we proposed to classify into this category, this is not intended to reflect any judgment on the importance of recognizing and treating these conditions, but merely that there are more specific diagnoses than those mapped to ''Return to Provider'' or that we do not believe that the diagnosis should serve as the primary diagnosis for a Part-A covered SNF stay. Our proposed changes were as follows:

On October 1, 2021, D75.839 ''*Thrombocytosis, unspecified,*'' took effect and was mapped to the clinical category of ''Cardiovascular and Coagulations.'' However, there are more specific codes to indicate why a patient with thrombocytosis would require SNF care. If the cause is unknown, the SNF could use D47.3, ''*Essential (hemorrhagic) thrombocythemia*'' or D75.838, ''*other thrombocytosis*'' which is a new code that took effect on October 1, 2021. Further, elevated platelet count without other symptoms is not reason enough for SNF skilled care so this would not be used as a primary diagnosis. For this reason, we proposed to change the assignment of D75.839 to ''*Return to Provider.*''

On October 1, 2021, D89.44, ''*Hereditary alpha tryptasemia*'' went into effect and was mapped to the clinical category, ''Medical Management.'' However, this is not a diagnosis that would be treated as a primary condition in the SNF, rather it would be treated in the outpatient setting. Therefore, we proposed to change the assignment of D89.44 to ''*Return to Provider.*''

On October 1, 2021, F32.A, ''*Depression, unspecified*'' went into effect and was mapped to ''Medical Management.'' However, there are more specific codes that would more adequately capture the diagnosis of depression. Further, as we noted in the proposed rule, while we believe that SNFs serve an important role in providing services to those beneficiaries suffering from mental illness, the SNF setting is not the setting that would be most appropriate to treat a patient whose primary diagnosis is depression. For this reason, we proposed to change the assignment of F32.A to ''Return to Provider.''

On October 1, 2021, G92.9, ''*Unspecified toxic encephalopathy*'' took effect and was mapped to the clinical category of ''Acute Neurologic.'' However, there are more specific codes that should be used to describe encephalopathy treated in a SNF. Therefore, we proposed to change the assignment of G92.9 to ''*Return to Provider.*''

On October 1, 2021, M54.50, ''*Low back pain, unspecified*'' went into effect and was mapped to the clinical category of ''Non-surgical Orthopedic/Musculoskeletal.'' However, if low back pain were the primary diagnosis, the SNF should have a greater understanding of what is causing the pain. There are more specific codes to address this condition. Therefore, we proposed to change the assignment of M54.50 to ''Return to Provider.''

In the FY 2022 proposed rule (86 FR 19984 through 19985), we proposed to reclassify K20.81, ''*Other esophagitis with bleeding,*'' K20.91, ''*Esophagitis, unspecified with bleeding,*'' and K21.01, ''*Gastro-esophageal reflux disease with esophagitis, with bleeding*'' from ''Return to Provider'' to ''Medical Management.'' Our rationale for the change was a recognition that these codes represent these esophageal conditions with more specificity than originally considered because of the bleeding that is part of the conditions and that they would more likely be found in SNF patients. We received one comment suggesting additional changes to similar ICD–10 code mappings and comorbidity lists that at the time were outside the scope of rulemaking. This commenter suggested that we consider remapping the following similar diagnosis codes that frequently require SNF skilled care, from ''Return to Provider'' to ''Medical Management'': K22.11, ''*Ulcer of esophagus with bleeding;*'' K25.0, ''*Acute gastric ulcer with hemorrhage;*'' K25.1, ''*Acute gastric ulcer with perforation;*'' K25.2, ''*Acute gastric ulcer with both hemorrhage and perforation;*'' K26.0, ''*Acute duodenal ulcer with hemorrhage;*'' K26.1, ''*Acute duodenal ulcer with perforation;*'' K26.2, ''*Acute duodenal ulcer with both hemorrhage and perforation;*'' K27.0 ''*Acute peptic ulcer, site unspecified with hemorrhage;*'' K27.1, ''*Acute peptic ulcer, site unspecified with perforation;*''

K27.2, ''*Acute peptic ulcer, site unspecified with both hemorrhage and perforation;*'' K28.0, ''*Acute gastrojejunal ulcer with hemorrhage;*'' K28.1, ''*Acute gastrojejunal ulcer with perforation;*'' K28.2, ''*Acute gastrojejunal ulcer with both hemorrhage and perforation;*'' and K29.01, ''*Acute gastritis with bleeding.*'' Upon review of these codes, we recognize that they represent conditions with more specificity than originally considered because of the bleeding (or perforation) that is part of the conditions and that they would more likely be found in SNF patients.'' Therefore, we proposed to remap these ICD–10 codes to ''Medical Management.''

We also received a comment requesting we consider remapping M62.81, ''*Muscle weakness (generalized)*'' from ''Return to Provider'' to ''Non-orthopedic Surgery'' with the rationale that there is currently no sequela or late-effects ICD–10 code available when patients require skilled nursing and therapy due to late effects of resolved infections such as pneumonia or urinary tract infections. We considered the request and determined that muscle weakness (generalized) is nonspecific and if the original condition is resolved, but the resulting muscle weakness persists because of the known original diagnosis, there are more specific codes that exist that would account for why the muscle weakness is on-going, such as muscle wasting or atrophy. Therefore, we did not propose this specific remapping. This commenter also requested that that we consider remapping R62.7, ''*Adult failure to thrive*'' from ''Return to Provider'' to ''Medical Management.'' According to this commenter, physicians often diagnose adult failure to thrive when a resident has been unable to have oral intake sufficient for survival. Typically, this diagnosis is appended when the physician has determined that a feeding tube should be considered to provide sufficient intake for survival. According to the commenter, it would then appropriately become the primary diagnosis for a skilled stay. We considered this request and believe that R6.2 is a nonspecific code and SNF primary diagnoses should be coded to the highest level of specificity. If the patient has been unable to have oral intake, the primary diagnosis (for example, Ulcerative Colitis) for admission to a SNF should explain why the patient is unable to have oral intake sufficient for survival. Therefore, we did not propose this specific remapping.

We solicited comments on the proposed substantive changes to the ICD–10 code mappings discussed previously in this section, as well as comments on additional substantive and non-substantive changes that commenters believe are necessary. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed changes to the PDPM ICD–10 mappings. Some commenters expressed concerns with the proposed reclassification of certain conditions from a given clinical category to a Return to Provider status. For example, some commenters stated that, in the case of code F32.A (*Depression, unspecified*), this may be the most appropriate diagnosis, based on the information provided in the medical record. These commenters also stated that while it may be appropriate to remap code D75.839 to Return to Provider, they do not believe the more specific codes discussed in the proposed rule for this condition would be appropriate. Similarly, some commenters opposed remapping code D89.44 to Return to Provider, as skilled care may be necessary to treat the symptoms associated with this condition.

Response: We appreciate the support for these proposed changes. Regarding the comments related to the potential lack of additional documentation to support more specific diagnoses, ICD 10 coding guidance indicates to code with the highest specificity. The suggestion of codes, D47.3 and D75.838, was given to provide examples of more specific coding that could potentially be used if appropriate. SNF primary diagnoses should be coded to the highest level of specificity. By the time a person is in the SNF, the reason for thrombocytosis, should be known and since ICD 10 guidelines state that coding should be to the highest specificity, the reason for thrombocytosis could be listed as the principal diagnosis. Additionally, our goal is to ensure that Medicare beneficiaries receive the best care in the appropriate place. If a patient requires treatment in a facility for the primary reason of depression, Not Otherwise Specified (NOS), then their Medicare benefits provide access to treatment in an inpatient psychiatric hospital so that the type of depression, as well as treatment can be determined by specialists in the field. We remind commenters that the ICD–10 mapping reflects diagnoses which may be used as the primary diagnosis for a Part-A covered stay, not merely for a comorbidity associated with the patient's care. For conditions like D89.44 (*Hereditary Alpha Tryptasemia*), if there are symptoms or manifestations of this condition that require skilled care, then those symptoms should be provided as the primary diagnosis for the SNF stay, rather than the underlying condition which, often times, may be treated using oral medications.

Comment: Some commenters stated that CMS should reconsider mapping code M62.81 (*Muscle weakness, generalized*) and R62.7 (*Adult failure to thrive*) to a clinical category, as these conditions may serve as the source of treatment to maintain the patient's existing functional status before further decline.

Response: We considered this request and continue to believe that muscle weakness (generalized) is nonspecific and if the original condition is resolved, but the resulting muscle weakness persists because of the known original diagnosis, there are more specific codes that exist that would account for why the muscle weakness is on-going. This symptom, without any specification of the etiology or severity, is not a reason for daily skilled care in a SNF. Patients with generalized weakness should obtain a more specific diagnosis causing the generalized weakness. The specific diagnosis should be used to develop an appropriate care plan can for the patient. Similarly, in the case of a failure to thrive, this diagnosis is nonspecific and does not suggest the interventions needed to care for the patient, thus it should not be used as a reason for SNF admission. It may indicate that the patient's condition has not been thoroughly investigated which would be needed to develop an appropriate treatment plan.

Comment: Several commenters recommended that CMS consider revising the PDPM ICD–10 mapping to reclassify certain humeral fracture codes. These commenters highlighted that certain select encounter codes for humeral fracture are permitted to be coded under the current ICD–10 mapping, but not other encounter codes. The commenters suggested that all the encounter codes associated with these fracture codes be included in the appropriate clinical category.

Response: We appreciate the commenters' suggestion and agree that the various encounter codes should be treated in the same manner. We will examine the specific codes suggested to determine the most efficient manner for addressing this discrepancy.

Comment: Several commenters raised concerns with areas of discordance between the PDPM ICD–10 mapping

and the Medicare Code Edits (MCE) listing used by Medicare Administrative Contractors (MACs) when evaluating the primary diagnosis codes listed on claims. These commenters referred to instances when claims were denied for including a primary diagnosis code that may be found in the PDPM ICD–10 mapping as a valid code but is not accepted by the MACs. These commenters recommended that CMS seek to align these two code lists.

Response: We appreciate commenters raising this concern. While outside the scope of this rule, we intend to consult with MACs on this issue to determine an appropriate path forward.

After consideration of public comments, we finalize the proposed changes to the PDPM ICD–10 mappings, as proposed.

C. Recalibrating the PDPM Parity Adjustment

1. Background

On October 1, 2019, we implemented the Patient Driven Payment Model (PDPM) under the SNF PPS, a new case-mix classification model that replaced the prior case-mix classification model, the Resource Utilization Groups, Version IV (RUG–IV). As discussed in the FY 2019 SNF PPS final rule (83 FR 39256), as with prior system transitions, we proposed and finalized implementing PDPM in a budget neutral manner. This means that the transition to PDPM, along with the related policies finalized in the FY 2019 SNF PPS final rule, were not intended to result in an increase or decrease in the aggregate amount of Medicare Part A payment to SNFs. We believe ensuring parity is integral to the process of providing ''for an appropriate adjustment to account for case mix'' that is based on appropriate data in accordance with section 1888(e)(4)(G)(i) of the Act. Section V.I. of the FY 2019 SNF PPS final rule (83 FR 39255 through 39256) discusses the methodology that we used to implement PDPM in a budget neutral manner. Specifically, we multiplied each of the PDPM case-mix indexes (CMIs) by an adjustment factor that was calculated by comparing total payments under RUG–IV using FY 2017 claims and assessment data (the most recent final claims data available at the time) to what we expected total payments would be under PDPM based on that same FY 2017 claims and assessment data. In the FY 2020 SNF PPS final rule (84 FR 38734 through 38735), we finalized an updated standardization multiplier and parity adjustment based on FY 2018 claims and assessment data. This analysis resulted in an adjustment factor of 1.46, by which all the PDPM CMIs were multiplied so that total estimated payments under PDPM would be equal to total actual payments under RUG–IV, assuming no changes in the population, provider behavior, and coding. By multiplying each CMI by 1.46, the CMIs were inflated by 46 percent to achieve budget neutrality.

We used a similar type of parity adjustment in FY 2011 when we transitioned from RUG–III to RUG–IV. As discussed in the FY 2012 SNF PPS final rule (76 FR 48492 through 48500), we observed that once actual RUG–IV utilization data became available, the actual RUG–IV utilization patterns differed significantly from those we had projected using the historical data that grounded the RUG–IV parity adjustment. We then used actual FY 2011 RUG–IV utilization data to recalibrate the RUG–IV parity adjustment and decreased the nursing CMIs for all RUG–IV therapy groups from an adjustment factor of 61 percent to an adjustment factor of 19.84 percent, while maintaining the original 61 percent total nursing CMI increase for all non-therapy RUG–IV groups. As a result of this recalibration, FY 2012 SNF PPS rates were reduced by 12.5 percent, or $4.47 billion, in order to achieve budget neutrality under RUG–IV prospectively.

Since PDPM implementation, we have closely monitored SNF utilization data to determine if the parity adjustment finalized in the FY 2020 SNF PPS final rule (84 FR 38734 through 38735) provided for a budget neutral transition between RUG–IV and PDPM as intended. Similar to what occurred in FY 2011 with RUG–IV implementation, we observed significant differences between the expected SNF PPS payments and case-mix utilization based on historical data, and the actual SNF PPS payments and case-mix utilization under PDPM, based on FY 2020 and FY 2021 utilization data. As discussed in the FY 2022 SNF PPS final rule (86 FR 42466 through 42469), we initially estimated that PDPM may have inadvertently triggered a significant increase in overall payment levels under the SNF PPS of approximately 5 percent and that recalibration of the parity adjustment may be warranted.

Following the methodology utilized in calculating the initial PDPM parity adjustment, we would typically use claims and assessment data for a given year to classify patients under both the current system and the prior system to compare aggregate payments and determine an appropriate adjustment factor to achieve parity. However, we acknowledged that the typical methodology for recalibrating the parity adjustment may not provide an accurate recalibration under PDPM for several reasons. First, the ongoing COVID–19 PHE has had impacts on nursing home care protocols and many other aspects of SNF operations that affected utilization data in FY 2020 and FY 2021. Second, given the significant differences in payment incentives and patient assessment requirements between RUG–IV and PDPM, using the same methodology that we have used in the past to calculate a recalibrated PDPM parity adjustment could lead to a potential overcorrection in the recalibration.

In the FY 2022 SNF PPS proposed rule (86 FR 19987 through 19989), we solicited comments from interested parties on a potential methodology for recalibrating the PDPM parity adjustment to account for these potential effects without compromising the accuracy of the adjustment. After considering the feedback and recommendations received, summarized in the FY 2022 SNF PPS final rule (86 FR 42469 through 42471), we proposed an updated recalibration methodology and presented results from our data monitoring efforts to provide transparency on our efforts to parse out the effects of PDPM implementation from the effects of the COVID–19 PHE in section V.C.2.d. of the proposed rule. We solicited comments on this proposal for recalibrating the PDPM parity adjustment to ensure that PDPM is implemented in a budget neutral manner, as originally intended. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters noted that they understood the need to implement PDPM in a budget neutral manner, but requested that CMS reconsider the necessity of the parity adjustment. These commenters stated that it was unreasonable to expect a budget-neutral transition given the ''new normal'' that includes the impacts of COVID–19 and questioned the appropriateness of comparing a pre-COVID–19 RUG–IV system to a COVID–19 era PDPM system. Other commenters stated that even if the COVID–19 PHE had not occurred, it was unreasonable to expect a budget-neutral transition given that PDPM encourages providers to put a greater emphasis on capturing all patient characteristics. That is, while providers have always treated and considered such highly individualized characteristics, commenters noted that these were not necessarily captured by the MDS under the previous RUG–IV

payment system and were underrepresented in the data. Therefore, commenters disagreed with the notion that an overpayment is occurring between the PDPM model and RUG–IV model; rather, they stated the increased cost is an appropriate reflection of better capturing of patient complexities on the MDS.

Response: We believe there were significant changes in the coding of patient acuity directly following PDPM implementation and before the COVID–19 PHE that would have warranted a parity adjustment. In section V.C.2.d. of the proposed rule, we described numerous changes observed in the data that demonstrate the different impacts of PDPM implementation and the COVID–19 PHE on reported patient clinical acuity. For example, commenters stated that limitations regarding visitation and other infection control protocols due to the PHE led to higher levels of mood distress, cognitive decline, functional decline, compromised skin integrity, change in appetite, and weight loss requiring diet modifications among the non-COVID–19 population. However, our data show that many of these metrics had already exhibited clear changes concurrent with PDPM implementation and well before the start of the COVID–19 PHE. For example, the data showed an average of 4 percent of stays with depression and 5 percent of stays with a swallowing disorder in the fiscal year prior to PDPM implementation (FY 2019). In the 3 months directly following PDPM implementation and before the start of the COVID–19 PHE (October 2019 through December 2019), these averages increased to 11 percent of stays with depression and 17 percent of stays with a swallowing disorder.

The parity adjustment is meant to correct for the very changes in coding intensity of patient characteristics that these commenters describe, and similar changes in provider behavior and coding in response to payment incentives have occurred in past transitions from one payment system to another. As discussed in the FY 2012 SNF PPS final rule (76 FR 48492 through 48500), we implemented a similar type of parity adjustment in 2011 after observing a large difference between expected and actual utilization patterns in the transition from the RUG–III to RUG–IV payment system. As with prior system transitions, we proposed and finalized implementing PDPM in a budget neutral manner in the FY 2019 SNF PPS final rule (83 FR 39256). This meant that the transition to PDPM was not intended to result in an increase or decrease in the aggregate amount of Medicare Part A payment to SNFs.

Comment: Some commenters pointed to unintended consequences of implementing the parity adjustment on Medicare beneficiaries and other residents. Medicare's reimbursement rates for SNF care are higher than those of other payers such as Medicaid, and therefore, are a crucial support for an otherwise financially challenged SNF industry, particularly given the ongoing COVID–19 PHE. Any decrease to those rates would be acutely detrimental, especially to smaller, independent providers serving low-income populations, possibly resulting in facility closures and decreased access to care for beneficiaries.

Response: We remind commenters that Medicare Part A payments under the SNF PPS are solely intended to reflect the costs of providing care to beneficiaries covered under Medicare Part A and are not intended to augment payments from other payers that may be lower than Medicare Part A payment rates.

After consideration of public comments, we are finalizing our proposal to recalibrate the PDPM parity adjustment to ensure that PDPM is implemented in a budget neutral manner, as originally intended.

2. Methodology for Recalibrating the PDPM Parity Adjustment

a. Effect of COVID–19 Public Health Emergency

FY 2020 was a year of significant change under the SNF PPS. In addition to implementing PDPM on October 1, 2019, a national COVID–19 PHE was declared beginning January 27, 2020. With the announcement of the COVID–19 PHE, and under authority granted us by section 1812(f) of the Act, we issued two temporary modifications to the limitations of section 1861(i) of the Act beginning March 1, 2020, that affected SNF coverage. The 3-day prior hospitalization modification allows a SNF to furnish Medicare Part A services without requiring a 3-day qualifying hospital stay, and the benefit period exhaustion modification allows a one-time renewal of benefits for an additional 100 days of Part A SNF coverage without a 60-day break in a spell of illness. These COVID–19 PHE-related modifications allow coverage for beneficiaries who would not typically be able to access the Part A SNF benefit, such as community and long-term care nursing home patients without a prior qualifying hospitalization.

We acknowledged that the COVID–19 PHE had significant impacts on nursing home care protocols and many other aspects of SNF operations. For months, infection and mortality rates were high among nursing home residents. Additionally, facilities were often unable to access testing and affordable personal protective equipment (PPE) and were effectively closed to visitors and barred from conducting communal events to help control infections (March 2021 MedPAC Report to Congress, 204, available at *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch7_sec.pdf*). As described in the FY 2022 SNF PPS final rule (86 FR 42427), many commenters voiced concerns about additional costs due to the COVID–19 PHE that could be permanent due to changes in patient care, infection control staff and equipment, personal protective equipment, reporting requirements, increased wages, increased food prices, and other necessary costs. Some commenters who received CARES Act Provider Relief funds indicated that those funds were not enough to cover these additional costs. Additionally, a few commenters from rural areas stated that their facilities were heavily impacted from the additional costs, particularly the need to raise wages, and that this could affect patients' access to care.

However, we noted that the relevant issue for a recalibration of the PDPM parity adjustment is whether or not the COVID–19 PHE caused changes in the SNF case-mix distribution. In other words, the issue is whether patient classification, or the relative percentages of beneficiaries in each PDPM group, was different than what it would have been if not for the COVID–19 PHE. The parity adjustment addresses only to the transition between case-mix classification models (in this case, from RUG–IV to PDPM) and is not intended to include other unrelated SNF policies such as the market basket increase, which is intended to capture the change over time in the input prices for skilled nursing facility services described previously. A key aspect of our recalibration methodology, described in further detail later in this section, involved parsing out the impacts of the COVID–19 PHE and the PHE-related modifications from those that occurred solely, or at least principally, due to the implementation of PDPM.

b. Effect of PDPM Implementation

As discussed in the FY 2022 SNF PPS final rule (86 FR 42467), we presented evidence that the transition to PDPM impacted certain aspects of SNF patient classification and care provision prior to the beginning of the COVID–19 PHE.

For example, our data showed that SNF patients received an average of approximately 93 therapy minutes per utilization day in FY 2019. Between October 2019 and December 2019, the 3 months after PDPM implementation and before the onset of the COVID–19 PHE, the average number of therapy minutes SNF patients received per day dropped to approximately 68 minutes per utilization day, a decrease of approximately 27 percent. Given this reduction in therapy provision since PDPM implementation, we found that using patient assessment data collected under PDPM would lead to a significant underestimation of what RUG–IV case-mix and payments would have been (for example, the Ultra-High and Very-High Rehabilitation assignments are not nearly as prevalent using PDPM-reported data), which would in turn lead to an overcorrection in the parity adjustment. Additionally, there were significant changes in the patient assessment schedule such as the removal of the Change of Therapy Other Medicare Required Assessment (COT–OMRA). Without having an interim assessment between the 5-day assessment and the patient's discharge from the facility, we were unable to determine if the RUG–IV group into which the patient classified on the 5-day assessment changed during the stay, or if the patient continued to receive an amount of therapy services consistent with the initial RUG–IV classification.

Therefore, given the significant differences in payment incentives and patient assessment requirements between RUG–IV and PDPM, using the same methodology that we have used in the past to calculate a recalibrated PDPM parity adjustment could lead to a potential overcorrection in the recalibration. In the FY 2022 SNF PPS proposed rule (86 FR 19988), we described an alternative recalibration methodology that used FY 2019 RUG–IV case-mix distribution as a proxy for what total RUG–IV payments would have been absent PDPM implementation. We believed that this methodology provided a more accurate representation of what RUG–IV payments would have been, were it not for the changes precipitated by PDPM implementation, than using data reported under PDPM to reclassify these patients under RUG–IV. We solicited comments from interested parties on this aspect of our potential methodology for recalibrating the PDPM parity adjustment and they were generally receptive to this approach, as described in the FY 2022 SNF PPS final rule (86 FR 42468 through 42470).

c. FY 2022 SNF PPS Proposed Rule Potential Parity Adjustment Methodology and Comments

In the FY 2022 SNF PPS proposed rule (86 FR 19986 through 19987), we presented a potential methodology that attempted to account for the effects of the COVID–19 PHE by removing those stays with a COVID–19 diagnosis and those stays using a PHE-related modification from our data set, and we solicited comment on how interested parties believed the COVID–19 PHE affected the distribution of patient case-mix in ways that were not sufficiently captured by our subset population methodology. According to our data analysis, 10 percent of SNF stays in FY 2020 and 17 percent of SNF stays in FY 2021 included a COVID–19 ICD–10 diagnosis code either as a primary or secondary diagnosis, while 17 percent of SNF stays in FY 2020 and 27 percent of SNF stays in FY 2021 utilized a PHE-related modification (with the majority of these cases using the prior hospitalization modification), as identified by the presence of a ''Disaster Relief (DR)'' condition code on the SNF claim. As compared to prior years, when approximately 98 percent of SNF beneficiaries had a qualifying prior hospital stay, approximately 86 percent and 81 percent of SNF beneficiaries had a qualifying prior hospitalization in FY 2020 and FY 2021, respectively. These general statistics are important, as they highlight that while the PHE for COVID–19 certainly impacted many aspects of nursing home operations, the large majority of SNF beneficiaries entered into Part A SNF stays in FY 2020 and FY 2021 as they would have in any other year; that is, without using a PHE-related modification, with a prior hospitalization, and without a COVID–19 diagnosis.

Moreover, as discussed FY 2022 SNF PPS proposed rule (86 FR 19988), we found that even after removing those using a PHE-related modification and those with a COVID–19 diagnosis from our data set, the observed inadvertent increase in SNF payments since PDPM was implemented was approximately the same. To calculate expected total payments under RUG–IV, we used the percentage of stays in each RUG–IV group in FY 2019 and multiplied these percentages by the total number of FY 2020 days of service. We then multiplied the number of days for each RUG–IV group by the RUG–IV per diem rate, which we obtained by inflating the FY 2019 SNF PPS RUG–IV rates by the FY 2020 market basket update factor. The total payments under RUG–IV also accounted for the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) add-on of a 128 percent increase in the PPS per diem payment under RUG–IV, and a provider's FY 2020 urban or rural status. To calculate the actual total payments under PDPM, we used data reported on FY 2020 claims. Specifically, we used the Health Insurance Prospective Payment System (HIPPS) code on the SNF claim to identify the patient's case-mix assignment and associated CMIs, utilization days on the claim to calculate stay payments and the variable per diem adjustment, the presence of an HIV diagnosis on the claim to account for the PDPM AIDS add-on of 18 percent to the nursing component and the highest point value (8 points) to the NTA component, and a provider's urban or rural status. Using this approach, and as described in the FY 2022 SNF PPS final rule (86 FR 42468 through 42469), we initially estimated a 5.3 percent increase in aggregate spending under PDPM as compared to expected total payments under RUG–IV for FY 2020 when considering the full SNF population, and a 5 percent increase in aggregate spending under PDPM for FY 2020 when considering the subset population. This finding suggested that a large portion of the changes observed in SNF utilization are due to PDPM and not the PHE for COVID–19, as the ''new'' population of SNF beneficiaries (that is, COVID–19 patients and those using a PHE-related modification) did not appear to be the main cause of the increase in SNF payments after implementation of PDPM. Although these results are similar, we believed it would be more appropriate to pursue a potential recalibration using the subset population.

As described in the FY 2022 SNF PPS final rule (86 FR 42469 through 42471), some commenters agreed with our approach, stating that our subset population was a reasonable method to account for the effect of the COVID–19 PHE, and made a few suggestions for improvements. They stated that our analysis may have undercounted COVID–19 patients because there was no COVID–19 specific diagnosis code available before April 2020 and a shortage of tests at the beginning of the PHE led to SNFs being unable to report COVID–19 cases. To address these issues, commenters suggested that CMS consider using non-specific respiratory diagnoses or depression as proxies for COVID–19 cases. While we considered this option, we believed that such a change would overestimate the population to be excluded due to the

non-specific nature of those diagnoses. Additionally, because we did not provide our COVID–19 population definition in the FY 2022 SNF PPS proposed or final rules, commenters were concerned that our methodology did not include COVID–19 diagnoses from the Minimum Data Set (MDS) patient assessments in addition to SNF claims. Commenters were also concerned that we did not exclude transitional stays resulting from CMS' instruction to assess all patients anew in October 2019 using the PDPM MDS assessment, even though some patients were in the middle or end of their Medicare Part A coverage. We addressed these concerns by sharing a revised COVID–19 population definition in section V.C.2.d. of the proposed rule.

However, many commenters expressed concern that our subset population methodology would not accurately represent what the SNF patient case-mix would look like outside of the COVID–19 PHE environment, stating that data collected during the PHE was entirely too laden with COVID–19 related effects on the entire SNF population to be utilized and pointing to multiple reasons for greater clinical acuity even among our subset population. For example, because elective surgeries were halted, those admitted were the most compromised who could not be cared for at home. Additionally, limitations regarding visitation and other infection control protocols led to higher levels of mood distress, cognitive decline, functional decline, compromised skin integrity, change in appetite, and weight loss requiring diet modifications. In response to these comments, we conducted comprehensive data analysis and monitoring to identify changes in provider behavior and payments since implementing PDPM and presented a revised parity adjustment methodology in section V.C.2.d. of the proposed rule that we believed more accurately accounted for these changes while excluding the effect of the COVID–19 PHE on the SNF population.

d. FY 2023 SNF PPS Proposed Parity Adjustment Methodology

As outlined in section V.C.2.d. of the proposed rule, we proposed a revised methodology for the calculating the parity adjustment that considers the comments received in response to the potential methodology described in the FY 2022 SNF PPS proposed rule (86 FR 19986 through 19987). In response to the comments received about the subset population methodology, we modified our definition of COVID–19, which we derived from the Centers for Disease Control and Prevention (CDC) coding guidelines, to align with the definition used by publicly available datasets from CMS's Office of Enterprise Data and Analytics (OEDA) and found no significant impact on our calculations. For the FY 2022 SNF proposed rule, we defined the COVID–19 population to include stays that have either the interim COVID–19 code B97.29 recorded as a primary or secondary diagnosis in addition to one of the symptom codes J12.89, J20.8, J22, or J80, or the new COVID–19 code U07.1 recorded as a primary or secondary diagnosis on their SNF claims or MDS 5-day admission assessments. For the FY 2023 SNF proposed rule, we defined the COVID–19 population to include stays that have the interim COVID–19 code B97.29 from January 1, 2020 to March 31, 2020 or the new COVID–19 code U07.1 from April 1, 2020 onward recorded as a primary or secondary diagnosis on their SNF claims, MDS 5-day admission assessments, or MDS interim payment assessments. Both FY 2022 and FY 2023 definitions of the COVID–19 population excluded transitional stays. We noted that we found no significant impact on our calculations, as the COVID–19 population definition change only increased the stay count of our subset population by less than 1 percent.

In response to the comments described previously and based on additional data collection through FY 2021, we identified a recalibration methodology that we believed better accounted for COVID–19 related effects. We proposed to use the same type of subset population discussed in the FY 2022 SNF PPS proposed rule (86 FR 19960), which excluded stays that either used a section 1812(f) of the Act modification or that included a COVID–19 diagnosis, with a 1-year ''control period'' derived from both FY 2020 and FY 2021 data. Specifically, we used 6 months of FY 2020 data from October 2019 through March 2020 and 6 months of FY 2021 data from April 2021 through September 2021 (which our data suggests were periods with relatively low COVID–19 prevalence) to create a full 1-year period with no repeated months to account for seasonality effects. As shown in Table 11, we believed this combined approach provided the most accurate representation of what the SNF case-mix distribution would look like under PDPM outside of a COVID–19 PHE environment. While using the subset population method alone for FY 2020 and FY 2021 data results in differences of 0.31 percent and 0.40 percent between the full and subset populations, respectively, introducing the control period closed the gap between the full and subset population adjustment factors to 0.02 percent, suggesting that the control period captures additional COVID–19 related effects on patient acuity that the subset population method alone does not. Accordingly, the combined methodology of using the subset population with data from the control period resulted in the lowest parity adjustment factor. Table 12 shows that while using the subset population method would lead to a 4.9 percent adjustment factor ($1.6 billion) using FY 2020 data and a 5.3 percent adjustment factor ($1.8 billion) using FY 2021 data, introducing the control period reduced the adjustment factor to 4.6 percent ($1.5 billion). We note that these estimates are revised from those provided in the FY 2023 SNF PPS proposed rule, based on a more recent SNF baseline budget estimate provided by the CMS Office of the Actuary. The robustness of the control period approach was further demonstrated by the fact that using data from the control period, with either the full or subset population, would lead to approximately the same parity adjustment factor of 4.58 percent as compared to 4.6 percent.

TABLE 11: Adjustment Factors Based on Population and Data Period

Data Period	Full SNF Population	Subset SNF Population	Difference
FY 2020-based Adjustment Factor	5.21%	4.90%	-0.31%
FY 2021-based Adjustment Factor	5.65%	5.25%	-0.40%
Control Period-based Adjustment Factor	4.58%	4.60%	0.02%

TABLE 12: Budget Impact Based on Subset Population and Data Period

Data Period and Population	Adjustment Factor	Budget Impact (Reduction)
FY 2020 Data, Subset Population	4.9%	$1.6 billion
FY 2021 Data, Subset Population	5.3%	$1.8 billion
Control Period Data, Subset Population	4.6%	$1.5 billion

*We note that these estimates are revised from those provided in the FY 2023 SNF PPS proposed rule, based on a more recent SNF baseline budget estimate provided by the CMS Office of the Actuary.

Our data analysis and monitoring efforts provided further support for the accuracy and appropriateness of a 4.6 percent parity adjustment factor, as we have identified numerous changes that demonstrate the different impacts of PDPM implementation and the COVID–19 PHE on reported patient clinical acuity. As described earlier, commenters stated that limitations regarding visitation and other infection control protocols due to the PHE led to higher levels of mood distress, cognitive decline, functional decline, compromised skin integrity, change in appetite, and weight loss requiring diet modifications among the non-COVID–19 population. However, our data showed that most of these metrics, with the exception of functional decline and compromised skin integrity, had already exhibited clear changes concurrent with PDPM implementation and well before the start of the COVID–19 PHE. For example, in regard to higher levels of mood distress and cognitive decline, we observed an average of 4 percent of stays with depression and 40 percent of stays with cognitive impairment, with an average mood score of 1.9, in the fiscal year prior to PDPM implementation (FY 2019). In the 3 months directly following PDPM implementation and before the start of the COVID–19 PHE (October 2019 to December 2019), these averages increased to 11 percent of stays with depression and 44 percent of stays with cognitive impairment, with an average mood scale of 2.9. As for change in appetite and weight loss requiring diet modifications, we observed an average of 15 percent of stays with any SLP comorbidity, 5 percent of stays with a swallowing disorder, and 22 percent of stays with a mechanically altered diet in FY 2019. In the 3 months directly following PDPM implementation, these averages increased to 19 percent of stays with any SLP comorbidity, 17 percent of stays with a swallowing disorder, and 25 percent of stays with a mechanically altered diet. Notably, we also observed that the percentage of stays with a swallowing disorder that did not also receive a mechanically altered diet increased from 1 percent in FY 2019 to 5 percent in the 3 months directly following PDPM implementation. While many of these metrics increased further after the start of the COVID–19 PHE, they remained elevated at around their post-PDPM implementation levels even during periods of low COVID–19 prevalence. As a result, our parity adjustment calculations remained much the same even during months when rates of COVID–19 cases were quite low, suggesting that patient case mix classification has stabilized independent of the ongoing COVID–19 PHE.

Another reason that commenters cited to explain the greater clinical acuity among the subset population is that, because elective surgeries were halted, patients who were admitted were more severely ill and could not be treated at home. We acknowledged that the subset population methodology, or any method predicated on data from the COVID–19 PHE period, may not accurately represent what SNF patient case-mix would look like outside of the COVID–19 PHE environment because while we could remove data that we believed were due to COVID–19 impacts, it was more difficult to add data back in that was missing due to the COVID–19 PHE.

However, we believed that the addition of the control period to the subset population methodology helped to resolve this issue. For example, there likely would have been more joint replacements were it not for the COVID–19 PHE. Our data showed that the rate of major joint replacement or spinal surgery decreased from 7.6 percent of stays in FY 2019, to 5.5 percent of stays in FY 2021, to 5.2 percent of stays in FY 2022. Similarly, rates of orthopedic surgery decreased from 9.1 percent of stays in FY 2019, to 9.0 percent of stays in FY 2021, to 8.8 percent of stays in FY 2022. Using the control period, which excluded the periods of highest COVID–19 prevalence and lowest rates of elective surgeries, we arrived at rates of 6.4 percent of stays with major joint replacement or spinal surgery, and 9.5 percent of stays with orthopedic surgery. Therefore, as we noted in section V.C.2.d. the proposed rule, we believed that using the control period would be a closer representation of SNF patient case-mix outside of a COVID–19 PHE environment than using either FY 2021 or FY 2022 data alone.

Given the results of our data analyses, we proposed adopting the methodology based upon the subset population during the control period and lowering the PDPM parity adjustment factor from 46 percent to 38 percent for each of the PDPM case-mix adjusted components if we were to implement the 4.6 percent parity adjustment factor in FY 2023. We noted that the parity adjustment would be calculated and applied at a systemic level to all facilities paid under the SNF PPS, and there may be variation between facilities based on their unique patient population, share of non-case-

mix component payment, and urban or rural status. We invited comments on the methodology outlined in section V.C.2.d. of the proposed rule for recalibrating the PDPM parity adjustment, as well as the findings of our analysis described throughout section V.C.2. of the proposed rule.

To assist commenters in providing comments on this issue, we also posted a file on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/snfpps,* which provided the FY 2019 RUG IV case-mix distribution and calculation of total payments under RUG–IV, as well as PDPM case-mix utilization data at the case mix group and component level to demonstrate the calculation of total payments under PDPM.

We invited comments on our proposed combined methodology of using the subset population and data from the control period for the purposes of calculating the recalibrated parity adjustment factor. The following is a summary of the comments we received and our responses.

Comment: A few commenters provided comments in relation to the proposed methodology for calculating the parity adjustment. Some commenters noted our proposed methodology to be a reasonable and much improved approach compared to the approach proposed in FY 2022 SNF PPS proposed rule, as our revised methodology addresses many of the key issues raised by interested parties (86 FR 42469 through 42471).

However, one commenter suggested removing August and September 2021 due to the Delta variant. Another commenter suggested a modified control period to eliminate April and May 2021 as patients and healthcare personnel were still in the process of receiving the initial dose of the COVID–19 vaccine, and August and September 2021 due to early phase of the Delta variant surge. The commenter also provided analysis regarding COVID–19 spillover effects, which they defined as effects that occur in non-COVID–19 patient CMIs when MDS patient assessment patterns change from what would have occurred if not for the pandemic, using the percentage change over time in various patient clinical and zip-code level demographic characteristics, the latter used as proxies for the demographics of the SNF population in a particular zip code. The commenter stated that some metrics, such as HCC risk scores, English proficiency, educational level, and poverty level returned to or dropped below pre-COVID–19 PHE baseline levels, suggesting that the revised parity adjustment factor is adequate to account for COVID–19 spillover effects. However, the commenter also stated that other metrics, such as PDPM component CMI trends; MDS items for respiratory failure, pressure ulcers, and depression; and claim items for age, race, dual, and disability status did not return to pre-COVID–19 PHE baseline levels, suggesting that the revised parity adjustment factor may not be adequate to account for COVID–19 spillover effects. Based on these findings, the commenters stated that they believed that there are COVID–19 spillover effects that remain despite CMS's improved parity adjustment approach, and they recommended that CMS further evaluate the data to exclude the months of April, May, August, and September 2021 from the parity adjustment calculations, as discussed above. The commenter also stated that modifying the control period in this way would mitigate most of the remaining spillover effects and would result in an additional 0.1 to 0.2 percent reduction below the proposed 4.6 percent parity adjustment amount.

Response: We note that many of the differences shown in the data the commenter provided are quite small (some less than a small fraction of 1 percent) and could be attributed to the continuation of the impact of PDPM implementation or regular year-to-year variations in the composition of the SNF population (or zip-code level population more generally), rather than true COVID–19 spillover effects. We also note that the commenter did not consider data from before PDPM implementation to support what they believe should be a more appropriate parity adjustment factor, as they used data from October 2019 to February 2020 to define their ''pre-pandemic'' study population.

In contrast, the data analyses we presented earlier in the preamble show significant changes in the coding of patient case mix concurrent with PDPM implementation. For example, in the year prior to PDPM implementation (FY 2019), we observed an average of 4 percent of stays coded with depression and 5 percent of stays coded with a swallowing disorder. In the 3 months directly following PDPM implementation and before the start of the COVID–19 PHE (October 2019 to December 2019), these averages increased to 11 percent of stays coded with depression and 17 percent of stays coded with a swallowing disorder. While these and other clinical metrics increased in acuity after the start of the COVID 19 PHE in January 2020, they remained elevated at around their immediate post-PDPM implementation levels even during periods of low COVID–19 prevalence. As a result, our parity adjustment calculations remained much the same even during months when rates of COVID–19 cases were quite low, suggesting that the 4.6 percent parity adjustment factor captures the effect of PDPM implementation and excludes the effects of the COVID–19 PHE.

Moreover, we believe that it is important to have an adequate and representative amount of time in both 2020 and 2021 upon which to calculate a parity adjustment factor, rather than choosing specific months that would result in the lowest possible parity adjustment factor. Our analysis of Medicare Part A data from SNFs in April, May, August, and September 2021 show that these were months of low COVID–19 prevalence in SNFs compared to other months in FY 2020 and FY 2021. We intentionally chose 6 months of FY 2020 data from October 2019 through March 2020 and 6 months of FY 2021 data from April 2021 through September 2021, which our Medicare Part A monitoring data showed were periods with the lowest COVID–19 prevalence in SNFs, to create a full 1-year period with no repeated months to account for seasonality effects. While we used less than a year of data in calculating the recalibration of the RUG–IV parity adjustment when transitioning between RUG–III and RUG–IV in FY 2012 (76 FR 48493), that change was between two payment models that were, in several ways, very similar (for example, the relationship between therapy intensity and payment classification). This time, in light of the significant differences between the PDPM and the RUG–IV payment models, in addition to the impact of the COVID–19 PHE, we believe it is necessary to use a full year of data.

After consideration of these public comments, we are finalizing a parity adjustment factor of 4.6 percent using the combined subset population and control period methodology, as proposed. As discussed later in section VI.C.4. of this final rule, we are finalizing the implementation of the parity adjustment with a 2-year phase-in period, which means that, for each of the PDPM case-mix adjusted components, we would lower the PDPM parity adjustment factor from 46 percent to 42 percent in FY 2023 and we would further lower the PDPM parity adjustment factor from 42 percent to 38 percent in FY 2024.

3. Methodology for Applying the Recalibrated PDPM Parity Adjustment

As discussed in the FY 2022 SNF PPS proposed rule (86 FR 19988), we believed it would be appropriate to apply the recalibrated parity adjustment across all PDPM CMIs in equal measure, as the initial increase to the PDPM CMIs to achieve budget neutrality was applied equally, and therefore, this method would properly implement and maintain the integrity of the PDPM classification methodology as it was originally designed. Tables 5 and 6 in section III.C. of the proposed rule set forth what the PDPM CMIs and case-mix adjusted rates would be if we apply the recalibration methodology in equal measure in FY 2023.

We acknowledged that we received several comments in response to last year's rule objecting to this approach given that our data analysis, presented in Table 23 of the FY 2022 SNF PPS proposed rule (86 FR 19987), showed significant increases in the average CMI for the SLP, Nursing, and NTA components for both the full and subset FY 2020 populations as compared to what was expected, with increases of 22.6 percent, 16.8 percent, and 5.6 percent, respectively, for the full FY 2020 SNF population. As described in the FY 2022 SNF PPS final rule (86 FR 42471), some commenters disagreed with adjusting the CMIs across all case-mix adjusted components in equal measure, suggesting that this approach would harm patient care by further reducing PT and OT therapy minutes. Instead, the commenters recommended a targeted approach that focuses the parity adjustment on the SLP, Nursing, and NTA components in proportion to how they are driving the unintended increase observed under PDPM.

We considered these comments, but believe that it would be most appropriate to propose applying the parity adjustment across all components equally. First, as described earlier, the initial increase to the PDPM CMIs to achieve budget neutrality was applied across all components, and therefore, it would be appropriate to implement a revision to the CMIs in the same way. Second, the reason we did not observe the same magnitude of change in the PT and OT components is that, in designing the PDPM payment system, the data used to help determine what payment groups SNF patients would classify into under PDPM was collected under the prior payment model (RUG–IV), which included incentives that encouraged significant amounts of PT and OT. Given that PT and OT were furnished in such high amounts under RUG–IV, we had already assumed that a significant portion of patients would be classified into the higher paying PT and OT groups corresponding to having a Section GG function score of 10 to 23. Therefore, this left little room for additional increases in PT and OT classification after PDPM implementation. In other words, the PT and OT components results were as expected according to the original design of PDPM, while the SLP, Nursing, and NTA results were not.

However, to fully explore the alternative targeted approach that commenters suggested, we updated our analysis of the average CMI by PDPM component from Table 23 of the FY 2022 SNF PPS proposed rule (86 FR 19987) and found that a similar pattern still holds when comparing the expected average CMIs for FY 2019 and the expected actual CMIs for the subset population during the control period. Table 13 shows significant increases in average case-mix of 18.6 percent for the SLP component and the 10.8 percent for the Nursing component, a moderate increase of 3.0 percent for the NTA component, and a slight increase of 0.4 percent for the PT and OT components, respectively. We also provided Table 14 to show the potential impact of applying the 4.6 percent PDPM parity adjustment factor to the PDPM CMIs in a targeted manner in FY 2023, instead of an equal approach as presented in Tables 5 and 6 in section III.C. of the proposed rule. We invited comments on whether interested parties believe a targeted approach is preferable to our proposed equal approach.

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TABLE 13: Average Case-Mix Index, Expected and Actual, by PDPM Component

Component	Expected Average CMI (FY 2019 Estimate, Subset Population)	Actual CMI per Stay (Control Period, Subset Population)	Percentage Difference
PT	1.51	1.52	0.4%
OT	1.51	1.52	0.4%
SLP	1.40	1.66	18.6%
Nursing	1.45	1.60	10.8%
NTA	1.16	1.20	3.0%

TABLE 14: PDPM Case-Mix Adjusted Federal Rates and Associated Indexes

PDPM Group	PT CMI	OT CMI	SLP CMI	Nursing CMG	Nursing CMI	NTA CMI
A	1.53	1.49	0.62	ES3	3.72	2.97
B	1.70	1.63	1.67	ES2	2.81	2.32
C	1.88	1.69	2.45	ES1	2.68	1.69
D	1.92	1.53	1.34	HDE2	2.20	1.22
E	1.42	1.41	2.14	HDE1	1.82	0.88
F	1.61	1.60	2.73	HBC2	2.05	0.66
G	1.67	1.64	1.87	HBC1	1.70	-
H	1.16	1.15	2.62	LDE2	1.90	-
I	1.13	1.18	3.23	LDE1	1.58	-
J	1.42	1.45	2.74	LBC2	1.58	-
K	1.52	1.54	3.39	LBC1	1.31	-
L	1.09	1.11	3.86	CDE2	1.71	-
M	1.27	1.30	-	CDE1	1.48	-
N	1.48	1.50	-	CBC2	1.42	-
O	1.55	1.55	-	CA2	1.00	-
P	1.08	1.09	-	CBC1	1.23	-
Q	-	-	-	CA1	0.86	-
R	-	-	-	BAB2	0.95	-
S	-	-	-	BAB1	0.91	-
T	-	-	-	PDE2	1.44	-
U	-	-	-	PDE1	1.35	-
V	-	-	-	PBC2	1.12	-
W	-	-	-	PA2	0.65	-
X	-	-	-	PBC1	1.03	-
Y	-	-	-	PA1	0.60	-

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We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to apply the parity adjustment evenly over all CMIs for all case-mix groups, the same approach that was taken when the original adjustment was implemented. One commenter stated that the targeted approach, which results in a larger reduction for some CMIs than others, may have unintended adverse effects on some facilities and that an equally distributed percentage reduction would have a more equitable impact on all facilities. Another commenter believed an equal approach would be the least disruptive policy implementation, rather than set a precedent for potential future changes to the individual CMI components. The commenter also added that regardless of which CMIs are reduced, facilities are still receiving a single per-diem payment. A third commenter agreed that, in the absence of re-designing the PDPM payment model from the ground-up based on observed PDPM CMIs, the adoption of an even distribution for the parity adjustment would best maintain the stability of the PDPM payment model. A fourth commenter strongly opposed a targeted approach to all categories, believing that SLP services were undervalued in the RUG–IV system and utilization of SLP services appropriately meets beneficiary needs under PDPM, but were not previously reported since there were no financial incentives for SNFs to report SLP services under RUG–IV.

Two commenters supported a targeted approach and expressed concern about a reduction in payment for the PT and OT components, given that the majority of increased spending is not attributed to these components, leading to a reduction in PT and OT services. The commenters urged CMS to use the data to adjust PDPM in an accurate and precise manner, rather than simply reducing every CMI.

Response: We agree that applying the parity adjustment equally across all PDPM CMIs would be the most equitable and least disruptive policy implementation, rather than set a precedent for potential future changes to the individual CMI components. We also agree that regardless of which CMIs are reduced, facilities are still receiving a single per-diem payment and a reduction in the PT and OT CMIs should not impact the provision of these services, as the main driver for determining the appropriate provision of these services should the unique characteristics, goals, or needs, of each SNF patient. As we stated in the FY 2020 SNF PPS final rule (84 FR 38748), financial motives should not override the clinical judgment of a therapist or therapy assistant or pressure a therapist or therapy assistant to provide less than appropriate therapy.

After consideration of public comments, we are finalizing the application of the parity adjustment equally across all components, as proposed.

4. Delayed and Phased Implementation

As we noted in the FY 2012 SNF PPS final rule (76 FR 48493), we believe it is imperative that we act in a well-considered but expedient manner once excess payments are identified, as we did in FY 2012. However, we acknowledged that applying a reduction in payments without time to prepare could create a financial burden for providers, particularly considering the ongoing COVID–19 PHE. Therefore, in the FY 2022 SNF PPS proposed rule (86 FR 19988 through 19990), we solicited comments on two potential mitigation strategies to ease the transition to prospective budget neutrality: delayed implementation and phased implementation. We noted that for either of these options, the adjustment would be applied prospectively, and the CMIs would not be adjusted to account for deviations from budget neutrality in years before the payment adjustments are implemented.

A delayed implementation strategy would mean that we would implement the reduction in payment in a later year than the year the reduction is finalized. For example, considering the 4.6 percent reduction discussed previously in this preamble, if this reduction is finalized in FY 2023 with a 1-year delayed implementation, this would mean that the full 4.6 percent reduction will be applied prospectively to the PDPM CMIs in FY 2024. By comparison, a phased implementation strategy would mean that the amount of the reduction would be spread out over some number of years. For example, if we were to implement a 2-year phase-in period to the 4.6 percent reduction discussed previously in the proposed rule with no delayed implementation, this would mean that the PDPM CMIs would be reduced by 2.3 percent in the first year of implementation in FY 2023 and then reduced by the remaining 2.3 percent in the second and final year of implementation in FY 2024. We could also use a combination of both mitigation strategies, such as a 1-year delayed implementation with a 2-year phase-in period, would mean that the PDPM CMIs would be reduced by 2.3 percent in the first year of implementation in FY 2024 and then reduced by the remaining 2.3 percent in the second and final year of implementation in FY 2025.

In the FY 2022 SNF PPS proposed rule (86 FR 19988 through 19990), we solicited comments on the possibility of combining the delayed and phased implementation approaches and what interested parties believed would be appropriate to appropriately mitigate the impact of the reduction in SNF PPS payments. As described in the FY 2022 SNF PPS final rule (86 FR 42470 through 42471), most commenters supported combining both mitigation strategies of delayed implementation of 2 years and a gradual phase-in of no more than 1 percent per year. MedPAC supported delayed implementation, but did not believe a phased-in approach was warranted given the high level of aggregate payment to SNFs. Further, MedPAC's March 2022 Report to Congress (available at *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch7_SEC.pdf*) has found that since 2000, the aggregate Medicare margin for freestanding SNFs has consistently been above 10 percent each year. In 2020, the aggregate Medicare margin was 16.5 percent, a sizable increase from 11.9 percent in 2019. Additionally, the aggregate Medicare margin in 2020 increased to an estimated 19.2 percent when including Federal relief funds for the COVID–19 PHE (March 2022 MedPAC Report to Congress, 251–252). Given these high Medicare margins, we did not believe that a delayed implementation or a phase-in approach was needed. Rather, these mitigation strategies would continue to pay facilities at levels that exceed intended SNF payments, had PDPM been implemented in a budget neutral manner as finalized by CMS in the FY 2019 SNF PPS final rule (83 FR 39256), which we cannot recoup.

It is also important to note that the parity adjustment recalibration would serve to remove an unintended increase in payments from moving to a new case mix classification system, rather than decreasing an otherwise appropriate payment amount. Thus, as we noted in section V.C.4. of the proposed rule, we did not believe that the recalibration should negatively affect facilities, beneficiaries, and quality of care, or create an undue hardship on providers.

Therefore, we proposed to recalibrate the parity adjustment in FY 2023 with no delayed implementation or phase-in period in order to allow for the most rapid establishment of payments at the appropriate level, ensuring that PDPM will be budget-neutral as intended and preventing the continued accumulation of excess SNF payments. We noted that while this proposal would lead to a prospective reduction in Medicare Part A SNF payments of approximately 4.6 percent in FY 2023, the reduction would be substantially mitigated by the proposed FY 2023 net SNF market basket update factor of 3.9 percent discussed in section III.B of the proposed rule. Taken together, we had stated that the preliminary net budget impact in FY 2023 would be an estimated decrease of $320 million in aggregate payment to SNFs if the parity adjustment is implemented in 1 year.

However, we continue to believe that in implementing PDPM, it is essential that we stabilize the baseline as quickly as possible without creating a significant adverse effect on the industry or to beneficiaries. Therefore, we solicited comments on our proposal to recalibrate the parity adjustment by 4.6 percent in FY 2023, and whether interested parties believe delayed implementation or a phase-in period are warranted, in light of the data analysis and policy considerations presented previously. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments in support of the proposed parity adjustment with no phase-in period. The commenters indicated that the SNF industry has been on notice for a year that an additional reduction to the payment rates would be necessary to maintain budget neutrality and noted that the parity adjustment of 4.6 percent proposed for FY 2023 was smaller than the SNF industry might have expected, given CMS's initial estimate of 5 percent in the FY 2022 SNF PPS proposed rule (86 FR 19988). The commenters also stated that no phase-in period is warranted in FY 2023 as, based on CMS' final calculations, it has overpaid the industry about 4.6 percent per year since the PDPM was implemented in FY 2020, or approximately $5 billion over FY 2020, FY 2021, and FY 2022.

Response: We appreciate these comments and agree that the SNF industry was made aware of the potential for CMS to implement parity adjustment in prior rulemaking.

Comment: The majority of commenters strongly objected to implementing the 4.6 percent adjustment all in 1 year, instead requesting that CMS implement a mitigation strategy of phasing the parity adjustment in over a number of years, with the majority requesting a 3-year phase-in period and a significant number requesting a 2- to 3-year phase-in period. Some commenters requested a 1-year delay combined with a 4- to 5-year phase-in period of no more than 1 percent of the parity adjustment implemented per year.

The commenters stated that a phased-in approach would assure some predictability and stability to the SNF industry by making a negative net annual update less likely to occur each

year of the phase-in. The commenters pointed to several reasons why the SNF industry could not withstand a negative payment adjustment at this time. Many commenters stated that their facilities are still facing financial difficulties due to the ongoing COVID–19 PHE, with decreased census numbers, the continued need to purchase PPE, and the discontinuation of CARES Act Provider Relief funds. Many commenters also pointed to the unfavorable current economic climate with inflation at above 8 percent and historically high fuel prices, which they did not believe were adequately accounted for in the market basket. Finally, the majority of commenters pointed to the high cost of labor, resulting in staffing shortages as healthcare workers opt for other healthcare or non-healthcare settings offering higher pay.

Response: We appreciate the comments raised on the potential impact on providers of finalizing this adjustment with no delay or phase-in period. We acknowledge the concerns raised about financial difficulties due to the ongoing COVID–19 PHE and due to the current economic climate. The parity adjustment addresses the transition between case-mix classification models (in this case, from RUG–IV to PDPM) and is not intended to include other unrelated SNF policies such as the market basket increase, which is intended to capture the change over time in the prices of skilled nursing facility services.

As stated in section V.C.4. of the proposed rule, we believe that it is essential to stabilize the baseline budget without creating a significant adverse effect on SNFs. While we understand the comments raised on the potential financial impact on providers of finalizing this adjustment with less than a 3-year phase-in period, we believe that it would be best to implement this adjustment as soon as possible in order to maintain budget neutrality in the SNF payment system. We remind commenters that, in the FY 2022 SNF PPS final rule, we stated it would be imperative to act in a well-considered but expedient manner once excess payments are identified (86 FR 42471).

However, we also recognize that the ongoing COVID–19 PHE provides a basis for taking a more cautious approach in order to mitigate the potential negative impacts on providers, such as the potential for facility closures or disproportionate impacts on rural and small facilities. Given this, we believe that it would be appropriate to implement a phased-in approach to recalibrating the PDPM parity adjustment. Therefore, after considering these comments, and in order to balance mitigating the financial impact on providers of recalibrating the PDPM parity adjustment with ensuring accurate Medicare Part A SNF payments, we are finalizing the proposed recalibration of the PDPM parity adjustment with a 2-year phase-in period, resulting in a 2.3 percent reduction in FY 2023 ($780 million) and a 2.3 percent reduction in FY 2024.

D. Request for Information: Infection Isolation

Under the SNF PPS, various patient characteristics are used to classify patients in Medicare-covered SNF stays into payment groups. One of these characteristics is isolation due to an active infection. In order for a patient to qualify to be coded as being isolated for an active infectious disease, the patient must meet all of the following criteria:

1. The patient has active infection with highly transmissible or epidemiologically significant pathogens that have been acquired by physical contact or airborne or droplet transmission.
2. Precautions are over and above standard precautions. That is, transmission-based precautions (contact, droplet, and/or airborne) must be in effect.
3. The patient is in a room alone because of active infection and cannot have a roommate. This means that the resident must be in the room alone and not cohorted with a roommate regardless of whether the roommate has a similar active infection that requires isolation.
4. The patient must remain in his or her room. This requires that all services be brought to the resident (for example, rehabilitation, activities, dining, etc.).

Being coded for infection isolation can have a significant impact on the Medicare payment rate for a patient's SNF stay. The increase in a SNF patient's payment rate as a result of being coded under infection isolation is driven by the increase in the relative costliness of treating a patient who must be isolated due to an infection. More specifically, in 2005, we initiated a national nursing home staff time measurement (STM) study, the Staff Time and Resource Intensity Verification (STRIVE) Project. The STRIVE project was the first nationwide time study for nursing homes in the United States to be conducted since 1997, and the data collected were used to establish payment systems for Medicare skilled nursing facilities (SNFs) as well as Medicaid nursing facilities (NFs).

In the STRIVE project final report, titled ''Staff Time and Resource Intensity Verification Project Phase II'' section 4.8 (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/TimeStudy*), we discussed how infection isolation was categorized into the Extensive Services RUG–III category based on the high resource intensity that was required for treating patients for whom facilities would code this category on the MDS. The significant increase in payment associated with this item is intended to account for the increase in relative resource utilization and costs associated with treating a patient isolated due to an active infection, as well as the PPE and additional protocols which must be followed treating such a patient, which are significantly greater than treating patients outside of such an environment.

During the COVID–19 PHE, a number of interested parties raised concerns with the definition of ''infection isolation'', as it relates to the treatment of SNF patients being cohorted due to either the diagnosis or suspected diagnosis of COVID–19. Specifically, interested parties took issue with criterion 1, which requires that the patient have an active infection, rather than suspicion of an active infection, and criterion 3, which requires that the patient be in the room alone, rather than being cohorted with other patients. To this point, we have maintained that the definition of ''infection isolation'' is appropriate and should not be changed in response to the circumstances of the COVID–19 PHE. Due to the ubiquitous nature of the PHE and precautions that are being taken throughout SNFs with regard to PPE and other COVID–19 related needs, we understand that the general costs for treating all SNF patients may have increased. However, as the case-mix classification model is intended to adjust payments based on relative differences in the cost of treating different SNF patients, we are unclear on if the relative increase in resource intensity for each patient being treated within a cohorted environment is the same relative increase as it would be for treating a single patient isolated due to an active infection.

We invited the public to submit their comments about isolation due to active infection and how the PHE has affected the relative staff time resources necessary for treating these patients. Specifically, we invited comments on whether or not the relative increase in resource utilization for each of the patients within a cohorted room, all with an active infection, is the same or

comparable to that of the relative increase in resource utilization associated with a patient that is isolated due to an active infection. We received public comments on this request for information. The following is a summary of the comments we received and our responses.

Comment: We received several comments on this request for information. Commenters suggested that criterion 1 and criterion 3 above should be revised. More specifically, commenters recommended that criterion 1 be revised to allow for ''suspected,'' rather than only active, cases of infection. Additionally, commenters recommended that criterion 3 be revised to allow providers to code infection isolation in cases where patients are cohorted due to an active infection. These commenters provided evidence to suggest that the costs of caring for cohorted patients are similar to those of a patient that is isolated due to active infection. Some commenters further suggested that CMS consider adding items to the MDS that would allow coding for cohorted patients, with the possibility of a lower CMI adjustment for such patients, as compared to those in full isolation. Some commenters also recommended revisions to the MDS manual and coding guidance to ensure that coding for infection isolation is consistent with CDC guidance. Finally, some commenters suggested that CMS consider a new time study to evaluate the cost of treating cohorted patients isolated with an active infection.

Response: We appreciate the comments that we received on this request for information and will consider these comments as we plan for future rulemaking on this issue.

VII. Skilled Nursing Facility Quality Reporting Program (SNF QRP)

A. Background and Statutory Authority

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act, and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-critical access hospital (CAH) swing-bed rural hospitals. Section 1888(e)(6)(A)(i) of the Act requires the Secretary to reduce by 2 percentage points the annual market basket percentage update described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year, after application of section 1888(e)(5)(B)(ii) of the Act (the productivity adjustment) and section 1888(e)(5)(B)(iii) of the Act, in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for that fiscal year. For more information on the requirements we have adopted for the SNF QRP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429), FY 2017 SNF PPS final rule (81 FR 52009 through 52010), FY 2018 SNF PPS final rule (82 FR 36566 through 36605), FY 2019 SNF PPS final rule (83 FR 39162 through 39272), and FY 2020 SNF PPS final rule (84 FR 38728 through 38820).

B. General Considerations Used for the Selection of Measures for the SNF QRP

For a detailed discussion of the considerations we use for the selection of SNF QRP quality, resource use, or other measures, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431).

1. Quality Measures Currently Adopted for the FY 2023 SNF QRP

The SNF QRP currently has 15 measures for the FY 2023 SNF QRP, which are outlined in Table 15. For a discussion of the factors used to evaluate whether a measure should be removed from the SNF QRP, we refer readers to § 413.360(b)(3).

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TABLE 15: Quality Measures Currently Adopted for the FY 2023 SNF QRP

Short Name	Measure Name & Data Source
Resident Assessment Instrument Minimum Data Set (Assessment-Based)	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment/Care Plan	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility Score	Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care Score	Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
TOH-Provider*	Transfer of Health (TOH) Information to the Provider Post-Acute Care (PAC).
TOH-Patient*	Transfer of Health (TOH) Information to the Patient Post-Acute Care (PAC).
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) (NQF #3481).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
SNF HAI	SNF Healthcare-Associated Infections (HAI) Requiring Hospitalization
NHSN	
HCP COVID-19 Vaccine	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

*In response to the public health emergency (PHE) for the Coronavirus Disease 2019 (COVID-19), CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for collection and reporting of the Transfer of Health (TOH) Information measures for at least 2 full fiscal years after the end of the PHE.

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C. SNF QRP Quality Measures Beginning With the FY 2025 SNF QRP

Section 1899B(h)(1) of the Act permits the Secretary to remove, suspend, or add quality measures or resource use or other measures described in sections 1899B(c)(1) and (d)(1) of the Act, respectively, so long as the Secretary publishes in the **Federal Register** (with a notice and comment period) a justification for such removal, suspension, or addition. Section 1899B(a)(1)(B) of the Act requires that all of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act (including resource use or other measure data under section 1899B(d)(1) of the Act) be standardized and interoperable to allow for the exchange of the information among post-acute care (PAC) providers and other providers and the use by such providers of such data to enable access to longitudinal information and to facilitate coordinated care.

We proposed to adopt one new measure for the SNF QRP beginning with the FY 2025 SNF QRP: the Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431) measure as an ''other measure'' under section 1899B(d)(1) of the Act. In accordance with section 1899B(a)(1)(B) of the Act, the data used to calculate this measure are standardized and interoperable. As proposed, the measure supports the ''Preventive Care'' Meaningful Measure area and the ''Promote Effective Prevention and Treatment of Chronic Disease'' healthcare priority.[9] The Influenza Vaccination Coverage among HCP measure (the HCP Influenza Vaccine measure) is a process measure, developed by the Centers for Disease Control and Prevention (CDC), and reports on the percentage of HCP who receive the influenza vaccination. This measure is currently used in other post-acute care (PAC) Quality Reporting Programs (QRPs), including the Inpatient Rehabilitation Facility (IRF) QRP and the Long-Term Care Hospital (LTCH) QRP. The measure is described in more detail in section VII.C.1. of this final rule.

In addition, we proposed to revise the compliance date for the collection of the Transfer of Health (TOH) Information to the Provider-PAC measure, the TOH Information to the Patient-PAC measure, and certain standardized patient assessment data elements from October 1st of the year that is at least 2 full fiscal

[9] CMS Measures Inventory Tool. (2022). Influenza Vaccination Coverage among Healthcare Personnel. Retrieved from *https://cmit.cms.gov/CMIT_public/ReportMeasure?measureId=854.*

years after the end of the COVID–19 PHE to October 1, 2023. We believe the COVID–19 PHE revealed why the TOH Information measures and standardized patient assessment data elements are important to the SNF QRP. The new data elements will facilitate communication and coordination across care settings as well as provide information to support our mission of analyzing the impact of the COVID–19 PHE on patients to improve the quality of care in SNFs. We described the proposal in more detail in section VI.C.2. of the proposed rule.

We also proposed to make certain revisions to regulation text at § 413.360 to include a new paragraph to reflect all the data completion thresholds required for SNFs to meet the compliance threshold for the annual payment update (APU), as well as certain conforming revisions. We described the proposal in more detail in section VI.C.3. of the proposed rule.

1. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) Measure Beginning With the FY 2025 SNF QRP

a. Background

The CDC Advisory Committee on Immunization Practices (ACIP) recommends that all persons 6 months of age and older, including HCP and persons training for professions in healthcare, should be vaccinated annually against influenza.[10] The basis of this recommendation stems from the spells of illness, hospitalizations, and mortality associated with the influenza virus. Between 2010 and 2020, the influenza virus resulted in 12,000 to 52,000 deaths in the United States each year, depending on the severity of the strain.[11] [12] Preliminary estimates from the CDC revealed 35 million cases, 380,000 hospitalizations, and 20,000 deaths linked to influenza in the United States during the 2019 to 2020 influenza season.[13] Persons aged 65 years and older are at higher risk for experiencing burdens related to severe influenza due to the changes in immune defenses that come with increasing age.[14] [15] The CDC estimates that 70 to 85 percent of seasonal influenza-related deaths occur among people aged 65 years and older, and 50 to 70 percent of influenza-related hospitalizations occur among this age group.[16] Residents of long-term care facilities, who are often of older age, have greater susceptibility for acquiring influenza due to general frailty and comorbidities, close contact with other residents, interactions with visitors, and exposure to staff who rotate between multiple facilities.[17] [18] [19] Therefore, monitoring and reporting influenza vaccination rates among HCP is important as HCP are at risk for acquiring influenza from residents and exposing influenza to residents.[20] For example, one early report of HCP influenza infections during the 2009 H1N1 influenza pandemic estimated 50 percent of HCP had contracted the influenza virus from patients or coworkers within the healthcare setting.[21]

Despite the fact that influenza commonly spreads between HCP and SNF residents, vaccine hesitancy and organizational barriers often prevent influenza vaccination. For example, although the CDC emphasizes the importance for HCP to receive the influenza vaccine, the 2017 to 2018 influenza season shows higher influenza vaccination coverage among HCP working in hospitals (approximately 92 percent) and lower coverage among those working in long-term care facilities (approximately 68 percent).[22] [23] HCP working in long-term care facilities, including SNFs, have expressed concerns about the influenza vaccine's effectiveness and safety, fearing potential side effects and adverse reactions.[24] Other HCP believe healthy individuals are not susceptible to infection and therefore find vaccination unnecessary.[25] In addition, many HCP do not prioritize influenza vaccination, expressing a lack of time to get vaccinated.[26] Lower HCP influenza vaccination in long-term care facilities also stems from organizational barriers,

[10] Grohskopf, L.A., Alyanak, E., Broder, K.R., Walter, E.B., Fry, A.M., & Jernigan, D.B. (2019). Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2019–20 Influenza Season. *MMWR Recommendations and Reports,* 68(No. RR–3), 1–21. *https://www.cdc.gov/mmwr/volumes/68/rr/rr6803a1.htm?s_cid=rr6803a1_w.*

[11] Centers for Disease Control and Prevention (CDC). (2021). Disease Burden of Flu. Retrieved from *https://www.cdc.gov/flu/about/burden/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fflu%2Fabout%2Fdisease%2Fus_flu-related_deaths.htm.*

[12] Frentzel, E., Jump, R., Archbald-Pannone, L., Nace, D.A., Schweon, S.J., Gaur, S., Naqvi, F., Pandya, N., Mercer, W., & Infection Advisory Subcommittee of AMDA, The Society for Post-Acute and Long-Term Care Medicine (2020). Recommendations for Mandatory Influenza Vaccinations for Health Care Personnel From AMDA's Infection Advisory Subcommittee. *Journal of the American Medical Directors Association,* 21(1), 25–28.e2. *https://doi.org/10.1016/j.jamda.2019.11.008.*

[13] Centers for Disease Control and Prevention (CDC). (2021). Estimated Flu-Related Illnesses, Medical Visits, Hospitalizations, and Deaths in the United States—2019–2020 Flu Season. Retrieved from *https://www.cdc.gov/flu/about/burden/2019-2020.html.*

[14] Centers for Disease Control and Prevention (CDC). (2021). Retrieved from Flu & People 65 Years and Older: *https://www.cdc.gov/flu/highrisk/65over.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fflu%2Fabout%2Fdisease%2F65over.htm.*

[15] Frentzel, E., Jump, R., Archbald-Pannone, L., Nace, D.A., Schweon, S.J., Gaur, S., Naqvi, F., Pandya, N., Mercer, W., & Infection Advisory Subcommittee of AMDA, The Society for Post-Acute and Long-Term Care Medicine (2020). Recommendations for Mandatory Influenza Vaccinations for Health Care Personnel From AMDA's Infection Advisory Subcommittee. *Journal of the American Medical Directors Association,* 21(1), 25–28.e2. *https://doi.org/10.1016/j.jamda.2019.11.008.*

[16] Centers for Disease Control and Prevention (CDC). (2021). Retrieved from Flu & People 65 Years and Older: *https://www.cdc.gov/flu/highrisk/65over.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fflu%2Fabout%2Fdisease%2F65over.htm.*

[17] Lansbury, L.E., Brown, C.S., & Nguyen-Van-Tam, J.S. (2017). Influenza in long-term care facilities. *Influenza Other Respir Viruses,* 11(5), 356–366. *https://dx.doi.org/10.1111%2Firv.12464.*

[18] Pop-Vicas, A., & Gravenstein, S. (2011). Influenza in the elderly: a mini-review. *Gerontology,* 57(5), 397–404. *https://doi.org/10.1159/000319033.*

[19] Strausbaugh, L.J., Sukumar, S.R., & Joseph, C.L. (2003). Infectious disease outbreaks in nursing homes: an unappreciated hazard for frail elderly persons. *Clinical Infectious Diseases,* 36(7), 870–876. *https://doi.org/10.1086/368197.*

[20] Wilde, J.A., McMillan, J.A., Serwint, J., Butta, J., O'Riordan, M.A., & Steinhoff, M.C. (1999). Effectiveness of influenza vaccine in health care professionals: a randomized trial. *JAMA,* 281(10), 908–913. *https://doi.org/10.1001/jama.281.10.908.*

[21] Harriman, K., Rosenberg, J., Robinson, S., et al. (2009). Novel influenza A (H1N1) virus infections among health-care personnel—United States, April-May 2009. *MMWR Morbidity and Mortality Weekly Report,* 58(23), 641–645. Retrieved from *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5823a2.htm.*

[22] Black, C.L., Yue, X., Ball, S.W., Fink, R.V., de Perio, M.A., Laney, A.S., Williams, W.W., Graitcer, S.B., Fiebelkorn, A.P., Lu, P.J., & Devlin, R. (2018). Influenza Vaccination Coverage Among Health Care Personnel—United States, 2017–18 Influenza Season. MMWR *Morbidity and Mortality Weekly Report,* 67(38), 1050–1054. *https://doi.org/10.15585/mmwr.mm6738a2.*

[23] Jaklevic, M.C. (2020). Flu Vaccination Urged During COVID–19 Pandemic. *JAMA.* 324(10), 926–927. *https://doi.org/10.1001/jama.2020.15444.*

[24] Frentzel, E., Jump, R., Archbald-Pannone, L., Nace, D.A., Schweon, S.J., Gaur, S., Naqvi, F., Pandya, N., Mercer, W., & Infection Advisory Subcommittee of AMDA, The Society for Post-Acute and Long-Term Care Medicine (2020). Recommendations for Mandatory Influenza Vaccinations for Health Care Personnel From AMDA's Infection Advisory Subcommittee. *Journal of the American Medical Directors Association,* 21(1), 25–28.e2. *https://doi.org/10.1016/j.jamda.2019.11.008.*

[25] Kenny, E., McNamara, Á., Noone, C., & Byrne, M. (2020). Barriers to seasonal influenza vaccine uptake among health care workers in long-term care facilities: A cross-sectional analysis. *British Journal of Health Psychology,* 25(3), 519–539. *https://doi.org/10.1111/bjhp.12419.*

[26] Kose, S., Mandiracioglu, A., Sahin, S., Kaynar, T., Karbus, O., & Ozbel, Y. (2020). Vaccine hesitancy of the COVID–19 by health care personnel. *International Journal of Clinical Practice,* 75(5), e13917. *https://doi.org/10.1111/ijcp.13917.*

such as inadequate vaccine recordkeeping, frequent staff turnover, an absence of influenza vaccine mandates, a lack of communication about vaccination rates, and a lack of incentives encouraging HCP flu vaccination.[27] Given the fact that influenza vaccination coverage among HCP is typically lower in long-term care settings, such as SNFs, when compared to other care settings, we noted in the proposed rule that we believe the measure as proposed has the potential to increase influenza vaccination coverage in SNFs, promote patient safety, and increase the transparency of quality of care in the SNF setting.

Although concerns about vaccine effectiveness often prevent some HCP from getting the influenza vaccine, the CDC notes that higher influenza vaccination rates reduce the risk of influenza-related illness between 40 to 60 percent among the overall population during seasons when the circulating influenza virus is well-matched to viruses used to make influenza vaccines.[28] During the 2019 to 2020 influenza season, vaccinations prevented 7.5 million influenza-related illnesses, 105,000 influenza-related hospitalizations, and 6,300 deaths.[29] Additionally, among adults with influenza-associated hospitalization, influenza vaccination is also associated with a 26 percent lower risk of intensive care unit admission, and a 31 percent lower risk of influenza-related deaths compared to individuals who were unvaccinated against influenza.[30] Several cluster-randomized trials comparing HCP influenza vaccination groups to control groups demonstrate reductions in long-term care resident mortality rates as related to HCP influenza vaccination.[31 32 33 34] To reduce vaccine hesitancy and organizational barriers to influenza vaccination, several strategies can be used to increase influenza vaccination among HCP. These include availability of on-site influenza vaccinations and educational campaigns about influenza risks and vaccination benefits.[35 36 37]

Addressing HCP influenza vaccination in SNFs is particularly important as vulnerable populations often reside in SNFs. Vulnerable populations are less likely to receive the influenza vaccine, and thus, are susceptible to contracting the virus. For example, not only are Black residents more likely to receive care from facilities with lower overall influenza vaccination rates, but Black residents are also less likely to be offered and receive influenza vaccinations in comparison to White residents.[38 39 40 41] Racial and ethnic disparities in influenza vaccination, specifically among Black and Hispanic populations, are also higher among short-stay residents receiving care for less than 100 days in the nursing home.[42] Additionally, Medicare fee-for-service beneficiaries of Black, Hispanic, rural, and lower-income populations are less likely to receive inactivated influenza vaccines, and non-White beneficiaries are generally less likely to receive high-dose influenza vaccines in comparison to White beneficiaries.[43 44 45] Therefore, the measure as proposed has the potential to increase influenza vaccination coverage of HCP in SNFs, as well as prevent the spread of the influenza virus to vulnerable populations who are less likely to receive influenza vaccinations.

The COVID–19 pandemic has exposed the importance of implementing infection prevention strategies, including the promotion of HCP influenza vaccination. Activity of the influenza virus has been lower during the COVID–19 pandemic as several strategies to reduce the spread of COVID–19 have also reduced the spread of influenza, including mask mandates, social distancing, and increased hand

[27] Ofstead, C.L., Amelang, M.R., Wetzler, H.P., & Tan, L. (2017). Moving the needle on nursing staff influenza vaccination in long-term care: Results of an evidence-based intervention. *Vaccine,* 35(18), 2390–2395. *https://doi.org/10.1016/j.vaccine.2017.03.041.*

[28] Centers for Disease Control and Prevention (CDC). (2021). Retrieved from Vaccine Effectiveness: How Well Do Flu Vaccines Work?: *https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm.*

[29] Centers for Disease Control and Prevention (CDC). (2021). Retrieved from Vaccine Effectiveness: How Well Do Flu Vaccines Work?: *https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm.*

[30] Ferdinands, J.M., Thompson, M.G., Blanton, L., Spencer, S., Grant, L., & Fry, A.M. (2021). Does influenza vaccination attenuate the severity of breakthrough infections? A narrative review and recommendations for further research. *Vaccine,* 39(28), 3678–3695. *https://doi.org/10.1016/j.vaccine.2021.05.011.*

[31] Carman, W.F., Elder, A.G., Wallace, L.A., McAulay, K., Walker, A., Murray, G.D., & Stott, D.J. (2000). Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. *Lancet (London, England), 355*(9198), 93–97. *https://doi.org/10.1016/S0140-6736(99)05190-9.*

[32] Hayward, A.C., Harling, R., Wetten, S., Johnson, A.M., Munro, S., Smedley, J., Murad, S., & Watson, J.M. (2006). Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *BMJ (Clinical Research ed.), 333*(7581), 1241. *https://doi.org/10.1136/bmj.39010.581354.55.*

[33] Lemaitre, M., Meret, T., Rothan-Tondeur, M., Belmin, J., Lejonc, J.L., Luquel, L., Piette, F., Salom, M., Verny, M., Vetel, J.M., Veyssier, P., & Carrat, F. (2009). Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. *Journal of the American Geriatrics Society, 57*(9), 1580–1586. *https://doi.org/10.1111/j.1532-5415.2009.02402.x.*

[34] Potter, J., Stott, D.J., Roberts, M.A., Elder, A.G., O'Donnell, B., Knight, P.V., & Carman, W.F. (1997). Influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. *Journal of Infectious Diseases, 175*(1), 1–6. *https://doi.org/10.1093/infdis/175.1.1.*

[35] Bechini, A., Lorini, C., Zanobini, P., Mandò Tacconi, F., Boccalini, S., Grazzini, M., Bonanni, P., & Bonaccorsi, G. (2020). Utility of Healthcare System-Based Interventions in Improving the Uptake of Influenza Vaccination in Healthcare Workers at Long-Term Care Facilities: A Systematic Review. *Vaccines (Basel),* 8(2), 165. *https://doi.org/10.3390/vaccines8020165.*

[36] Ofstead, C.L., Amelang, M.R., Wetzler, H.P., & Tan, L. (2017). Moving the needle on nursing staff influenza vaccination in long-term care: Results of an evidence-based intervention. *Vaccine,* 35(18), 2390–2395. *https://doi.org/10.1016/j.vaccine.2017.03.041.*

[37] Yue, X., Black, C., Ball, S., Donahue, S., de Perio, M.A., Laney, A.S., & Greby, S. (2019). Workplace Interventions and Vaccination-Related Attitudes Associated With Influenza Vaccination Coverage Among Healthcare Personnel Working in Long-Term Care Facilities, 2015–2016 Influenza Season. *Journal of the American Medical Directors Association,* 20(6), 718–724. *https://doi.org/10.1016/j.jamda.2018.11.029.*

[38] Cai, S., Feng, Z., Fennell, M.L., & Mor, V. (2011). Despite small improvement, black nursing home residents remain less likely than whites to receive flu vaccine. *Health Affairs (Project Hope),* 30(10), 1939–1946. *https://doi.org/10.1377/hlthaff.2011.0029.*

[39] Luo, H., Zhang, X., Cook, B., Wu, B., & Wilson, M.R. (2014). Racial/Ethnic Disparities in Preventive Care Practice Among U.S. Nursing Home Residents. *Journal of Aging and Health,* 26(4), 519–539. *https://doi.org/10.1177/0898264314524436.*

[40] Mauldin, R.L., Sledge, S.L., Kinney, E.K., Herrera, S., & Lee, K. (2021). Addressing Systemic Factors Related to Racial and Ethnic Disparities among Older Adults in Long-Term Care Facilities. IntechOpen.

[41] Travers, J.L., Dick, A.W., & Stone, P.W. (2018). Racial/Ethnic Differences in Receipt of Influenza and Pneumococcal Vaccination among Long-Stay Nursing Home Residents. *Health Services Research,* 53(4), 2203–2226. *https://doi.org/10.1111/1475-6773.12759.*

[42] Riester, M.R., Bosco, E., Bardenheier, B.H., Moyo, P., Baier, R.R., Eliot, M., Silva, J.B., Gravenstein, S., van Aalst, R., Chit, A., Loiacono, M.M., & Zullo, A.R. (2021). Decomposing Racial and Ethnic Disparities in Nursing Home Influenza Vaccination. *Journal of the American Medical Directors Association,* 22(6), 1271–1278.e3. *https://doi.org/10.1016/j.jamda.2021.03.003.*

[43] Hall, L.L., Xu, L., Mahmud, S.M., Puckrein, G.A., Thommes, E.W., & Chit, A. (2020). A Map of Racial and Ethnic Disparities in Influenza Vaccine Uptake in the Medicare Fee-for-Service Program. *Advances in Therapy,* 37(5), 2224–2235. *https://doi.org/10.1007/s12325-020-01324-y.*

[44] Inactivated vaccines use the killed version of the germ that causes a disease. Inactivated vaccines usually don't provide immunity (protection) that is as strong as the live vaccines. For more information regarding inactivated vaccines we refer readers to the following web page: *https://hhs.gov/immunization/basics/types/index.html.*

[45] High-dose flu vaccines contain four times the amount of antigen (the inactivated virus that promotes a protective immune response) as a regular flu shot. They are associated with a stronger immune response following vaccination. For more information regarding high-dose flu vaccines, we refer readers to the following web page: *https://www.cdc.gov/flu/highrisk/65over.htm.*

hygiene.[46] However, even though more people are receiving COVID–19 vaccines, it is still important to encourage annual HCP influenza vaccination to prevent healthcare systems from getting overwhelmed by the co-circulation of COVID–19 and influenza viruses. A 2020 literature search revealed several studies in which those with severe cases of COVID–19, requiring hospitalization, were less likely to be vaccinated against influenza.[47] HCP vaccinations against influenza may prevent the spread of illness between HCP and residents, thus reducing resident morbidities associated with influenza and pressure on already stressed healthcare systems. In fact, several thousand nursing homes voluntarily reported weekly influenza vaccination coverage through a National Healthcare Safety Network (NHSN) module based on the NQF #0431 measure during the overlapping 2020 to 2021 influenza season and COVID–19 pandemic. Even after the COVID–19 pandemic ends, promoting HCP influenza vaccination is important in preventing morbidity and mortality associated with influenza.

As discussed in the proposed rule, variation in influenza vaccination coverage rates indicate the proposed measure's usability and use. A CDC analysis during the 2020 to 2021 influenza season revealed that among 16,535 active, CMS-certified nursing homes, 17.3 percent voluntarily submitted data for the proposed measure through the NHSN. Average staff influenza vaccination coverage was approximately 64 percent, ranging from 0.3 percent to 100 percent with an interquartile range of 40 to 93.9 percent. Variation in influenza vaccination coverage rates by facility demonstrates the utility of the measure for resident choice of facility. Variation in influenza vaccination rates by type of HCP demonstrates the utility of the proposed measure for targeted quality improvement efforts.

For these reasons, we proposed to adopt the CDC-developed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure for the SNF QRP, as collected through the CDC's NHSN, to report the percentage of HCP who receive the influenza vaccine. We explained in the proposed rule that we believe this measure will encourage HCP to receive the influenza vaccine, resulting in fewer cases, less hospitalizations, and lower mortality associated with the virus.

b. Stakeholder Input and Pilot Testing

In the development and specification of this measure, a transparent process was employed to seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input in accordance with section 1890A of the Act. To meet this requirement, opportunities were provided for stakeholder input by a Delphi panel and Steering Committee through the measure's pilot testing. The measure's pilot testing assessed reliability and validity among 234 facilities and five facility types (that is, long-term care facilities, acute care hospitals, ambulatory surgery centers, physician practices, and dialysis centers) across four jurisdictions (that is, California, New Mexico, New York City, and western Pennsylvania) between 2010 and 2011.[48] [49]

Two methods were used to conduct reliability testing, including interrater reliability testing and the use of case studies. Interrater reliability was assessed among 96 facilities, including 19 long-term care facilities, by comparing agreement between two raters: facility staff and project staff. Project staff reviewed individual-level records from randomly selected facilities to assess agreement with how facility staff classified HCP into numerator and denominator categories. For more information regarding numerator and denominator definitions, refer to section VI.C.1.e. of the proposed rule. Interrater reliability results demonstrated high adjusted agreement between facility and project staff for numerator data (91 percent) and denominator data (96 percent). Most numerator disagreements resulted from healthcare facilities reporting verbal declinations in the ''declined vaccination'' numerator rather than categorizing verbal declinations as ''missing/unknown'' as there was no written documentation of the declination. There was also numerator disagreement related to contraindications as HCP did not properly cite true medical contraindications. Adhering to true medical contraindications and tracking declinations of the influenza vaccine among HCP should additionally improve reliability.

Case studies were also used to assess reliability. Facilities received a series of 23 vignettes, in which they were instructed to select appropriate numerator and denominator categories for the hypothetical cases described in each vignette. Most numerator and denominator elements were categorized correctly. For example, 95.6 percent of facility staff correctly categorized employees that were vaccinated at the facility, 88.6 percent correctly categorized employees vaccinated elsewhere, etc.[50] However, problematic denominator elements included poor facility understanding of how to classify physician-owners of healthcare facilities who work part-time and physicians who were credentialed by a facility but had not admitted patients in the past 12 months. Problematic numerator elements were related to confusion about reporting persistent deferrals of vaccination and verbal vaccine declinations for non-medical reasons.

Two methods were also used for validity testing: convergent validity assessments and face validity assessment. Convergent validity examined the association between the number of evidence-based strategies used by a healthcare facility to promote influenza vaccination and the facility's reported vaccination rate among each HCP denominator group. The association between employee vaccination rates and the number of strategies used was borderline significant. The association between credentialed non-employee vaccination rates and the number of strategies used was significant, and the association between other non-employee vaccination rates and the number of strategies used was also significant, demonstrating convergent validity.

Face validity was assessed through a Delphi panel, which convened in June 2011 and provided stakeholder input on the proposed measure. The Delphi

[46] Wang, X., Kulkarni, D., Dozier, M., Hartnup, K., Paget, J., Campbell, H., Nair, H., & Usher Network for COVID–19 Evidence Reviews (UNCOVER) group (2020). Influenza vaccination strategies for 2020–21 in the context of COVID–19. *Journal of Global Health,* 10(2), 021102. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7719353/.*

[47] Del Riccio, M., Lorini, C., Bonaccorsi, G., Paget, J., & Caini, S. (2020). The Association between Influenza Vaccination and the Risk of SARS–CoV–2 Infection, Severe Illness, and Death: A Systematic Review of the Literature. *International Journal of Environmental Research and Public Health,* 17(21), 7870. *https://doi.org/10.3390/ijerph17217870.*

[48] Libby, T.E., Lindley, M.C., Lorick, S.A., MacCannell, T., Lee, S.J., Smith, C., Geevarughese, A., Makvandi, M., Nace, D.A., & Ahmed, F. (2013). Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel. *Infection Control and Hospital Epidemiology,* 34(4), 335–345. *https://doi.org/10.1086/669859.*

[49] The Libby et al. (2013) article (preceding footnote) is referenced throughout the entirety of section VI.C.1.b. of this rule.

[50] For a full list of case study categorization results, please refer to the following study: Libby, T.E., Lindley, M.C., Lorick, S.A., MacCannell, T., Lee, S.J., Smith, C., Geevarughese, A., Makvandi, M., Nace, D.A., & Ahmed, F. (2013). Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel. *Infection Control and Hospital Epidemiology,* 34(4), 335–345. *https://doi.org/10.1086/669859.*

panel, comprised of nine experts in influenza vaccination measurement and quality improvement from several public and private organizations, rated elements of the proposed measure using a Likert scale. The Delphi panel discussed pilot testing results from the first round of ratings during a one-hour moderated telephone conference. After the conference concluded, panelists individually rated a revised set of elements. Ultimately, the Delphi panel reached a consensus that the majority of the proposed measure's numerator definitions had strong face validity. However, the panel raised concerns regarding the accuracy of self-reported data and deemed validity lowest for denominator categories of credentialed and other nonemployees of the facility.

After the conclusion of measure testing, the proposed measure's specifications were revised in alignment with the Delphi panel's ratings and with guidance from a Steering Committee. The CDC-convened Steering Committee was comprised of representatives from several institutions, including CMS, the Joint Commission, the Federation of American Hospitals, the American Osteopathic Association, the American Medical Association, and others. To address concerns raised through pilot testing and to reduce institutional barriers to reporting, denominator specifications were revised to include a more limited number of HCP among whom vaccination could be measured with greater reliability and accuracy: employees; licensed independent practitioners; and adult students/trainees and volunteers. The measure was also revised to require vaccinations received outside of the facility to be documented, but allow for self-report of declinations and medical contraindications. Verbal declinations were assigned to the ''declined'' numerator category, and an ''unknown'' category was added to give facilities actionable data on unvaccinated HCP who may not have purposefully declined. For more information regarding pilot testing results and measure input from the Delphi panel and Steering Committee, refer to the article published in the Infection Control & Hospital Epidemiology journal by the measure developer.[51]

c. Measure Applications Partnership (MAP) Review

Our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures under Consideration (MUC) List that the Secretary is considering adopting through the Federal rulemaking process for use in Medicare programs. This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included in the list.

We included the Influenza Vaccination Coverage among HCP measure under the SNF QRP Program in the publicly available ''List of Measures Under Consideration for December 1, 2021'' (MUC List).[52] Shortly after, several National Quality Forum (NQF)-convened Measure Applications Partnership (MAP) workgroups met virtually to provide input on the proposed measure. The MAP Rural Health workgroup convened on December 8, 2021. Members generally agreed that the proposed measure would be suitable for use by rural providers within the SNF QRP program, noting the measure's rural relevance. Likewise, the MAP Health Equity workgroup met on December 9, 2021, in which the majority of voting members agreed that the proposed measure has potential for decreasing health disparities. The MAP Post-Acute Care/Long-Term Care (PAC/LTC) workgroup met on December 16, 2021, in which the majority of voting workgroup members supported rulemaking of the proposed measure. Finally, the MAP Coordinating Committee convened on January 19, 2022, in which the committee agreed with the MAP's preliminary measure recommendation of support for rulemaking.

In addition to receiving feedback from MAP workgroup and committee members, NQF received four comments by industry stakeholders during the proposed measure's MAP pre-rulemaking process. Commenters were generally supportive of the measure as SNF QRP adoption would promote measure interoperability, encourage vaccination, and likely decrease the spread of infection. One commenter was not supportive of the measure due to burdens of NHSN data submission.

Overall, the MAP offered support for rulemaking, noting that the measure aligns with the IRF and LTCH PAC QRPs and adds value to the current SNF QRP measure set since influenza vaccination among HCP is not currently addressed within the SNF QRP program. The MAP noted the importance of vaccination coverage among HCP as an actionable strategy that can decrease viral transmission, morbidity, and mortality within SNFs. The final MAP report is available at *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

d. Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, each measure specified under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a) of the Act, currently the NQF. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed Influenza Vaccination Coverage among HCP measure initially received NQF endorsement in 2008 as NQF #0431. Measure endorsement was renewed in 2017, and the measure is due for maintenance in the spring 2022 cycle. The measure was originally tested in nursing homes and has been endorsed by NQF for use in nursing home settings since the measure was first endorsed. No additional modifications were made to the proposed measure for the spring 2022 measure maintenance cycle, but as noted in section VI.C.1.a. of the proposed rule, several thousand nursing homes voluntarily reported weekly influenza vaccination coverage through an NHSN module based on the NQF #0431 measure during the overlapping 2020 to 2021 influenza season and COVID–19 pandemic. The measure is currently used in several of our programs, including the Hospital Inpatient and Prospective Payment System (PPS)-Exempt Cancer Hospital QRPs. Among PAC programs, the proposed measure is also reported in the IRF and LTCH QRPs as adopted in the FY 2014 IRF PPS final rule (78 FR 47905 through 47906) and the FY 2013 Inpatient Prospective Payment System (IPPS)/LTCH PPS final rule (77 FR 53630 through 53631), respectively.

[51] Libby, T.E., Lindley, M.C., Lorick, S.A., MacCannell, T., Lee, S.J., Smith, C., Geevarughese, A., Makvandi, M., Nace, D.A., & Ahmed, F. (2013). Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel. *Infection Control and Hospital Epidemiology,* 34(4), 335–345. *https://doi.org/10.1086/669859.*

[52] Centers for Medicare & Medicaid Services. (2021). List of Measures Under Consideration for December 1, 2021. *CMS.gov. https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf.*

After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF-endorsed measures for SNFs focused on capturing influenza vaccinations among HCP. For example, although the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) and the Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (Long Stay) (NQF #0681) measures are both NQF-endorsed and assess rates of influenza vaccination, they assess vaccination rates among residents in the nursing home rather than HCP in the SNF. Additionally, the Percent of Programs of All-Inclusive Care for the Elderly (PACE) Healthcare Personnel with Influenza Immunization measure resembles the proposed measure since it assesses influenza vaccination among HCP; however, it is not NQF-endorsed and is not specific to the SNF setting.

Therefore, after consideration of other available measures, we found the NQF-endorsed Influenza Vaccination Coverage among HCP measure appropriate for the SNF QRP, and we proposed the measure beginning with the FY 2025 SNF QRP. Application of the Influenza Vaccination Coverage among HCP measure within the SNF QRP promotes measure harmonization across quality reporting programs that also report this measure. This proposed measure has the potential to generate actionable data on vaccination rates that can be used to target quality improvement among SNF providers.

e. Quality Measure Calculation

The Influenza Vaccination Coverage among HCP measure is a process measure developed by the CDC to track influenza vaccination coverage among HCP in facilities such as SNFs. The measure reports on the percentage of HCP who receive influenza vaccination. The term ''healthcare personnel'' refers to all paid and unpaid persons working in a healthcare setting, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. As explained in the proposed rule, since the proposed measure is a process measure, rather than an outcome measure, it does not require risk-adjustment.

The proposed measure's denominator is the number of HCP who are physically present in the healthcare facility for at least 1 working day between October 1st and March 31st of the following year, regardless of clinical responsibility or patient contact. The proposed measure's reporting period is October 1st through March 31st; this reporting period refers to the proposed measure's denominator only. The denominator would be calculated separately for three required categories: Employees, meaning all persons who receive a direct paycheck from the reporting facility (that is, on the SNF's payroll); Licensed independent practitioners,[53] such as physicians, advanced practice nurses, and physician assistants who are affiliated with the reporting facility, who do not receive a direct paycheck from the reporting facility; and Adult students/trainees and volunteers who do not receive a direct paycheck from the reporting facility. A denominator can be calculated for an optional category as well: Other contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the three required denominator categories.

The proposed measure's numerator consists of all HCP included in the denominator population who received an influenza vaccine any time from when it first became available (such as August or September) through March 31st of the following year and who fall into one of the following categories: (a) received an influenza vaccination administered at the healthcare facility; (b) reported in writing (paper or electronic) or provided documentation that an influenza vaccination was received elsewhere; (c) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or other component(s) of the vaccine, or a history of Guillain-Barré syndrome (GBS) within 6 weeks after a previous influenza vaccination; (d) were offered but declined the influenza vaccination; or (e) had an unknown vaccination status or did not meet any of the definitions of the other numerator categories (a through d). As described in the FY 2014 IRF PPS final rule, measure numerator data are required based on data collected from October 1st or whenever the vaccine becomes available.[54] Therefore, if the vaccine is available prior to October 1st, any vaccine given before October 1st is credited toward vaccination coverage. Likewise, if the vaccine becomes available after October 1st, the vaccination counts are to begin as soon as possible after October 1st.

We proposed that SNFs submit data for the measure through the CDC/NHSN data collection and submission framework.[55] In alignment with the data submission frameworks utilized for this measure in the IRF and LTCH QRPs, SNFs would use the HCP influenza data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component and complete two forms. SNFs would complete the first form (CDC 57.203) to indicate the type of data they plan on reporting to the NHSN by selecting the ''Influenza Vaccination Summary'' option under ''Healthcare Personnel Vaccination Module'' to create a reporting plan. SNFs would then complete a second form (CDC 57.214) to report the number of HCP who have worked at the healthcare facility for at least 1 day between October 1st and March 31st (denominator) and the number of HCP who fall into each numerator category. To meet the minimum data submission requirements, SNFs would enter a single influenza vaccination summary report at the conclusion of the measure reporting period. If SNFs submit data more frequently, such as on a monthly basis, the information would be used to calculate one summary score for the proposed measure which would be publicly reported on Care Compare. See sections VI.G.2. and VI.H.2. of the proposed rule for more information regarding data submission requirements for this measure and its public reporting plan. Details related to the use of NHSN for data submission can be found at the CDC's NHSN HPS Component web page at *https://www.cdc.gov/nhsn/hps/vaccination/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fnhsn%2Finpatient-rehab%2Fvaccination%2Findex.html.*

We solicited public comment on our proposal to add a new measure, Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), to the SNF QRP beginning with the FY 2025 SNF QRP. The following is a summary of the comments we received and our responses.

Comment: We received several supportive comments for our proposal to adopt the Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431) measure for the SNF QRP. Several commenters agreed that regular reporting of influenza

[53] Refer to the proposed measure's specifications in The National Healthcare Safety Network (NSHN) Manual Healthcare Personnel Safety Component Protocol—Healthcare Personnel Vaccination Module: Influenza Vaccination Summary linked at *https://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/hps-flu-vaccine-protocol.pdf* for an exhaustive list of those included in the licensed independent practitioners' definition.

[54] FY 2014 IRF PPS final rule. 78 FR 47906.

[55] Centers for Disease Control and Prevention (CDC). (2021). *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.* Healthcare Personnel Safety Component (HPS). *CDC.gov.*

vaccination rates among SNF HCP would reduce the risk of infection transmission from HCP to SNF patients. Another commenter supported the measure, noting that (1) influenza causes significant healthcare costs and mortality of elderly patients and (2) the measure provides an opportunity for nursing leaders to educate their staff and use evidence-based strategies, such as motivational interviewing, to encourage staff to adopt a behavior change that is beneficial for public health. Two facilities supported the proposal, noting that they already require employees to receive annual influenza vaccinations unless there is an appropriate medical or religious exemption. Multiple commenters supported the reporting of HCP influenza vaccination rates as it may encourage SNFs to take responsibility for supporting HCP access to recommended immunizations, incentivize facilities to adopt programs encouraging workers to receive influenza vaccines, provide additional information about a SNF's infection response and readiness efforts, and increase the transparency of quality of care among SNFs. Other commenters supported the measure for other reasons, such as the fact that it is consistent with CDC guidelines for long-term care workers, promotes alignment and consistency across PAC QRPs, and is NQF-endorsed.

Response: We believe the proposed measure will promote the health and well-being of SNF patients and HCP, and that reporting this measure will contribute to overall infection control within SNFs.

Comment: One commenter supported the measure, but expressed concern that it could create an administrative burden for community and long-term care pharmacies or consultant pharmacists within long-term care settings. The commenter pointed out staffing issues experienced by long-term care pharmacies when pharmacists leave the pharmacy to perform on-site vaccinations at the SNF.

Response: We note that the measure neither requires the influenza vaccine to be administered to HCP at SNFs, nor does it require the vaccine to be administered by a pharmacist or a long-term care pharmacy in order for HCP to be captured in the measure's numerator.[56] The influenza vaccination may either be received at the SNF or an HCP may provide written or electronic documentation that the vaccine was received elsewhere. We provide a full description of the measure numerator earlier in this section (VII.C.1.e.) of this final rule.

Comment: One commenter noted concern over payment reductions if a specified percentage of HCP are not vaccinated against influenza, and noted that SNFs are already struggling financially to overcome pandemic costs.

Response: The SNF QRP is a pay-for-reporting program, which means that SNFs are only financially penalized if they fail to comply with the QRP's data submission standards. For the HCP Influenza Vaccine measure, the data submission standard consists of one data submission per year at the conclusion of the measure reporting period. SNFs would not have to reach a particular threshold of HCP influenza vaccination among HCP to comply with measure data submission standards. Additionally, the HCP Influenza Vaccine measure would be submitted through the CDC's NHSN collection and submission framework, which is free to SNF providers. While we acknowledge the challenges the PHE has presented, we refer SNFs to section XI.A.5. of this final rule, where we estimate the measure will only require an annual cost of $9.38 per SNF for annual data submission. Because of the minimal cost associated with annual data submission and the fact that data submission requirements are not associated with vaccination thresholds, we believe that SNFs will be able to successfully meet the data submission requirements for the HCP Influenza Vaccine measure at a minimal cost.

Comment: One commenter supported CMS's increased focus on infection control but is concerned about whether the measure aligns with the Improving Medicare Post-Acute Care Transformation (IMPACT) Act. The commenter noted that the IMPACT Act requires the reporting of standardized patient assessment data, while the Influenza Vaccination Coverage among HCP measure collects HCP data rather than patient data, and therefore may not be useful to consumers.

Response: The IMPACT Act added section 1899B to the Act and requires the reporting of standardized patient assessment data with regard to quality measures and standardized patient assessment data elements.[57] The IMPACT Act does not state that quality reporting programs can only report patient-level data. The Act also requires the submission of data pertaining to quality measures, resource use, and other domains. The Influenza Vaccination Coverage among HCP measure is proposed for adoption as an ''other'' measure under section 1899B(d)(1) of the Act. In accordance with section 1899B(a)(1)(B) of the Act, the data used to calculate this measure are standardized and interoperable. A similar NHSN-based measure, COVID–19 Vaccination Coverage among HCP, was added to the SNF QRP under the same statutory authority in the FY 2022 SNF PPS final rule.[58] The statute intends for standardized PAC data to improve Medicare beneficiary outcomes through shared-decision making, care coordination, and enhanced discharge planning. As the Influenza Vaccination Coverage among HCP measure's purpose is to report HCP vaccination rates and encourage infection prevention and control within a facility, we disagree with the commenter and find the measure useful to consumers' shared decision-making processes.

Comment: Several commenters did not support the proposal to adopt the Influenza Vaccination Coverage among HCP (NQF #0431) measure due to staffing concerns. Some of these commenters noted that mandated HCP vaccination may hamper efforts to increase facility staffing levels, and one commenter questioned whether CMS intends to mandate influenza vaccination as a condition of employment at a later time. One commenter expressed concern that collecting vaccination information would invade staff's personal lives and intensify staff shortages.

Response: We disagree with the commenter that the HCP Influenza Vaccine measure may hamper efforts to increase facility staffing levels because CMS is not mandating SNF employees receive an influenza vaccine as a condition of employment. The SNF QRP is a pay-for-reporting program and the actual number of SNF HCP who have been vaccinated does not impact SNFs' ability to successfully report the measure. Additionally, hospitals, IRFs, and LTCHs have been collecting HCP influenza vaccination data for almost 10 years and have not reported to CMS that it hampers their hiring ability. In regards to privacy concerns, the NHSN HPS Component used to report HCP influenza data collects summary

[56] Centers for Disease Control and Prevention (CDC). (2021). Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. Retrieved from *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[57] Centers for Medicare & Medicaid Services (CMS). (2021). IMPACT Act of 2014 Data Standardization & Cross Setting Measures. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-Measures.*

[58] 86 FR 42424.

information and does not require SNFs to enter staff personal identifiable information.

Comment: Some commenters stated that the proposal to add the HCP Influenza Vaccine measure to the SNF QRP is an unfunded mandate. A few commenters were concerned about the amount of unfunded mandated reporting that has occurred over the course of the COVID–19 PHE, and another commenter urged CMS not to finalize new data reporting requirements during the COVID–19 PHE, because SNFs do not have the resources to manage another unfunded mandate.

Response: We acknowledge the commenters' concerns. However, we have examined the impacts of this proposed measure 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), and section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4). 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.

As required, we have considered the benefits and costs of the proposed measure. This measure would facilitate patient care and care coordination during the discharge planning process. A discharging hospital or facility, in collaboration with the patient and family, could use this measure to coordinate care and ensure patient preferences are considered in the discharge plan. Patients at high risk for negative outcomes due to influenza (perhaps due to underlying conditions) can use healthcare provider vaccination rates when they are selecting a SNF for next-level care. Additionally, the data submission method is free to SNFs, and we estimate the annual data submission will require a cost $9.38 per SNF annually. We believe we have selected an approach that maximizes net benefits.

Comment: One commenter requested that CMS consider hybrid care delivery models where staff, including, but not limited to, respiratory therapists, physical therapists, or dieticians/dietary aides, may cross between different quality reporting programs on the same campus. The commenters requested that inclusion and exclusion criteria must be clearly stated for valid comparisons.

Response: We thank the commenter for their suggestion, and will take it under consideration. Further we note that the criteria for HCP included and excluded from the HCP Influenza Vaccine measure can be found in the NHSN Healthcare Personnel Safety Component Protocol at *https://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/hps-flu-vaccine-protocol.pdf.*

Comment: Some commenters noted the importance of how the measure's denominator is defined. Specifically, two commenters suggested the measure's denominator should be modified to exclude non-employed staff, such as agency and contracted staff, and/or be limited to direct care staff in the SNF. One of these commenters noted that such modifications to the measure's denominator will better assess a SNF's ability to engage with and vaccinate its staff while not necessarily rewarding or penalizing SNFs based on vaccination coverage that may occur outside of the facility's control. Other commenters stated how CMS will define ''employee'' in reference to the measure's denominator will be significant.

Response: As described in section VII.G.2. of this final rule, the proposed measure does not require SNFs to report all facility contract personnel. The proposed measure requires vaccination information to be reported for three required categories of HCP who are physically present in the healthcare facility for at least 1 working day within the measure's data collection period. Healthcare personnel captured in the measure's denominator include: (1) employees of the SNF (or those who receive a direct paycheck from the reporting facility), (2) licensed independent practitioners (including MD, DO, advanced practice nurses, physician assistants, and post-residency fellows affiliated with the reporting facility, but who are not directly employed by the facility), and (3) adult students/trainees and volunteers regardless of clinical responsibility or patient contact. SNFs are not required (but have the option) to report influenza vaccination status on other contract personnel. Since the SNF QRP is a pay-for-reporting program, SNFs are not rewarded or penalized based on the rate of HCP vaccination. While CMS acknowledges that SNFs do not have direct control over an HCP's choice to receive a vaccine, the SNF does have direct control over reporting the data required for the HCP Influenza Vaccine measure, which is the only requirement to comply with the SNF QRP.

SNFs should use the specifications and data collection tools for the HCP Influenza Vaccine measure as required by CDC as of the time that the data are submitted. For more information about HCP included in the measure's denominator, please refer to the NHSN Manual Healthcare Personnel Safety Component Protocol Healthcare Personnel Vaccination Module: Influenza Vaccination Summary web page at *https://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/hps-flu-vaccine-protocol.pdf.*

Comment: One commenter expressed concern about adopting infection-specific regulations for particular viruses as these actions could set a precedent for future regulations that potentially burden both CMS as well as SNFs.

Response: We strive to promote high quality and efficiency in the delivery of healthcare to the beneficiaries we serve. Valid, reliable, and relevant quality measures are fundamental to the effectiveness of our QRPs. We are aware of potential provider burdens and only implement quality initiatives that have the potential to assure quality healthcare for Medicare beneficiaries through accountability and public disclosure. The Influenza Vaccination Coverage among HCP measure is consistent with CMS's Meaningful Measures 2.0, which includes safety as a key component of achieving value-based care and promoting health equity. The COVID–19 PHE has exposed the threat that emerging infectious diseases pose, and the importance of implementing infection prevention strategies, including the promotion of HCP influenza vaccination. We believe the proposed measure has the potential to generate actionable data on vaccination rates that can be used to target quality improvement among SNF providers.

Comment: One commenter expressed concerns about the HCP Influenza Vaccine measure due to the commenter's belief that SNFs are already required to report vaccine status to CMS on a weekly basis and are financially penalized for a failure to report. The commenter was also concerned that SNFs would receive a double penalty if the proposal were finalized.

Response: It is unclear what the commenter means by the term ''double penalty,'' but we interpret the commenter to be concerned about being penalized twice: once for a failure to report COVID–19 vaccine data to CMS on a weekly basis and a second time for failure to report HCP influenza vaccine data. The LTC facility requirements of participation (requirements) at § 483.80(g) and the SNF QRP are two separate requirements. The LTC facility requirements require nursing homes to

report weekly on the COVID–19 vaccination status of all residents and staff as well as COVID–19 therapeutic treatment administered to residents. As discussed in section VII.C.1.e. of this final rule, we proposed that SNFs would report the number of HCP who receive influenza vaccination. The reporting requirement for the HCP Influenza Vaccine measure is different from the COVID–19 vaccination information reporting requirement in the May 2021 IFC.[59] Each system has its own methods of validation and carries separate penalties.

Comment: One commenter stated that evidence continues to support that the best measures to prevent transmission from person to person are consistent infection control measures by the healthcare providers and encouraged CMS to review literature evidence more critically, and be able to discern between conflicting evidence in a more effective manner. Another commenter noted that although vaccines are beneficial, other infection control practices, such as mask wearing, can prevent influenza outbreaks within the SNF.

Response: We appreciate the comment and agree with the commenter that evidence continues to support the use of consistent infection control measures. Evidence also points to the importance of vaccination as a part of a multi-pronged approach within SNF infection prevention and control programs, especially to prevent the transmission of highly contagious conditions, such as influenza. We will continue to critically review evidence in our measure development processes.

Comment: Commenters suggested CMS delay implementation of the measure due to the PHE and staffing crisis. One commenter stated the data may be misleading to consumers due to changes in staffing from one influenza season to the next, the effectiveness of the vaccine, and the fact that the measure includes all HCP regardless of possible contact with the Medicare beneficiary.

Response: The PHE further emphasizes the need for CMS to prioritize infection prevention and control initiatives, such as HCP influenza vaccination. HCP vaccinations against influenza may prevent the spread of illness between HCP and residents, thus reducing resident morbidities associated with influenza and pressure on already stressed healthcare systems. The HCP Influenza Vaccine measure has been successfully reported in the IRF QRP since 2014 and the LTCH QRP since 2013, and CMS has had no questions or complaints from consumers about the value of the information when selecting a PAC provider. We disagree with the commenter that including all HCP in the measure, regardless of possible contact with the Medicare beneficiary, could result in misleading measure data because it is possible for any and all HCP to come into contact with Medicare beneficiaries. We do not require SNFs to differentiate between HCP who come into contact with Medicare beneficiaries versus those who do not as this would place additional reporting burdens on SNFs. Therefore, as described in section VII.G.2. of this final rule, we proposed the Influenza Vaccination Coverage among HCP measure to include HCP (as defined by the measure's denominator) who are physically present in the healthcare facility for at least 1 working day within the measure's data collection period since all types of HCP may come into contact with SNF residents.

Comment: One commenter urged CMS to add the HCP Influenza Vaccine measure to the SNF QRP as soon as possible because influenza season is anticipated as an annual occurrence nationally. In addition, the commenter stated that because the data used to calculate the measure are standardized and interoperable, CMS should be able to support an earlier implementation than the FY 2025 QRP.

Response: We agree with the commenter that we should adopt the measure sooner than the FY 2025 SNF QRP because it has the potential to increase influenza vaccination coverage in SNFs, promote patient safety, and increase the transparency of quality of care in the SNF setting as described in section VII.C.1.a. of this final rule. Therefore, we are finalizing this measure beginning with the FY 2024 SNF QRP. We are also finalizing our proposal to require SNFs to begin reporting data on this measure for the period October 1, 2022 through March 31, 2023, with a reporting deadline of May 15, 2023. This initial data reporting deadline gives us sufficient time to calculate the first year of measure results for the FY 2024 SNF QRP. Accordingly, we are finalizing our adoption of the measure beginning with the FY 2024 SNF QRP rather than the FY 2025 SNF QRP as proposed.

Comment: We received several comments that were not related to our SNF QRP proposals. One commenter responded to several proposals from the FY 2022 SNF PPS proposed rule,[60] while another commenter encouraged CMS to ensure immunizations are affordable and accessible. One commenter noted the number of measures currently reported on Care Compare and emphasized the importance of risk-adjusting measures due to COVID–19. Another commenter stated it is critical that changes to the QRP are accompanied with appropriate financial incentives so SNFs may invest in technologies that improve patient safety and compliance with data submission thresholds. Another commenter recommended the COVID–19 Vaccination Coverage among HCP numerator be aligned with the Influenza Vaccination Coverage among HCP measure. Finally, two commenters suggested CMS explore inclusion of Medicare Advantage patients in quality measure calculations.

Response: These comments fall outside the scope of the FY 2023 SNF PPS proposed rule.

After consideration of public comments, we are finalizing our proposal to adopt the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure beginning with the FY 2024 SNF QRP, since this measure influences patient safety and should be implemented within the SNF QRP as soon as possible.

2. Revised Compliance Date for Certain Skilled Nursing Facility Quality Reporting Program Requirements Beginning With the FY 2024 SNF QRP

a. Background

Section 1888(d)(6)(B)(i)(III) of the Act requires that, for FY 2019 and each subsequent year, SNFs must report standardized patient assessment data required under section 1899B(b)(1) of the Act. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including SNFs, to submit standardized patient assessment data under the Medicare program. In the FY 2020 SNF PPS final rule (84 FR 38755 through 38817), we adopted two TOH Information quality measures as well as standardized patient assessment data that would satisfy five categories defined by section 1899B(c)(1). The TOH Information to the Provider—Post-Acute Care (PAC) measure and the TOH Information to the Patient—PAC measure are process-based measures that assess whether or not a current reconciled medication list is given to the subsequent provider when a patient is discharged or

[59] Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (CFs–IID) Residents, Clients, and Staff. 86 FR 26306. May 13, 2021.

[60] 86 FR 19990 through 20005.

transferred from his or her current PAC setting or is given to the patient, family, or caregiver when the patient is discharged from a PAC setting to a private home/apartment, a board and care home, assisted living, a group home, or transitional living. Section 1899B(b)(1)(B) of the Act defines standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories: (1) functional status; (2) cognitive function; (3) special services, treatments, and interventions; (4) medical conditions and comorbidities; (5) impairments; and (6) other categories deemed necessary and appropriate by the Secretary.

The interim final rule with comment period that appeared in the May 8, 2020 **Federal Register** (85 FR 27550) (hereafter referred to as the ''May 8th COVID–19 IFC''), delayed the compliance date for certain reporting requirements under the SNF QRP (85 FR 27596 through 27597). Specifically, we delayed the requirement for SNFs to begin reporting the TOH Information to the Provider-PAC and the TOH Information to the Patient-PAC measures and the requirement for SNFs to begin reporting certain standardized patient assessment data elements from October 1, 2020, to October 1st of the year that is at least 2 full fiscal years after the end of the COVID–19 PHE. We also delayed the adoption of the updated version of the Minimum Data Set (MDS) 3.0 v1.18.1 [61] which SNFs would have used to report the TOH Information measures and certain standardized patient assessment data elements.

Currently, SNFs must use the MDS 3.0 v1.18.11 to begin collecting data on the two TOH Information measures beginning with discharges on October 1st of the year that is at least 2 full fiscal years after the end of the COVID–19 PHE. SNFs must also begin collecting data on certain standardized patient assessment data elements on the MDS 3.0 v1.18.11, beginning with admissions and discharges (except for the preferred language, need for interpreter services, hearing, vision, race, and ethnicity standardized patient assessment data elements, which would be collected at admission only) on October 1st of the year that is at least 2 full fiscal years after the end of the COVID–19 PHE. The delay to begin collecting data for these measures was intended to provide relief to SNFs from the added burden of implementing an updated instrument during the COVID–19 PHE. As discussed in the proposed rule, we wanted to provide maximum flexibilities for SNFs to respond to the public health threats posed by the COVID–19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time the May 8th COVID–19 IFC was published, we believed this delay would not have a significant impact on the SNF QRP. However, we were in the initial months of the COVID–19 PHE, and very little was known about the SARS–CoV–2 virus. Additionally, we believed the delay in the collection of the TOH Information measures and standardized patient assessment data elements were necessary to allow SNFs to focus on patient care and staff safety. However, the COVID–19 PHE has illustrated the important need for these TOH Information measures and standardized patient assessment data elements under the SNF QRP. The PHE's disproportionate impact among non-Hispanic Black, and Hispanic and Latino persons [62 63 64 65 66 67 68] demonstrates the importance of analyzing this impact in order to improve quality of care within SNFs especially during a crisis. One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across post-acute care programs and policies. The information will inform our Meaningful Measures framework.

b. Current Assessment of SNFs' Capabilities

To accommodate the COVID–19 PHE, we provided additional guidance and flexibilities, and as a result SNFs have had the opportunity to adopt new processes and modify existing processes to accommodate the significant health crisis presented by the COVID–19 PHE. For example, we held regular ''Office Hours'' conference calls to provide SNFs regular updates on the availability of supplies, as well as answer questions about delivery of care, reporting, and billing. We also supported PAC providers, including SNFs, by providing flexibilities in the delivery of care in response to the PHE,[69] such as waiving the requirements at § 483.30 for physician and non-physician practitioners to perform in-person visits, allowing them to use telehealth methods where deemed appropriate. We also waived the nurse aide training and certification requirements § 483.35(d) (with the exception of § 483.35(d)(1)(i)), allowing SNFs to employ nurse aides for longer than 4 months even when they have yet not met the standard training and certification requirements, and we waived the requirement at § 483.95(g)(1) for nursing aides to receive at least 12 hours of in-service training annually. To reduce provider burden, we waived the Pre-Admission Screening and Annual Resident Review (PASARR) at § 483.20(k), allowing SNFs more flexibility in scheduling Level 1 assessments. We narrowed the scope of requirements for a SNF's Quality Assurance and Performance Improvement (QAPI) program to the aspects of care most associated with COVID–19 (§ 483.75), that is infection control and adverse events. Additionally, we waived timeframe

[61] The MDS version referred to in IFC–2 was MDS 3.0 v1.18.1. This version number, MDS 3.0 v1.18.11, reflects the version that would be implemented if the proposal is finalized.

[62] Bhumbra, S., Malin, S., Kirkpatrick, L., et al. (2020). Clinical Features of Critical Coronavirus Disease 2019 in Children. Pediatric Critical Care Medicine, 02, 02. *https://doi.org/10.1097/PCC.0000000000002511.*

[63] Ebinger, J.E., Achamallah, N., Ji, H., Claggett, B.L., Sun, N., Botting, P., et al. (2020). Pre-existing Traits Associated with Covid–19 Illness Severity. PLoS ONE, 15(7), e0236240. *https://doi.org/10.1101/2020.04.29.20084533.*

[64] Gold, J.A.W., Wong, K.K., Szablewski, C.M., Patel, P.R., Rossow, J., da Silva, J., et al. (2020). Characteristics and Clinical Outcomes of Adult Patients Hospitalized with COVID–19—Georgia, March 2020. MMWR *Morbidity and Mortality Weekly Report,* 69(18), 545–550. *http://dx.doi.org/10.15585/mmwr.mm6918e1.*

[65] Hsu, H.E., Ashe, E.M., Silverstein, M., Hofman, M., Lange, S.J., Razzaghi, H., et al. (2020). Race/Ethnicity, Underlying Medical Conditions, Homelessness, and Hospitalization Status of Adult Patients with COVID–19 at an Urban Safety-Net Medical Center—Boston, Massachusetts, 2020. MMWR *Morbidity and Mortality Weekly Report,* 69(27), 864–869. *http://dx.doi.org/10.15585/mmwr.mm6927a3.*

[66] Kim, L., Whitaker, M., O'Hallaran, A., et al. (2020). Hospitalization Rates and Characteristics of Children Aged <18 Years Hospitalized with Laboratory-confirmed COVID–19—COVID–NET, 14 states, March 1–July 25, 2020. MMWR *Morbidity and Mortality Weekly Report,* 69(32), 1081–1088. *http://dx.doi.org/10.15585/mmwr.mm6932e3.*

[67] Killerby, M.E., Link-Gelles, R., Haight, S.C., Schrodt, C.A., England, L., Gomes, D.J., et al. (2020). Characteristics Associated with Hospitalization Among Patients with COVID–19—Metropolitan Atlanta, Georgia, March–April 2020. *MMWR Morbidity and Mortality Weekly Report,* 69(25), 790–794. *http://dx.doi.org/10.15585/mmwr.mm6925e1.*

[68] Price-Haywood, E.G., Burton, J., Fort, D., & Seoane, L. (2020). Hospitalization and Mortality among Black Patients and White Patients with Covid–19. New England Journal of Medicine, 382(26), 2534–2543. *https://doi.org/10.1056/NEJMsa2011686.*

[69] Centers for Medicare & Medicaid Services (CMS). COVID–19 Emergency Declaration Blanket waivers for Health Care Providers. Retrieved from *https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf.* Accessed 11/23/2021.

requirements on MDS assessments and transmission at § 483.20, along with waiving requirements for submitting staffing data through the Payroll-Based Journal (PBJ) system at § 483.70(q), to grant SNFs the greater flexibility needed to adapt to the rapidly evolving burdens of the PHE. While the MDS and PBJ requirements have since been terminated, many of these waivers for SNFs are still in effect today.

In addition, as of March 1, 2022, 86.2 percent of the population aged 12 and older (81.3 percent of those 5 and older) had received at least one COVID–19 vaccination.[70] Further, although there was a recent increase in COVID–19 cases, vaccinated individuals aged 18 years and older through March 4, 2022 were 3.2 times less likely to test positive, over 9 times less likely to be hospitalized, and experienced 41 times lower risk of death, compared to unvaccinated individuals.[71] We also believe that SNFs have more information and interventions to deploy to effectively prevent and treat COVID–19 than they had at the time the May 8th COVID–19 IFC was finalized,[72 73 74 75] including three vaccines that are either approved or authorized in the United States to prevent COVID–19, and antiviral drugs that are approved or authorized to treat COVID–19.[76 77 78 79 80] Also, recent reports suggest that the rollout of COVID–19 vaccines has alleviated some of the burden on SNFs imposed by the PHE.[81 82]

Despite the COVID–19 PHE, we must maintain our commitment to the quality of care for all patients, and we continue to believe that the collection of the standardized patient assessment data elements and TOH Information measures will contribute to this effort. That includes an ongoing commitment to achieving health equity by improving data collection to better measure and analyze disparities across programs and policies.[83 84 85 86 87 88 89 90] We also note that in response to the ''Request for Information to Close the Health Equity Gap'' in the FY 2022 SNF PPS proposed rule (86 FR 20000), we heard from stakeholders that it is important to gather additional information about race, ethnicity, gender, language, and other social determinants of health (SDOH). Some SNFs noted they had already begun to collect some of this information for use in their operations. Our commitment to the quality of care for all patients also includes improving the quality of care in SNFs through a reduction in preventable adverse events. Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.[91 92 93 94 95 96] Poor communication and coordination across healthcare settings contributes to patient complications, hospital readmissions, emergency department visits, and medication

[70] CDC COVID Data Tracker. Retrieved from *https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-onedose-pop-5yr.* Accessed 3/4/2022.

[71] CDC COVID Data Tracker. Accessed 3/4/2022. Retrieved from *https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status.*

[72] COVID research: a year of scientific milestones. Nature. May 5, 2021. Retrieved from *https://www.nature.com/articles/d41586-020-00502-w.*

[73] CDC COVID Data Tracker. Accessed 2/10/2022. Retrieved from *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[74] Clinical trial of therapeutics for severely ill hospitalized COVID–19 patients begins. National Institutes of Health News Releases. April 22, 2021. Retrieved from *https://www.nih.gov/news-events/news-releases/clinical-trialtherapeutics-severely-ill-hospitalized-covid-19-patients-begins.*

[75] COVID–19 Treatment Guidelines. National Institutes of Health. Updated October 27, 2021. Retrieved from *https://www.covid19treatmentguidelines.nih.gov/whats-new/.*

[76] Here's Exactly Where We are with Vaccine and Treatments for COVID–19. Healthline. November 9, 2021. Retrieved from *https://www.healthline.com/health-news/heres-exactly-where-were-at-with-vaccines-and-treatments-forcovid-19.*

[77] U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.* Accessed 7/8/2022.

[78] On January 31, 2021, FDA approved a second COVID–19 vaccine. Available at *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.* Accessed 7/8/22. The Moderna COVID–19 Vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2022). Spikevax and Moderna COVID–19 Vaccine. *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine.* Accessed 7/8/22.

[79] FDA Approves First COVID–19 Vaccine. Available at *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.* Accessed 7/8/22. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID–19 Vaccine. Available at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine.* Accessed 7/8/2022.

[80] FDA Approves First Treatment for COVID–19. October 22, 2020. Available at *https://www.fda.gov/newsevents/press-announcements/fda-approves-first-treatment-covid-19.* Accessed 9/9/2021. Emergency Use Authorization, *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* Accessed7/8 2022.

[81] Domi, M., Leitson, M., Gifford, D., Nicolaou, A., Sreenivas, K., & Bishnoi, C. (2021). The BNT162b2 vaccine is associated with lower new COVID–19 cases in nursing home residents and staff. *Journal of the American Geriatrics Society,* 69(8), 2079–2089. *https://doi.org/10.1111/jgs.17224.*

[82] American Health Care Association and National Center for Assisted Living. COVID–19 Vaccines Helping Long Term Care Facilities Rebound From The Pandemic. May 25, 2021. Retrieved from *https://www.ahcancal.org/News-and-Communications/Press-Releases/Pages/COVID-19-Vaccines-Helping-Long-Term-Care-Facilities-Rebound-From-The-Pandemic.aspx.*

[83] COVID–19 Health Equity Interactive Dashboard. Emory University. Accessed January 12, 2022. Retrieved from *https://covid19.emory.edu/.*

[84] COVID–19 is affecting Black, Indigenous, Latinx, and other people of color the most. The COVID Tracking Project. March 7, 2021. Accessed January 12, 2022. Retrieved from *https://covidtracking.com/race.*

[85] Centers for Medicare & Medicaid Services (CMS). CMS Quality Strategy. 2016. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[86] Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.*

[87] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[88] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[89] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[90] Poteat, T.C ., Reisner, S.L., Miller, M., Wirtz, A.L. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv,* 2020.07.21.20159327. *https://doi.org/10.1101/2020.07.21.20159327.*

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[92] Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K.A., Nebeker, J.R., & Yeh, J. (2011). Effect of admission medication reconciliation on adverse drug events from admission medication changes. *Archives of Internal Medicine,* 171(9), 860–861.

[93] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R. (2011). Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases. *JAMA,* 306(8), 840–847.

[94] Basey, A.J., Krska, J., Kennedy, T.D., & Mackridge, A.J. (2014). Prescribing errors on admission to hospital and their potential impact: a mixed-methods study. *BMJ Quality & Safety,* 23(1), 17–25.

[95] Desai, R., Williams, C.E., Greene, S.B., Pierson, S., & Hansen, R.A. (2011). Medication errors during patient transitions into nursing homes: characteristics and association with patient harm. *American Journal of Geriatric Pharmacotherapy,* 9(6), 413–422.

[96] Boling, P.A. (2009). Care transitions and home health care. *Clinical Geriatric Medicine,* 25(1), 135–148.

[97] Barnsteiner, J.H. (2005). Medication Reconciliation: Transfer of medication information across settings—keeping it free from error. *American Journal of Nursing,* 105(3 Suppl), 31–36.

[98] Arbaje, A.I., Kansagara, D.L., Salanitro, A.H., Englander, H.L., Kripalani, S., Jencks, S.F., & Lindquist, L.A. (2014). Regardless of age: incorporating principles from geriatric medicine to improve care transitions for patients with complex needs. *Journal of General Internal Medicine,* 29(6), 932–939.

[99] Jencks, S.F., Williams, M.V., & Coleman, E.A. (2009). Rehospitalizations among patients in the Medicare fee-for-service program. *New England Journal of Medicine,* 360(14), 1418–1428.

[100] Institute of Medicine. (2007). Preventing medication errors: quality chasm series.

errors.[97 98 99 100 101 102 103 104 105 106] Further delaying the data collection has the potential to further exacerbate these issues. We believe the benefit of having this information available in a standardized format outweighs the potential burden of collecting these data, as data availability is a necessary step in addressing health disparities in SNFs.

Given the flexibilities described earlier in this section, SNFs' increased knowledge and interventions to deploy to effectively prevent and treat COVID–19, and the trending data on COVID–19, we believe that SNFs are in a better position to accommodate the reporting of the TOH Information measures and certain standardized patient assessment data elements. Specifically, we believe SNFs have learned how to adapt and now have the administrative capacity to attend training, train their staff, and work with their vendors to incorporate the updated assessment instruments into their operations. Moreover, these standardized patient assessment data elements are reflective of patient characteristics that providers may already be recording for their own purposes, such as preferred language, race, ethnicity, hearing, vision, health literacy, and cognitive function. It is also important to align the collection of these data with the IRFs and LTCHs that will begin collecting this information on October 1, 2022, and home health agencies (HHAs) that will begin collecting this information on January 1, 2023.[107]

c. Collection of the Transfer of Health (TOH) Information to the Provider-PAC Measure, the Transfer of Health (TOH) Information to the Patient-PAC Measure and Certain Standardized Patient Assessment Data Elements Beginning October 1, 2023

We proposed to revise the compliance date specified in the May 8th COVID–19 IFC from October 1st of the year that is at least 2 full FYs after the end of the COVID–19 PHE to October 1, 2023. This revised date would begin the collection of data on the TOH Information to the Provider-PAC measure and TOH Information to the Patient-PAC measure, and certain standardized patient assessment data elements on the updated version of the MDS assessment instrument referred to as MDS 3.0 v1.18.11. We believe this revised date of October 1, 2023, which is a 3-year delay from the original compliance date finalized in the FY 2020 SNF PPS final rule (84 FR 38755 through 38764), balances the support that SNFs have needed during much of the COVID–19 PHE, the flexibilities we provided to support SNFs, and the time necessary to develop preventive and treatment options along with the need to collect these important data. We believe this date is sufficiently far in advance for SNFs to make the necessary preparations to begin reporting these data elements and the TOH Information measures. As described in section VI.C.2 of the proposed rule, the need for the standardized patient assessment data elements and TOH Information measures has been shown to be even more pressing with issues of health inequities, exacerbated by the COVID–19 PHE. These data, which include information on SDOH, provides information that is expected to improve quality of care for all, and is not already found in assessment or claims data currently available. Consequently, we proposed to revise the compliance date to reflect this balance and assure that data collection begins on October 1, 2023.

As stated in the FY 2020 SNF PPS final rule (84 FR 38774), we will provide the training and education for SNFs to be prepared for this implementation date. In addition, if we adopt an October 1, 2023 compliance date, we would release a draft of the updated version of the MDS 3.0 v1.18.11 in early 2023 with sufficient lead time to prepare for the October 1, 2023 start date.

Based upon our evaluation, we proposed that SNFs collect the TOH Information to the Provider-PAC measure, the TOH Information to the Patient-PAC measure, and certain standardized patient assessment data elements beginning October 1, 2023. We also proposed that SNFs begin collecting data on the two TOH Information measures beginning with discharges on October 1, 2023. We proposed that SNFs begin collecting data on the six categories of standardized patient assessment data elements on the MDS 3.0 v1.18.11, beginning with admissions and discharges (except for the preferred language, need for interpreter services, hearing, vision, race, and ethnicity standardized patient assessment data elements, which would be collected at admission only) on October 1, 2023. We solicited public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to revise the compliance date for the TOH Information measures and certain standardized patient assessment data elements beginning with the FY 2024 QRP. One commenter acknowledged that CMS must maintain its commitment to quality of care for all patients and they support the collection of certain standardized patient assessment data as an important part of improving patient care. Two commenters stated that they recognize the importance of collecting these data to advance health equity and improve quality of care for all beneficiaries. These commenters also noted that the date was further into the future than the IRF and LTCH QRPs, and therefore they appreciated CMS's acknowledgement of the unique support needs of SNFs during the COVID–19 public health emergency. Other commenters noted that despite the ongoing challenges of the pandemic, they believe SNFs will be able to report this information. Another commenter supported the prompt initiation of the data collection to enhance holistic care, call attention to impairments to be mitigated or resolved, and to facilitate clear communication between residents and providers. Further, the commenters noted that such data collection could allow for examination of SNF performance stratified for factors associated with healthcare disparities, such as race and ethnicity.

Response: We agree that the data will advance quality of care for all patients.

Washington, DC: The National Academies Press. Available at *https://www.nap.edu/read/11623/chapter/1.*

[101] Kitson, N.A., Price, M., Lau, F.Y., & Showler, G. (2013). Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach. *BMC Health Services Research,* 13(1), 1–10.

[102] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C. (2010). The revolving door of rehospitalization from skilled nursing facilities. *Health Affairs,* 29(1), 57–64.

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[104] Kitson, N.A., Price, M., Lau, F.Y., & Showler, G. (2013). Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach. *BMC Health Services Research,* 13(1), 1–10.

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[107] Calendar Year 2020 Home Health final rule (86 FR 62385 through 62390).

We believe that as the healthcare community continues to learn about the enormous impact that social determinants of health (SDOH) and social risk factors (SRFs) have on patient health and health outcomes,[108] it becomes more critical to collect this information to better understand the impact of the PHE on our healthcare system, as well as how to address the inequities that the PHE has made so visible. We believe it will help SNFs, physicians, and other practitioners caring for patients in SNFs better prepare for the complex and resource-intensive care needs of patients with new and emerging viruses.

We also agree with the commenter that despite the COVID–19 PHE, SNFs will be able to successfully report the standardized patient assessment data and TOH Information measures. As of July 6, 2022, 89.86 percent of the population aged 12 and older (83.3 percent of those 5 and older) had received at least one COVID–19 vaccination, indicating an increase of 3.5 percent and 2 percent, respectively in the last 4 months.[109] Further strengthening our conclusion that SNFs are able to meet the revised compliance date is that there are even more treatments available to treat COVID–19.[110] As of May 31, 2022, there are two treatments currently approved by the FDA for use in COVID–19 and 13 COVID–19 treatments authorized for Emergency Use.[111]

Comment: Several commenters supported the proposal to revise the compliance date for the TOH Information measures and certain standardized patient assessment data elements beginning with the FY 2024 QRP, but at the same time reminding CMS that concerns exist around the timing for the release of the newer version of the MDS 3.0, which contains new data elements. The commenters specifically raised questions about the ability of providers and health IT developers to develop, test, and implement software for the new MDS and its associated reporting requirements. One commenter requested adequate time to develop, test, and deploy new software, noting that in the past, health IT developers have indicated they need 18 months for this process. Two commenters also urged CMS to provide adequate lead time for training staff on the changes required by the new assessment items.

Response: We understand providers' concerns with developing software for the new MDS and the need to train staff. However, SNFs have known since July 30, 2019 [112] that CMS would be implementing an updated version of the MDS to collect the TOH Information measures and certain standardized patient assessment data elements. As described in section VII.C.2.a., the May 8th COVID–19 IFC only delayed the compliance date for these reporting requirements.

On July 31, 2019, we posted the specifications for the TOH Information measures and standardized patient assessment data elements on the IMPACT Act Downloads and Videos web page which SNFs could use to begin developing their software and train their staff. Specifically, the Final Specifications for SNF QRP Quality Measures and SPADEs document,[113] provides information on each of the TOH Information measures, including the items' description, measure numerator and denominator, as well as the assessment items and responses. Additionally, each of the new standardized patient assessment data elements is described and accompanied by the assessment item and response(s). We also suggest SNF information technology (IT) vendors look at the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF–PAI) Version 4.0 and the Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) Version 5.0 to see how these assessment items are embedded into those assessment tools. As we discussed in section VI.2.b. of the SNF PPS proposed rule, the new items that will be collected are standardized and interoperable data elements. As such, the items that would be collected by the MDS are the same items that will be collected by IRFs and LTCHs on October 1, 2022, and home health agencies (HHAs) on January 1, 2023.[114] Since the Final Specifications for SNF QRP Quality Measures and SPADEs document has been available to SNFs since July 31, 2019, we believe IT vendors will have enough time to update their software prior to October 1, 2023. We also note that since IT vendors for IRFs, LTCHs and HH agencies will have already updated their systems, IT vendors in SNFs may benefit from their experience.

In response to the comment that health IT vendors need 18 months to develop, test, and deploy new software, we note that historically we have tried to provide vendors with the information they need to make adjustments to their software well ahead of the implementation date. This was especially important in the early years of assessment data submission to CMS, but we have found in recent years, vendors are very mature in the software development process for MDS and do not require such extensive lead times. The time, form, and manner in which the MDS will be submitted is not changing; rather it is a variation in the data elements being collected. Therefore, the implementation of this proposal should not require health IT vendors to completely rewrite their software.

In response to the commenters' concerns for training staff, we plan to provide multiple training resources and opportunities for SNFs to take advantage of, reducing the burden to SNFs in creating their own training resources. These training resources may include online learning modules, tip sheets, questions and answers documents, and/or recorded webinars and videos, and would be available to providers in early 2023, allowing SNFs several months to ensure their staff take advantage of the learning opportunities. Having the materials online and on-demand would give staff the flexibility of learning about the new items at times that minimize disruption to patient care schedules. The SNF QRP Helpdesk would also be available for providers to submit their follow-up questions by email, further enhancing the educational resources.

We received several comments urging us not to revise the compliance date for the TOH Information measures and certain standardized patient assessment data elements beginning with the FY 2024 QRP. We will address each of these comments here.

[108] Hood, C.M., Gennuso, K.P., Swain, G.R., & Catlin, B.B. (2016). County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. *American Journal of Preventive Medicine,* 50(2), 129–135. Available at *https://pubmed.ncbi.nlm.nih.gov/26526164/.* Accessed 9/1/21.

[109] CDC COVID Data Tracker. Accessed 3/4/2022. Retrieved from *https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-onedose-pop-5yr.*

[110] Coronavirus Treatment Acceleration Program (CTAP). Available at *https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap.* Accessed 7/8/22.

[111] Please see the Emergency Use Authorization web page for more details. This number includes 1 EUA authorizing both medical devices and a drug for emergency use.

[112] Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2020. 84 FR 38728.

[113] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Final-Specifications-for-SNF-QRP-Quality-Measures-and-SPADEs.pdf.*

[114] Calendar Year 2020 Home Health final rule (86 FR 62385 through 62390).

Comment: Many commenters raised concerns with revising the compliance date from October 1st of the year that is at least 2 full fiscal years after the end of the PHE to October 1, 2023 given the fact that the PHE is still in effect as of the date of our proposal, while another suggested no new quality metrics should be implemented within 1 calendar year from the date the COVID–19 PHE officially ends. One commenter stated that the delay was intended to provide relief to SNFs, and it would be inappropriate to move up the date while the PHE is still in effect. Another commenter supported the implementation of the TOH Information measures since it reflects a process already being completed in SNFs, but stated the proposed implementation of the MDS 3.0 with the new standardized patient assessment data elements would be overwhelming to facilities at this time given the impact on quality measures, care area triggers, and care plans. One commenter disagreed with CMS's assertion that the flexibilities and assistance granted by the agency during the PHE, as well as the promising trends in COVID–19 vaccination and death rates, have left providers in a better position to collect the standardized patient assessment data. Another commenter pointed to the uncertainty around current therapeutics' and vaccines' effectiveness against new variants, which they believe leave the SNF population potentially susceptible to an ever-changing COVID–19 ecosystem, and stated that further stressing SNFs with additional reporting at a time when the COVID–19 PHE may still be burdening SNFs and their residents may lead to unforeseen consequences like inaccurate and inconsistent data lessening the value of this reporting. Other commenters acknowledged that the acute impacts of COVID–19 have lessened but are concerned that COVID–19's rippling effects continue to impact SNF operations.

Response: As stated in section VI.C.2 of the FY 2023 SNF PPS proposed rule (87 FR 22750 through 22754), we have provided SNFs a number of flexibilities to accommodate the COVID–19 PHE, including delaying the adoption of the updated version of the MDS 3.0 v1.18.0 with which SNFs would have used to report the TOH Information measures and standardized patient assessment data elements (85 FR 27595 through 27596). Despite the COVID–19 PHE, we must maintain our commitment to quality of care for all patients, and we continue to believe that the collection of the standardized patient assessment data elements and TOH Information measures will contribute to this effort. That includes staying committed to achieving health equity by improving data collection to better measure and analyze disparities across programs and policies [115] [116] [117] [118] [119] [120] and improving the quality of care in SNFs through a reduction in preventable adverse events. Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.[121] [122] [123] [124] [125] [126] Poor communication and coordination across healthcare settings contribute to patient complications, hospital readmissions, emergency department visits, and medication errors.[127] [128] [129] [130] [131] [132] [133] [134] [135] [136] While we understand that there are concerns related to the timeline proposed, we believe specifying an earlier date for the data collection is necessary to maintain our commitment to quality of care for all patients. Furthermore, it is important to align the collection of these data with the IRFs and LTCHs that will begin collecting this information on October 1, 2022, and HHAs that will begin collecting this information on January 1, 2023.[137] We have strived to balance the scope and level of detail of the data elements against the potential burden placed on SNFs.

Comment: Several commenters stated that implementing the MDS 3.0 v1.18.11 would require additional staffing, specifically nursing staff, at a time when there is a national staffing crisis. Two commenters noted that the workforce shortages have been compounded by burnout among SNF workers resulting in experienced professionals leaving the workforce earlier than expected, with one stating it would take years to replace them. Another commenter cited a Kaiser Family Foundation study reporting more than a quarter of nursing

[115] Centers for Medicare & Medicaid Services (CMS). CMS Quality Strategy. 2016. Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[116] Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.*

[117] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[118] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[119] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[120] Poteat, T.C., Reisner, S.L., Miller, M., & Wirtz, A.L. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. medRxiv, 2020.07.21.20159327. *https://doi.org/10.1101/2020.07.21.20159327.*

[121] Kwan, J.L., Lo, L., Sampson, M., & Shojania, K. G. (2013). Medication reconciliation during transitions of care as a patient safety strategy: a systematic review. Annals of Internal Medicine, 158(5), 397–403.

[122] Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K.A., Nebeker, J.R., & Yeh, J. (2011). Effect of admission medication reconciliation on adverse drug events from admission medication changes. Archives of Internal Medicine, 171(9), 860–861.

[123] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R. (2011). Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases. JAMA, 306(8), 840–847.

[124] Basey, A.J., Krska, J., Kennedy, T.D., & Mackridge, A.J. (2014). Prescribing errors on admission to hospital and their potential impact: a mixed-methods study. BMJ Quality & Safety, 23(1), 17–25.

[125] Desai, R., Williams, C.E., Greene, S.B., Pierson, S., & Hansen, R.A. (2011). Medication errors during patient transitions into nursing homes: characteristics and association with patient harm. American Journal of Geriatric Pharmacotherapy, 9(6), 413–422.

[126] Boling, P.A. (2009). Care transitions and home health care. Clinical Geriatric Medicine, 25(1), 135–148.

[127] Barnsteiner, J.H. (2005). Medication Reconciliation: Transfer of medication information across settings—keeping it free from error. *American Journal of Nursing,* 105(3 Suppl), 31–36.

[128] Arbaje, A.I., Kansagara, D.L., Salanitro, A.H., Englander, H.L., Kripalani, S., Jencks, S.F., & Lindquist, L.A. (2014). Regardless of age: incorporating principles from geriatric medicine to imp rove care transitions for patients with complex needs. Journal of General Internal Medicine, 29(6), 932–939.

[129] Jencks, S.F., Williams, M.V., & Coleman, E.A. (2009). Rehospitalizations among patients in the Medicare fee-for-service program. New England Journal of Medicine, 360(14), 1418–1428.

[130] Institute of Medicine. Preventing medication errors: quality chasm series. Washington, DC: The National Academies Press 2007. Available at *https://www.nap.edu/read/11623/chapter/1.*

[131] Kitson, N. A., Price, M., Lau, F.Y., & Showler, G. (2013). Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach. BMC Health Services Research, 13(1), 1–10.

[132] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C. (2010). The revolving door of rehospitalization from skilled nursing facilities. Health Affairs, 29(1), 57–64.

[133] Institute of Medicine. Preventing medication errors: quality chasm series. Washington, DC: The National Academies Press 2007. Available at *https://www.nap.edu/read/11623/chapter/1.*

[134] Kitson, N.A., Price, M., Lau, F.Y., & Showler, G. (2013). Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach. BMC Health Services Research, 13(1), 1–10.

[135] Forster, A.J., Murff, H.J., Peterson, J.F., Gandhi, T.K., & Bates, D.W. (2003). The incidence and severity of adverse events affecting patients after discharge from the hospital. Annals of Internal Medicine, 138(3), 161–167.

[136] King, B.J., Gilmore- Bykovsky, A.L., Roiland, R.A., Polnaszek, B.E., Bowers, B.J., & Kind, A.J. (2013). The consequences of poor communication during transitions from hospital to skilled nursing facility: a qualitative study. Journal of the American Geriatrics Society, 61(7), 1095–1102.

[137] Calendar Year 2020 Home Health final rule (86 FR 62385 through 62390).

homes have reported staffing shortages as recently as March of this year.

Response: The impacts of the COVID–19 PHE on the healthcare system, including staffing shortages, make it especially important now to monitor quality of care.[138] Still, we are mindful of burden that may occur from the collection and reporting of our measures. We emphasize, however, that the TOH Information Provider-PAC and TOH Information Patient-PAC measures consist of one item each, and further, the activities associated with the measures align with the existing Requirements of Participation for SNFs related to transferring information at the time of discharge to safeguard patients.[139] As a result, the information gathered will reflect a process that SNFs should already be conducting, and will demonstrate the quality of care provided by SNFs.

We do not believe that shortages in staffing will affect implementation of the new MDS because many of the data elements adopted as standardized patient assessment data elements in the FY 2020 SNF PPS final rule are already collected on the MDS 1.17.2 using current SNF staffing levels. For example, the hearing, vision, preferred language, Brief Interview for Mental Status (BIMS), Confusion Assessment Method (CAM©), and the Patient Health Questionnaire (PHQ) are items that were finalized as standardized patient assessment data elements in the FY 2020 SNF PPS final rule and are already being collected by SNFs on the MDS 1.17.2. However, those items have not historically been collected in the IRF and LTCH settings, and therefore will be ''new'' items to collect beginning October 1, 2022. Therefore, MDS 1.18.11 results in fewer ''new'' standardized patient assessment data elements for SNFs, as compared to other PAC settings.

Examples of the ''new'' standardized patient assessment data elements that will be collected on the MDS 1.18.11 include ethnicity, access to transportation, health literacy, social isolation, and pain interference.[140] We note that in response to the ''Request for Information to Close the Health Equity Gap'' in the FY 2022 SNF PPS proposed rule (86 FR 20000), we heard from SNFs that they had already started collecting additional information about race, ethnicity, gender, language, and other SDOH. Given the fact that some SNFs are able to collect this information at current staffing levels and many of the items categorized as standardized patient assessment data elements will not be new items for SNFs, we do not believe that staff shortages will interfere with implementing the MDS 3.0 v1.18.11.

Comment: Two commenters noted that the length of the revised MDS assessment instrument is expected to increase from 51 pages to approximately 61 pages, a change they believe will require significant investments in staff education and training, which would divert these resources from direct patient care.

Response: As stated earlier in this final rule, many of the data elements that would be adopted as standardized patient assessment data elements are already collected by SNFs. The increase in the number of pages is the result of providing additional response options for several of the existing data elements and does not necessarily translate to additional time and burden. Additionally, the new version of the MDS 3.0 is expected to be 58 pages, rather than 61 pages.

We plan to provide multiple training resources and opportunities for SNFs on the revised MDS assessment tool, which may include online learning modules, tip sheets, questions and answers documents, and/or recorded webinars and videos. We plan to make these training resources available to SNFs in early 2023, allowing SNFs several months to ensure their staff take advantage of the learning opportunities, and to allow SNFs to spread the cost of training out over several quarters.

Comment: One commenter supported collecting, analyzing, and using data on social risk factors. This commenter noted, however, that it would create confusion and unnecessary administrative burden for CMS to quickly add data elements to the MDS because they happen to be available now, only to replace them with other data elements developed with the feedback from CMS's Requests for Information (RFIs) and its ongoing work with its Disparity Methods.[141]

Response: To clarify, the standardized patient assessment data elements that would be collected in the MDS 3.0 v1.18.11 were finalized in the FY 2020 SNF PPS final rule (84 FR 38755 through 38817). The RFI published in section VI.E. of the FY 2023 SNF PPS proposed rule (87 FR 22754 through 22761) requested public comment on Overarching Principles for Measuring Equity and Healthcare Quality Disparities across CMS Quality Programs and on Approaches to Assessing Drivers of Healthcare Quality Disparities and Developing Measures of Healthcare Equity in the SNF QRP, which may or may not include using standardized patient assessment data elements. Any new data elements that may come out of the RFI would have to go through the public notice and comment period before being implemented. Therefore, we do not anticipate confusion or unnecessary administrative burden as a result of the feedback received to the FY 2023 SNF RFI.

Comment: Two commenters urged CMS to delay the implementation of the MDS 3.0 v1.18.11 until it has received the first full year of data collection on the TOH Information measures and standardized patient assessment data elements in the IRF and LTCH settings in order to better inform provider education and technical assistance for SNF providers.

Response: The revised date of October 1, 2023, is a 3-year delay from the original compliance date finalized in the FY 2020 SNF PPS final rule (84 FR 38755 through 38764), and balances the support that SNFs have needed during the COVID–19 PHE with the need to collect this important data. We believe the revised date is sufficiently far in advance for SNFs to make the necessary preparations to begin reporting these data elements and the TOH Information measures. As stated earlier, the IRF and LTCH will begin collecting the TOH Information measures and the standardized patient assessment data elements on October 1, 2022. CMS began answering questions from providers in November 2021, after the proposal was finalized.[142] CMS released virtual trainings programs for IRF and LTCH providers in April 2022 that reviewed the updated guidance for their respective updated assessment tools, and hosted two live Question and Answer sessions on June 15 and June 16, 2022. A major focus of the trainings was on the cross-setting implementation of the standardized patient assessment

[138] Nursing and Patient Safety. Agency for Healthcare Research and Quality. April 21, 2021. Available at *https://psnet.ahrq.gov/primer/nursing-and-patient-safety.* Accessed 10/4/2021.

[139] Requirements for Long-Term Care Facilities. Part 483-Requriements for States and Long-Term Care Facilities; Subpart B—Requirements for Long Term Care Facilities; 42 CFR 483.15—Admission, transfer and discharge rights.

[140] Although there are new pain interference items, the current assessment item for Pain Effect on Function will be removed.

[141] The Disparity Methods Confidential Reporting refers to CMS's confidential reporting to educate hospitals about two disparity methods and allow hospitals to review their results and data related to readmission rates for patients with social risk factors. Available at *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.* Accessed 7/8/22.

[142] Calendar Year 2020 Home Health final rule (86 FR 62385 through 62390).

data elements they begin collecting October 1, 2022. Therefore, CMS would have over a year to inform provider education and technical assistance for SNF providers prior to implementation.

We also note that in response to the ''Request for Information to Close the Health Equity Gap'' in the FY 2022 SNF PPS proposed rule (86 FR 20000), interested parties stressed the importance of gathering additional information about race, ethnicity, gender, language, and other SDOH. Some SNFs noted they had already begun to collect some of this information for use in their operations. We do not believe further delaying the data collection would provide any additional information to better inform provider education and technical assistance for SNF providers.

Comment: We received comments regarding states' and other payer programs use of section G data elements, the impact of changes to SNF regulations and requirements on the demands of these other payment systems, and the need for CMS to provide more infrastructure support to adopt certified electronic technology to facilitate meaningful data exchange.

Response: These comments fall outside the scope of the FY 2023 SNF PPS proposed rule.

Comment: One commenter stated their support for CMS' proposed update to the denominator of the TOH Information to the Patient-PAC measure.

Response: We believe this comment was directed at the proposals in the FY 2022 SNF proposed rule (86 FR 19998), and we thank the commenter for their support. In the FY 2022 SNF PPS Final Rule (86 FR 42490), we finalized the proposal to remove the location of home under the care of an organized home health service organization or hospice from the denominator of the TOH Information to the Patient-PAC measure.

After consideration of the comments received, we are finalizing our proposal that SNFs begin collecting the TOH Information to the Provider-PAC measure, the TOH Information to the Patient-PAC measure, and the six categories of standardized patient assessment data elements on the MDS v1.18.11 for admissions and discharges (except for the hearing, vision, race, and ethnicity standardized patient assessment data elements, which would be collected at admission only) on or after October 1, 2023.

3. Revisions to the Regulation Text (§ 413.360)

The FY 2022 SNF PPS final rule (86 FR 42480 through 42489) added the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP COVID–19 Vaccine) measure to the SNF QRP beginning with the FY 2024 QRP. The data submission method for the HCP COVID–19 Vaccine measure is the NHSN. The NHSN is a system maintained by the CDC, whose mission it is to protect the health security of the nation. The NHSN is used to collect and report on healthcare-acquired infections, such as catheter-associated urinary tract infections and central-line-associated bloodstream infections. The NHSN also collects vaccination information since vaccines play a major role in preventing the spread of harmful infections. Healthcare-acquired infections are a threat to beneficiaries, SNFs, and the public. Given the significance of the information collected through the NHSN, and the fact that infection prevention affects all beneficiaries, 100 percent of the information required to calculate the HCP COVID–19 Vaccine measure must be submitted to the NHSN. The HCP COVID–19 Vaccine measure is an important part of the nation's response to the COVID–19 PHE, and therefore 100 percent of the information is necessary to monitor the health and safety of beneficiaries.

For consistency in our regulations, we proposed conforming revisions to the Requirements under the SNF QRP at § 413.360. Specifically, we proposed to redesignate § 413.360(b)(2) to § 413.360(f)(2) and add a new paragraph (f) for the SNF QRP data completeness thresholds. The new paragraph would reflect all data completion thresholds required for SNFs to meet or exceed in order to avoid receiving a 2-percentage-point reduction to their APU for a given fiscal year.

At § 413.360(b), *Data submission requirement,* we proposed to remove paragraph (b)(2) and redesignate paragraph (b)(3) as paragraph (b)(2). At § 413.360, we proposed to add a new paragraph (f), *Data completion thresholds.*

At § 413.360(f)(1), we proposed to add new language to state that SNFs must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of required quality measures data and standardized patient assessment data collected using the MDS submitted through the CMS-designated data submission system, beginning with FY 2018 and for all subsequent payment updates; and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN, beginning with FY 2023 and for all subsequent payment updates.

At § 413.360(f)(2), we proposed to add new language to state that these thresholds (80 percent for completion of required quality measures data and standardized patient assessment data on the MDS; 100 percent for CDC NHSN data) will apply to all measures and standardized patient assessment data requirements adopted into the SNF QRP.

At § 413.360(f)(3), we proposed to add new language to state that a SNF must meet or exceed both thresholds to avoid receiving a 2-percentage-point reduction to their APU for a given fiscal year.

We solicited public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter urged CMS not to establish a 100 percent compliance threshold for measures submitted to the QRP using the NHSN. The commenter stated that SNFs need more experience with submitting data through the NHSN and that NHSN reporting requirements should be simplified in order to make a 100 percent compliance threshold more reasonable.

Response: We disagree that SNFs need more experience with submitting data through the NHSN before we finalize the proposal. Since May 21, 2021, SNFs have been submitting the COVID–19 vaccination status of all residents and staff through the NHSN on a weekly basis.[143] Similarly, SNFs would submit the HCP Influenza Vaccine measure through the NHSN at the conclusion of the measure reporting period.

If SNFs experience data submission issues, the NHSN has a Helpdesk to which providers can submit questions about data submission. If a facility continues to have questions or experience additional issues after a ticket has closed, the CDC encourages providers to submit a new email with a detailed subject line to ensure an expeditious Helpdesk reply with input from a subject matter expert team.

Comment: Several commenters requested that CMS clarify what 100 percent reporting means for purposes of meeting the compliance threshold.

Response: To meet the minimum data submission requirements for measure data collected and submitted using the CDC NHSN, SNFs must submit 100 percent of the data to the NHSN in order to calculate the measure. For example,

[143] Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs–IID) Residents, Clients, and Staff (86 FR 26315–26316). May 8, 2021.

NHSN is the data submission method for the HCP COVID–19 Vaccine measure for the SNF QRP. Therefore, SNFs must submit to the NHSN 100 percent of the information required to calculate the HCP COVID–19 Vaccine measure in order to meet the compliance threshold.

Similarly, for the HCP Influenza Vaccine measure, SNFs must submit to the NHSN 100 percent of the information required to calculate the measure. To meet the minimum data submission requirements for the HCP Influenza Vaccine measure, SNFs must enter a single influenza vaccination summary report at the conclusion of the measure reporting period. If SNFs submit data more frequently, such as on a monthly basis, the information would be used to calculate one summary score for the proposed measure which would be publicly reported on Care Compare and used to determine compliance with the SNF QRP.

Comment: One commenter requested clarification on the proposed conforming language to the regulatory text at § 413.360. Specifically, the commenter requested that CMS clarify the procedural steps SNFs must take to meet or exceed the two separate data completeness thresholds.[144] The commenter inquired how many files a SNF must submit and how often in order to meet the 100 percent completion threshold.

Response: The proposed revisions to the regulatory text at § 413.360 would add language to state that SNFs must meet or exceed two separate data completeness thresholds depending on the data submission method: (1) an 80 percent threshold for completion of required data elements collected using the MDS submitted through the CMS designated data submission system; and (2) a 100 percent threshold for measures collected and submitted using the NHSN.

With the addition of the HCP Influenza Vaccine measure adopted in this final rule, the SNF QRP would have two measures submitted via the NHSN: (1) the HCP COVID–19 Vaccine measure and (2) the HCP Influenza Vaccine measure. SNFs must follow separate data submission guidelines for each measure to meet the 100 percent completion threshold. For the HCP COVID–19 Vaccine measure, SNFs use the COVID–19 vaccination data collection module in the NHSN Long-term Care Component to report the number of HCP eligible to work at the facility for at least 1 day during the reporting period excluding persons with contraindications to COVID–19 vaccination that are described by the CDC[145] (denominator) and the number of those people who have received a completed COVID–19 vaccination course (numerator). To meet the minimum data submission requirements for the HCP COVID–19 Vaccine measure, SNFs submit COVID–19 vaccination data through the NHSN for at least 1 week each month. For example, if a SNF only submitted COVID–19 vaccination data for 1 week each month from January through September of a given calendar year, but failed to submit information for October, November, and December of that same calendar year, that SNF would not meet the 100 percent completion threshold for this measure and would face a 2-percentage-point reduction to its APU.

Similarly, for the HCP Influenza Vaccine measure, SNFs would use the HCP influenza data reporting module in the NHSN HPS Component and complete two forms. The first form (CDC 57.203) would indicate the type of data SNFs plan on reporting to the NHSN by selecting the ''Influenza Vaccination Summary'' option under ''Healthcare Personnel Vaccination Module'' to create a reporting plan. The second form (CDC 57.214) would report the number of HCP who have worked at the healthcare facility for at least 1 day between October 1st and March 31st (denominator) and the number of HCP who fall into each numerator category. To meet the minimum data submission requirements for the HCP Influenza Vaccine measure, SNFs would enter a single influenza vaccination summary report at the conclusion of the measure reporting period. If SNFs submit data more frequently, such as on a monthly basis, the information would be used to calculate one summary score for the proposed measure which would be publicly reported on Care Compare and used to determine compliance with the SNF QRP.

To meet the 100 percent compliance threshold for the HCP Influenza Vaccine measure, a SNF must submit a single influenza vaccination summary report at the conclusion of the reporting period. A SNF that submits an influenza vaccination summary report for October through December of an influenza season, but not for the remainder of the influenza season, would not meet the 100 percent completion threshold for this measure.

To meet the 80 percent compliance threshold for purposes of calculating the SNF's APU, a SNF would need to submit a minimum of 80 percent of its MDS with 100 percent of the required data elements collected during the reporting period to the CMS Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system or a successor system. The SNF QRP Table for Reporting Assessment-Based Measures for each FY SNF QRP APU is available for download on the SNF Quality Reporting Measures and Technical Information web page in the Downloads section.[146]

Comment: One commenter questioned whether a SNF would be compliant if it meets the 80 percent requirements but fails to meet the 100 percent requirements.

Response: We interpret the comment to be referring to the 80 percent compliance threshold for the required data elements submitted using the MDS 3.0 and the 100 percent compliance threshold proposed for measures submitted using the NHSN data submission framework. In accordance with section 1888(e)(6)(A)(i) of the Act, the Secretary must reduce by 2 percentage points the APU applicable to a SNF for a fiscal year if the SNF does not comply with the requirements of the SNF QRP for that fiscal year. Consistent with the measures we are finalizing, SNF providers must meet both the 80 percent and 100 percent compliance thresholds for that applicable fiscal year to comply with the requirements of the SNF QRP beginning with FY 2023 QRP and for all subsequent payment updates.

After consideration of the comments received, we are finalizing our proposal to make conforming revisions to the requirements under the SNF QRP at § 413.360. Specifically, we are redesignating § 413.360(b)(2) to § 413.360(f)(2) and adding a new paragraph (f) for the SNF QRP data completeness thresholds.

[144] One threshold set at 80 percent for completion of required quality measures data and standardized patient assessment data collected using the MDS submitted through the CMS-designated data submission system, beginning with FY 2018 and for all subsequent payment updates; and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN, beginning with FY 2023 and for all subsequent payment updates.

[145] Use of COVID–19 Vaccines in the United Stated. Interim Clinical Considerations. Available at *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.* Accessed 7/7/2022.

[146] SNF Quality Reporting Measures and Technical Information web page. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

D. SNF QRP Quality Measures Under Consideration for Future Years: Request for Information (RFI)

We solicited input on the importance, relevance, and applicability of the concepts under consideration listed in Table 16 in the SNF QRP. More specifically, we solicited input on a cross-setting functional measure that would incorporate the domains of self-care and mobility. Our measure development contractor for the cross-setting functional outcome measure convened a Technical Expert Panel (TEP) on June 15 and June 16, 2021 to obtain expert input on the development of a functional outcome measure for PAC. During this meeting, the possibility of creating one measure to capture both self-care and mobility was discussed. We also solicited input on measures of health equity, such as structural measures that assess an organization's leadership in advancing equity goals or assess progress toward achieving equity priorities. Finally, we solicited input on the value of a COVID–19 Vaccination Coverage measure that would assess whether SNF patients were up to date on their COVID–19 vaccine.

TABLE 16: Future Measures and Measure Concepts Under Consideration for the SNF QRP

Quality Concepts
Cross-Setting Function
Health Equity Measures
PAC – COVID-19 Vaccination Coverage among Patients

Comment: Most commenters supported the concept of a cross-setting functional outcome measure that is inclusive of both self-care and mobility items. Commenters provided information relative to potential risk adjustment methodologies as well as other tests and measures that could be used to capture functional outcomes. Commenters were mixed on whether they supported the measure concept of a PAC–COVID–19 vaccination coverage among patients. Two commenters noted the measure should account for other variables, such as whether the vaccine was offered, as well as patients with medical contraindications to the vaccine. Comments were generally supportive of the concept of measuring health equity in the SNF QRP. In addition, several commenters suggested other measures and measure concepts CMS should consider.

Response: As discussed in the proposed rule, we are not responding to specific comments submitted in response to this RFI in this final rule, but we intend to use this input to inform our future measure development efforts.

E. Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs—Request for Information (RFI)

1. Solicitation of Public Comments

The goal of the request for information was to describe some key principles and approaches that we would consider when advancing the use of quality measure development and stratification to address healthcare disparities and advance health equity across our programs.

We invited general comments on the principles and approaches described previously in this section of the rule, as well as additional thoughts about disparity measurement guidelines suitable for overarching consideration across CMS's QRP programs. Specifically, we invited comments on:

• *Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs:*

++ The use of the within- and between-provider disparity methods in SNFs to present stratified measure results.

++ The use of decomposition approaches to explain possible causes of measure performance disparities.

++ Alternative methods to identify disparities and the drivers of disparities.

• *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting:*

++ Principles to consider for prioritization of health equity measures and measures for disparity reporting, including prioritizing stratification for validated clinical quality measures, those measures with established disparities in care, measures that have adequate sample size and representation among healthcare providers and outcomes, and measures of appropriate access and care.

• *Principles for SRF and Demographic Data Selection and Use:*

++ Principles to be considered for the selection of SRFs and demographic data for use in collecting disparity data including the importance of expanding variables used in measure stratification to consider a wide range of SRFs, demographic variables, and other markers of historic disadvantage. In the absence of patient-reported data we will consider use of administrative data, area-based indicators, and imputed variables as appropriate.

• *Identification of Meaningful Performance Differences:*

++ Ways that meaningful difference in disparity results should be considered.

• *Guiding Principles for Reporting Disparity Measures:*

++ Guiding principles for the use and application of the results of disparity measurement.

• Measures Related to Health Equity:

++ The usefulness of a Health Equity Summary Score (HESS) for SNFs, both in terms of provider actionability to improve health equity, and in terms of whether this information would support Care Compare website users in making informed healthcare decisions.

++ The potential for a structural measure assessing a SNF's commitment to health equity, the specific domains that should be captured, and options for reporting these data in a manner that would minimize burden.

++ Options to collect facility-level information that could be used to support the calculation of a structural measure of health equity.

++ Other options for measures that address health equity.

We received several comments on the RFI for Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs. While we will not be responding to specific comments submitted in response to this RFI, the following is a summary of some comments received:

Comment: Several commenters provided feedback on the use of the within-provider and between-provider disparity methods to present stratified measure results. Overall, comments were generally supportive of

implementing both methods in order to provide a more complete picture of the quality of care provided to beneficiaries with SRFs. In terms of specific feedback related to the implementation of these stratification approaches, one commenter noted that when making between-facility comparisons, CMS should appropriately account for the share of patients within a facility with various risk factors. Another commenter noted that in the hospital setting, some stratification metrics moved widely across deciles when only a few patients improved performance, suggesting the importance of evaluating the statistical reliability of stratification methodologies implemented in the SNF setting.

One commenter expressed support for the measure performance disparity decomposition approach because it will likely provide valuable data while placing minimal burden on SNFs. Several commenters emphasized that providing stratified results alone to providers does not provide sufficient information to identify underlying factors that contribute to health inequities. While these commenters did not explicitly point to the disparity decomposition approach as a solution, the decomposition approach described could be a promising method to identify specific drivers of performance disparities, which would increase the actionability of stratified measure information while providing no additional burden to providers.

A handful of commenters responded to CMS's request for information about measures CMS could develop to assess and encourage health equity, including comments regarding the usefulness and actionability of a HESS and the potential for a structural measure to assess SNFs' commitment to health equity. We first summarize the comments regarding the HESS, then summarize comments related to a structural measure to assess commitment to equity.

Three commenters specifically addressed the HESS. One commenter encouraged CMS to clarify that the HESS would assess individual SNFs as opposed to the individual clinicians within each SNF. The two remaining commenters either supported or appreciated the HESS in concept, but raised several concerns pertaining to technical barriers, ambiguity in the methodology, and usability of the measure. In terms of technical concerns, one commenter noted that a standardized set of demographic data elements must be available for each patient, and stated that demographic data elements are not yet standardized across healthcare settings and organizations. Regarding methodological concerns, one commenter questioned how one could combine within-facility disparities and disparities across facilities into a single summary score in a manner that would accurately reflect the individual factors that may lead to these different types of disparities, without masking other factors. Other commenters raised similar concerns about the usability of the HESS, primarily stemming from the extent to which disparities across multiple measures and SRFs are aggregated into a single score. Specifically, one commenter noted that one SRF included in the HESS could mask the effects of other SRFs, which could potentially lead to misinterpretation of the overall score. Similarly, another commenter noted that performance on the composite HESS might obscure measure-level and SRF-specific disparities.

Two commenters addressed the potential for a structural measure to assess health equity. One commenter noted that the development of a structural measure to assess engagement and commitment of leadership toward advancing health equity should be included as one of several guiding principles to address health disparities and achieve health equity. Another commenter cautioned against the development of structural measures, suggesting that such measures would only demonstrate whether an organization is ''good at checking the box'' for the purpose of meeting the requirements of a measure.

Several commenters addressed the selection of SRFs and demographic data in collecting disparity data. One commenter supported the Center for Outcomes Research and Evaluation's (CORE's) efforts to categorize SDOH. Several commenters supported collecting data through current standardized resident assessment processes using variables with robust, established data sources. They believe revisions to an item already used across settings would capitalize on existing workflows and be easily updated within electronic health record (EHR) systems, resulting in minimal staff burden. One commenter recommended using existing items such as A1000 in Section A of the MDS assessment that addresses Race and Ethnicity, and revising gender identification options in MDS item A0800—Gender, which currently only includes binary Male/Female options. Another commenter recommended CMS consider how to best capture sexual orientation and gender identity among Medicare and Medicaid beneficiaries.

Several commenters preferred using self-reported social, economic, and demographic tools over imputed data sources, but also recognized the challenges with collecting self-reported data, and so they stated that in the absence of self-reported data, they would support the use of certain proxies, such as the Area Deprivation Index (ADI) or other area-based indicators of social risk. One commenter also suggested utilizing indexes from the Agency for Healthcare Research and Quality, CDC, and the Health Resources and Services Administration to incorporate data about area-based indicators of social risk would reduce burden on organizations or clinicians.

One commenter noted that using both methods of capturing data might be the best option: (1) a self-report demographic like the social determinants of health reported through the standardized patient assessment data elements that gives a picture of the unique resident's perspective, while (2) the area-based indices provide objective data on the risk factors present in the resident's usual environment.

Two commenters did not support selecting race and ethnicity for collecting disparity data. One commenter stated that ''race'' and ''ethnicity'' are social constructs that have no reliable biological basis in the clinical context, and are so overly broad, vague, and ill-defined that, even in combination with other indicators, they are unlikely to provide useful information and may even obscure individual experience to the detriment of individualized patient care. Another commenter also had significant reservations about using race and ethnicity data as the basis for stratifying measures and explaining differences in health and outcomes due to concerns about the variation in the manner in which race and ethnicity are defined and the categories collected by institutions.

Commenters suggested collecting other SRFs, including dual eligibility for Medicare and Medicaid, and detailed standardized demographic and language data. The Medicare Payment Advisory Commission (MedPAC) commented on its recent work to expand its definition of ''low-income'' as a proxy for beneficiary social risk. It defined ''low-income'' beneficiaries as those who are eligible for full or partial Medicaid benefits or receive the Part D low-income subsidy (LIS). This expanded definition includes beneficiaries who do not qualify for Medicaid benefits in their states but who do qualify for the LIS based on having limited assets and an income below 150 percent of the

federal poverty level. MedPAC found that compared to the non-LIS Medicare population, LIS beneficiaries have relatively low incomes and differ in other regards, including being twice as likely to be Black or Hispanic and three times as likely to be disabled.

Commenters spoke to the importance of considering how SRF data could be interoperable and constructed in a way to facilitate exchange. One commenter suggested that CMS consider recommendations from The Gravity Project. Another requested that CMS make a concerted effort to advance standards for the collection of socio-demographic information, using existing tools such as the United States Core Data for Interoperability (USCDI), Z-codes, HL7, and Fast Healthcare Interoperability Resources (FHIR) standards.

We received several comments on the topic of confidential reporting of stratified and unstratified measure results. Most commenters supported the concept of selecting and prioritizing measures for disparity reporting. One commenter stated they want meaningful, actionable data, while another commenter recommended that, in addition to providing confidential feedback to nursing homes on stratified measure results, CMS should also provide information to make this feedback meaningful to nursing homes, such as how to interpret the information and what can be done to address identified disparities. This commenter suggested using the cumulative data to identify disparities at a regional or national level on which targeted training and resources could be provided, either by CMS or by the Quality Improvement Organizations (QIOs). Another commenter urged CMS to use ease of data access as an additional guiding principle when making disparity reporting decisions.

As for public reporting of stratified and unstratified results, many commenters urged CMS to carefully evaluate performance using the confidential reporting of data prior to applying the same methodologies to public reporting of stratified measure results. Another commenter recommended CMS outline a clear plan for transitioning to public reporting as it plans for the initial private reporting. MedPAC, however, supported it because MedPAC believes it should enable comparisons of individual providers with State and national averages to give consumers meaningful reference points.

Response: We appreciate all of the comments and interest in this important topic. Public input is very valuable in the continuing development of our health equity quality measurement efforts and broader commitment to health equity, a key pillar of our strategic vision as well as a core agency function. Thus, we will continue to take all concerns, comments, and suggestions into account for future development and expansion of policies to advance health equity across the SNF QRP, including by supporting SNFs in their efforts to ensure equity for all of their patients, and to identify opportunities for improvements in health outcomes. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

F. Inclusion of the CoreQ: Short Stay Discharge Measure in a Future SNF QRP Program Year–Request for Information (RFI)

1. Solicitation of Public Comment

In the proposed rule, we requested stakeholder feedback on future adoption and implementation of the CoreQ: Short Stay Discharge Measure (CoreQ) into the SNF QRP.

Specifically, we sought comment on the following:

- Would you support utilizing the CoreQ to collect patient-reported outcomes (PROs)?
- Do SNFs believe the questions asked in the CoreQ would add value to their patient engagement and quality-of-care goals?
- Should CMS establish a minimum number of surveys to be collected per reporting period or a waiver for small providers?
- How long would facilities and customer satisfaction vendors need to accommodate data collection and reporting for all participating SNFs?
- What specific challenges do SNFs anticipate for collecting the CoreQ measure? What are potential solutions for those challenges?

Comment: We received a few comments on this RFI that were generally supportive of the addition of a PRO measure or patient experience measure to the SNF QRP. However, support for the CoreQ measure specifically was mixed among commenters. One commenter stated that since the CoreQ has a limited number of questions, it may not fully reflect patient experience at a given facility. Another commenter would not support the CoreQ since it excludes residents who leave a facility against medical advice and residents with guardians, and this commenter stated it would be important to hear from both of these resident populations. Two commenters cautioned CMS to consider the burden associated with contracting with vendors to administer such a measure.

Response: We are not responding to specific comments submitted in response to this RFI in this final rule, but we intend to use this input to inform our future measure development efforts.

G. Form, Manner, and Timing of Data Submission Under the SNF QRP

1. Background

We refer readers to the current regulatory text at § 413.360(b) for information regarding the policies for reporting SNF QRP data.

2. Proposed Schedule for Data Submission of the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) Measure Beginning With the FY 2024 SNF QRP

As discussed in section VI.C.1. of the proposed rule, we proposed to adopt the Influenza Vaccination Coverage among HCP quality measure beginning with the FY 2025 SNF QRP. However, after consideration of public comments, we are finalizing our proposal to adopt the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure beginning with the FY 2024 SNF QRP. The CDC has determined that the influenza vaccination season begins on October 1st (or when the vaccine becomes available) and ends on March 31st of the following year. Therefore, we proposed an initial data submission period from October 1, 2022 through March 31, 2023. We also noted that in subsequent years, data collection for this measure will be from October 1st through March 31st of the following year.

This measure requires that the provider submit a minimum of one report to the NHSN by the data submission deadline of May 15th for each influenza season following the close of the data collection period each year to meet our requirements. Although facilities may edit their data after May 15th, the revised data will not be shared with us.[147] SNFs would submit data for the measure through the CDC/NHSN web-based surveillance system. SNFs would use the Influenza Vaccination Summary option under the NHSN HPS Component to report the number of HCP

[147] Centers for Disease Control and Prevention (CDC). (2021). HCP Influenza Vaccination Summary Reporting FAQs. Retrieved from *https://www.cdc.gov/nhsn/faqs/vaccination/faq-influenza-vaccination-summary-reporting.html#:~:text=To%20meet%20CMS%20reporting%20requirements,not%20be%20shared%20with%20CMS.*

who receive the influenza vaccination (numerator) among the total number of HCP in the facility for at least 1 working day between October 1st and March 31st of the following year, regardless of clinical responsibility or patient contact (denominator).

We sought public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters urged CMS to be cautious in executing reporting for this measure since HCP influenza vaccination data are not currently reported by nursing homes and new processes will need to be implemented for measure data collection. Commenters recommended that (1) CMS provide ample notification to providers to ensure timely reporting of the measure, (2) reporting requirements of the measure should align with what is outlined in the proposed rule, and (3) CMS should only require reporting of the measure once per influenza season. Commenters also cautioned CMS that enforcement of any requirement must follow a traditional citation route without automatic financial penalties, given that SNFs that fail to report measure data will be penalized through the QRP framework itself.

One commenter expressed concerns that SNFs would be required to verify the influenza vaccination status of every employee, especially those who are immunized by an outside provider, and that the increase in administrative burden may take away resources to care for residents. Another commenter sought clarification about the measure's data collection process, noting that CMS must be clear and allow for ongoing flexibility in data collection and potential dispute.

Response: The HCP Influenza Vaccine measure reporting requirements would align with those outlined in the proposed rule. Specifically, the data collection period is October 1st to March 31st of the following year, with an annual data submission deadline due no later than May 15th. Additionally, we provide an updated SNF QRP Deadlines for Data Collection and Final Submission document on an annual basis. These deadlines provide sufficient notification to providers to ensure timely reporting of the measure. Providers may refer to this document on the *SNF QRP Data Submission Deadlines* web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Data-Submission-Deadlines#:~:text=When%20does%20SNF%20quality%20data,day%20of%20the%20submission%20deadline.* We also send out reminders of the data submission deadlines via CMS listserv announcements. Providers can subscribe to the listserv to receive these email updates and for the latest SNF quality reporting program information on the CMS *Email Updates* web page at *https://public.govdelivery.com/accounts/USCMS/subscriber/new?pop=t&topic_id=USCMS_7819.*

To report HCP influenza vaccination summary data to the NHSN, all facilities must complete two required forms: (1) HCP Safety Monthly Reporting Plan Form (57.203), and (2) HCP Influenza Vaccination Summary Form (57.214). Facilities reporting annual HCP influenza vaccination data would report through the NHSN's Healthcare Personnel Safety (HPS) Component; therefore, providers should use form 57.203 and select the ''Influenza Vaccination Summary'' option under the ''Healthcare Personnel Vaccination Module'' to create a reporting plan. For more data collection and submission details, we refer providers to the *HCP Influenza Vaccination Summary Reporting FAQs* on the CDC NHSN web page at *https://www.cdc.gov/nhsn/faqs/vaccination/faq-influenza-vaccination-summary-reporting.html.* We also provide additional information regarding provider trainings later in this section.

Although the measure may require that SNFs spend additional time obtaining verification of HCP influenza vaccination, the importance of preventing infection among susceptible residents warrants collection of HCP influenza vaccination rates. We note that SNFs already have a process in place for tracking employee vaccinations, since they have been reporting HCP COVID–19 vaccination since October 1, 2021. We emphasize that tracking influenza vaccination rates among HCP is less burdensome than tracking COVID–19 vaccination rates, since SNFs are only required to track and submit data for one annual vaccination per HCP instead of potentially multiple vaccinations and boosters for the COVID–19 vaccination.

Comment: Several commenters requested CMS not to finalize the Influenza Vaccination Coverage among HCP measure due to the burden associated with reporting it. Commenters expressed concern that additional NHSN reporting will place burden on facilities on top of the existing NHSN reporting requirement of COVID–19 data. One commenter noted provider confusion with NHSN data submission requirements as some have unintentionally submitted data for certain modules that were not required. This commenter also highlighted the burdens associated with obtaining Secure Access Management Services (SAMS) Level 3 access in accordance with the CDC's reporting requirements for SNFs. A final commenter recommended using National Immunization Records as a data source for the measure, rather than spending additional time to report HCP vaccination status to the NHSN.

Response: We emphasize that the Influenza Vaccination Coverage among HCP measure only requires providers to submit a minimum of one report to the NHSN for each influenza season. We also clarify a statement in section VI.C.1.a. of the FY 2023 SNF PPS proposed rule that a CDC analysis of the 2020 through 2021 influenza season revealed that among 16,535 active, CMS-certified nursing homes, 17.3 percent voluntarily submitted at *least 1 weekly influenza vaccination measurement* through the NHSN. We believe such voluntary reporting supports the feasibility of annual measure data collection and reporting by nursing homes. We also believe that the burden of submitting data should be reduced since providers will have some familiarity with the NHSN through their experience of reporting of the COVID–19 Vaccination Coverage among HCP measure.[148]

In response to provider confusion with NHSN data submission requirements, facilities may refer to the *Healthcare Personnel Safety Component—Healthcare Personnel Vaccination Module Influenza Vaccination Summary Comprehensive Training Slides* at *https://www.cdc.gov/nhsn/pdfs/training/hcp/hcp-flu-vaccination-summary-reporting-general-training.pdf,* to learn how to report required data. To view provider trainings that are specific to long-term care facilities, providers may refer to the *Healthcare Personnel Safety Component—Healthcare Personnel Vaccination Module Influenza Vaccination Summary Long-Term Care Facilities* training slides at the following CDC web page at *https://www.cdc.gov/nhsn/pdfs/training/vaccination/hcp-flu-vax-summary-reporting-ltc.pdf.* The CDC also plans to offer additional training in the fall of 2022 to review annual influenza vaccination reporting and answer provider questions in real time via a webinar chat feature.

[148] 86 FR 42424.

In regard to concerns about provider requirements to obtain SAMS Level 3 access, we would like to highlight that 14,849 long-term care facilities (98 percent) with a CMS Certification Number (CCN) already have at least one SAMS Level 3 user. We additionally note that 12,133 long-term care facilities (80 percent) have two or more SAMS level 3 users. Therefore, many facilities will not need to spend additional time requesting SAMS Level 3 access to meet the data submission requirements of the Influenza Vaccination Coverage among HCP measure. Additionally, SAMS has expedited the timeline for gaining Level 3 access by allowing users to submit identity verification documents to the CDC using Experian. More information for gaining SAMS Level 3 access can be retrieved at the *About SAMS* CDC web page at *https://www.cdc.gov/nhsn/sams/about-sams.html.*

Lastly, regarding commenter suggestions to retrieve HCP influenza vaccination from national immunization records, there is no such national organization.[149] While some vaccine providers participate in immunization registries such as the Immunization Information Systems (IIS), the HCP Influenza Vaccine measure would not require SNFs to participate in such registries,[150] making the NHSN the comprehensive method for tracking HCP influenza vaccination rates for purposes of the SNF QRP.

Comment: One commenter noted technical issues encountered with the NHSN reporting system since SNFs began using it in May 2021, suggesting that CMS should implement provider protections to mitigate NHSN data submission issues that may be beyond providers' control. Another commenter opposed the measure proposal due to technical issues with the NHSN reporting system that are beyond providers' control. One commenter outlined several NHSN technical issues experienced by providers, such as (1) frequent changing of NHSN module tables and required content, (2) NHSN acceptance of incomplete data resulting in SNF non-compliance, (3) mislabeling SNF CMS Certification Numbers (CCNs) by the NSHN, (4) errors with comma-separated items on group NHSN uploads, (5) auto-populated NHSN error messages that do not identify which portion of the submission may have an error, (6) delays in NHSN Helpdesk response and/or closing a ticket without ensuring the issue has been resolved, (7) provider software incompatibility and ransomware attacks which have prevented transmission of files, and (8) unavailability of telecommunication due to weather-related interruptions.

Response: We discussed providers' concerns regarding technical difficulties that may arise in submitting data to the NHSN. The CDC has provided responses to each concern as outlined throughout the remainder of this response. First, the CDC highlights that the NHSN conducted surveillance of annual influenza vaccination beginning with the 2012 through 2013 influenza season. Results of the surveillance reveal that multiple facility types (for example, acute care facilities, inpatient rehabilitation facilities, long-term acute care facilities, etc.) have successfully reported these data over several years. Surveillance to track influenza vaccination has not required frequent changes to NHSN module tables and required content because annual influenza vaccination recommendations for healthcare workers have not changed for several years, unlike COVID–19 vaccination data reporting where guidance is still evolving and changing.

Regarding concerns about NHSN acceptance of incomplete data submission leading to provider non-compliance, the CDC notes that fields are set as required in the current NHSN annual influenza module, which prevents incomplete data submission for this reporting metric. Resources and training materials for annual influenza surveillance are available on the *NHSN Healthcare Personnel (HCP) Flu Vaccination* CDC web page at *https://www.cdc.gov/nhsn/hps/vaccination/index.html.*

In response to concerns about mislabeled CMS CCNs, the CDC emphasizes that providers are responsible for correctly entering their CCNs into the NHSN application. If a SNF has correctly entered its CCN and influenza surveillance data appropriately, data will automatically be sent to CMS to meet SNF QRP data submission requirements. The NHSN continues to provide support and education to SNFs when they reach out about correcting their CCN in the NHSN application. SNFs may view checklists to ensure their annual influenza vaccination data are reported accurately on the *NHSN Healthcare Personnel (HCP) Flu Vaccination* CDC web page at *https://www.cdc.gov/nhsn/hps/vaccination/index.html,* under the ''Annual Flu Summary'' heading. In addition, providers can view information regarding data verification on the following CDC web page: *Submission of Healthcare Personnel (HCP) Influenza Vaccination Summary Data in NHSN* at *https://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/verification-hcp-flu-data.pdf.* If a provider seeks to change the CCN listed for a SNF in the NHSN, the provider may refer to the following CDC NHSN guidance document: *Long-Term Care Facility (LTCF) How to Add and Edit Facility CMS Certification Number (CCN) within NHSN* at the following web page at *https://www.cdc.gov/nhsn/pdfs/ltc/ccn-guidance-508.pdf.* Lastly, providers may view additional NHSN resources at the CDC NHSN *CMS Quality Reporting Program Frequently Asked Questions* web page at *https://www.cdc.gov/nhsn/faqs/cms/faq_cms_hai.html.*

Regarding concerns with comma-separated items on group uploads, the CDC notes that uploading data via a comma-separated values (CSV) file is not an option for annual influenza vaccination data reporting. However, the CDC anticipates having this option available in the upcoming 2022 through 2023 influenza season. The CDC acknowledged that as COVID–19 surveillance needs evolved, data fields changed accordingly, and at times it led to unexpected issues with CSV upload and short delays in reporting. The CDC prioritizes resolving such issues quickly and communicating with users and partners. The NHSN continues to offer support to facilitate data uploading.

Moreover, in response to concerns about auto-populated error messages, the NHSN continues to work to make error messages detailed and clear for users. For example, common errors are covered during user trainings (*i.e.,* webinars, email blasts, etc.). The CDC continues to revise error messages based on user feedback, encouraging plain language detailed messages. If there are specific alerts causing confusion for annual influenza vaccination data, providers are encouraged to contact *NHSN@cdc.gov.*

Regarding NHSN Helpdesk concerns, if a SNF continues to have questions or experience additional issues after a ticket has closed, the CDC encourages providers to submit a new email with a detailed subject line to ensure an expeditious Helpdesk reply with input from a subject matter expert team. When submitting annual influenza vaccination data, SNFs have been instructed to include ''HPS Flu Summary'' along with their facility type in the subject line of the email for a more immediate response.

[149] Centers for Disease Control and Prevention (CDC). (2016). Keeping your Vaccine Records Up to Date. Retrieved from *https://www.cdc.gov/vahccines/adults/vaccination-records.html.*

[150] Centers for Disease Control and Prevention (CDC). (2019). About Immunization Information systems. Retrieved from *https://www.cdc.gov/vaccines/programs/iis/about.html.*

In regard to general submission concerns such as software incompatibility and ransomware attacks that have prevented the transmission of data files, the NHSN provides CSV templates and CSV template example files if SNFs prefer to upload data directly to the platform. CSV templates will be made available to SNFs reporting annual influenza vaccination data for the 2022 through 2023 influenza season. Once available, CSV templates will appear similarly to how the COVID–19 Vaccination Coverage among HCP resources appear on the Weekly HCP & Resident COVID–19 Vaccination CDC NHSN web page *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html,* under a CSV Data Import header.

Lastly, in response to concerns about technical data submission issues that may arise beyond providers' control, such as telecommunication issues resulting from weather-related interruptions, the CMS reconsideration and exception and extension process is available to SNFs if they are found to be non-compliant with the SNF QRP data submission requirements and believe they have a valid reason for an exception. For information about the reconsideration and exception and extension request process, please visit the *SNF QRP Reconsideration and Exception & Extension* CMS web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-QR-Reconsideration-and-Exception-and-Extension.*

Comment: Two commenters expressed concern over the quality of provider-submitted data to the NHSN, noting the importance of data validation efforts, and oppose the adoption of the measure until there are data validation and provider Review and Correct Reports comparable to other provider-submitted SNF QRP data. The commenters noted that since SNFs receive their provider preview reports in July, SNFs do not have an opportunity to correct any discrepancies that could be found if given more time to review their data. Another commenter supported the measure concept but would like clarification regarding Review and Correct Reports.

Response: The Influenza Vaccination Coverage among HCP measure is stewarded by the CDC NHSN. To date, we have never added any of the CDC NHSN measures to the Review and Correct Report, as the data for these measures are at the CDC. In lieu of this, the CDC makes accessible to PAC providers, including SNFs, reports that are similar to the Review and Correct Reports that allow for real-time review of data submissions for all CDC NHSN measures adopted for use in the CMS PAC QRPs, including the SNF QRP. These reports are referred to as ''CMS Reports'' within the ''Analysis Reports'' page in the NHSN Application. Such a report exists for each CDC NHSN measure within each of the PAC programs, and each report is intended to mimic the data that will be sent to CMS on their behalf. This report will exist to serve the same ''review and correct'' purposes for the Influenza Vaccination Coverage among HCP measure. The CDC publishes reference guides for each facility type (including SNFs) and each NHSN measure, which explain how to run and interpret the reports.

Additionally, we will make available to SNFs a preview of SNF performance on the Influenza Vaccination Coverage among HCP measure on the SNF Provider Preview Report, which will be issued approximately 3 months prior to displaying the measure on Care Compare. As always, SNFs will have a full 30 days to preview their data. Should SNFs disagree with their measure results, they can request a formal review of their data by us. Instructions for submitting such a request are available on the CMS *SNF Quality Reporting Program Public Reporting* web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Public-Reporting.*

After consideration of public comments, we are finalizing the schedule of data submission for the Influenza Vaccination Coverage among HCP Measure (NQF #0431) as proposed.

H. Policies Regarding Public Display of Measure Data for the SNF QRP

1. Background

Section 1899B(g) of the Act requires the Secretary to establish procedures for making the SNF QRP data available to the public, including the performance of individual SNFs, after ensuring that SNFs have the opportunity to review their data prior to public display. SNF QRP measure data are currently displayed on the *Nursing homes including rehab services* website within Care Compare and the Provider Data Catalog. Both Care Compare and the Provider Data Catalog replaced Nursing Home Compare and *Data.Medicare.gov*, which were retired in December 2020. For a more detailed discussion about our policies regarding public display of SNF QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

2. Public Reporting of the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) Measure Beginning With the FY 2024 SNF QRP

We proposed to publicly report the Influenza Vaccination Coverage among HCP (NQF #0431) measure beginning with the October 2023 Care Compare refresh or as soon as technically feasible using data collected from October 1, 2022 through March 31, 2023. If finalized as proposed, a SNF's Influenza Vaccination Coverage among HCP rate would be displayed based on 6 months of data. Provider preview reports would be distributed in July 2023. Thereafter, Influenza Vaccination Coverage among HCP rates would be displayed based on 6 months of data, reflecting the reporting period of October 1st through March 31st, updated annually. We invited public comment on this proposal for the public display of the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure on Care Compare.

The following is a summary of the comments we received and our responses.

Comment: One commenter noted that public reporting of this measure would provide the previous influenza season's data to consumers and would not reflect the vaccination rates of the current influenza year.

Response: The measure's public reporting schedule is in alignment with those of the IRF and LTCH QRPs, supporting the standardized and interoperable requirement of the IMPACT Act, and the ability to compare data for the same time period across PAC providers when using Care Compare. Additionally, the public display of HCP influenza vaccine data in October 2023 allows for a 6-month data collection period (October 1, 2022 through March 31, 2023), a period of 6 weeks for providers to submit their data to the NHSN, our analysis of the data, and a period of time for SNFs to review their Provider Preview Report and alert us if they believe there are errors in the data. We believe this reporting schedule, outlined in section VI.G.2. of the proposed rule, is reasonable, and expediting this schedule may establish undue burden on providers and jeopardize the integrity of the data.

After consideration of public comments, we are finalizing the

proposal to publicly report the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0413) measure beginning with the October 2023 refresh or as soon as technically feasible, as proposed.

VIII. Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program

A. Statutory Background

Section 215(b) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) authorized the SNF VBP Program (the ''Program'') by adding section 1888(h) to the Act. Additionally, section 111 of the Consolidated Appropriations Act, 2021 authorized the Secretary to apply additional measures to the SNF VBP Program for payments for services furnished on or after October 1, 2023. The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing bed rural hospitals. We believe the SNF VBP Program has helped to transform how payment is made for care, moving increasingly towards rewarding better value, outcomes, and innovations instead of merely rewarding volume.

As a prerequisite to implementing the SNF VBP Program, in the FY 2016 SNF PPS final rule (80 FR 46409 through 46426), we adopted an all-cause, all-condition hospital readmission measure, as required by section 1888(g)(1) of the Act and discussed other policies to implement the Program such as performance standards, the performance period and baseline period, and scoring. SNF VBP Program policies have been codified in our regulations at 42 CFR 413.338. For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the following prior final rules:

- In the FY 2017 SNF PPS final rule (81 FR 51986 through 52009), we adopted an all-condition, risk-adjusted potentially preventable hospital readmission measure for SNFs, as required by section 1888(g)(2) of the Act, adopted policies on performance standards, performance scoring, and sought comment on an exchange function methodology to translate SNF performance scores into value-based incentive payments, among other topics.
- In the FY 2018 SNF PPS final rule (82 FR 36608 through 36623), we adopted additional policies for the Program, including an exchange function methodology for disbursing value-based incentive payments.
- In the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), we adopted more policies for the Program, including a scoring adjustment for low-volume facilities.
- In the FY 2020 SNF PPS final rule (84 FR 38820 through 38825), we adopted additional policies for the Program, including a change to our public reporting policy and an update to the deadline for the Phase One Review and Correction process. We also adopted a data suppression policy for low-volume SNFs.
- In the FY 2021 SNF PPS final rule (85 FR 47624 through 47627), we amended regulatory text definitions at § 413.338(a)(9) and (11) to reflect the definition of Performance Standards and the updated Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure name, respectively. We also updated the Phase One Review and Correction deadline and codified that update at § 413.338(e)(1). Additionally, we codified the data suppression policy for low-volume SNFs at § 413.338(e)(3)(i) through (iii) and amended § 413.338(e)(3) to reflect that SNF performance information will be publicly reported on the Nursing Home Compare website and/or successor website (84 FR 38823 through 38824), which since December 2020 is the Provider Data Catalog website (*https://data.cms.gov/provider-data/*).
- In the September 2nd interim final rule with comment (IFC) (85 FR 54837), we revised the performance period for the FY 2022 SNF VBP Program to be April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020, in response to the COVID–19 Public Health Emergency (PHE).
- In the FY 2022 SNF PPS final rule (86 FR 42502 through 42517), we adopted additional policies for the Program, including a measure suppression policy to offer flexibility in response to the COVID–19 PHE. We adopted policies to suppress the SNFRM for scoring and payment purposes for the FY 2022 SNF VBP program year, to revise the SNFRM risk-adjustment lookback period for the FY 2023 SNF VBP program year, and to use FY 2019 data for the baseline period for the FY 2024 SNF VBP program year. We also updated the Phase One Review and Correction process and updated the instructions for requesting an Extraordinary Circumstances Exception (ECE). Finally, we finalized a special scoring policy assigning all SNFs a performance score of zero, effectively ranking all SNFs equally in the FY 2022 SNF VBP program year. This policy was codified at § 413.338(g) of our regulations.

To improve the clarity of our regulations, we proposed to update and renumber the ''Definitions'' used in § 413.338 by revising paragraphs (a)(1) and (4) through (17). We invited public comment on these proposed updates.

We did not receive any public comments on our proposal to update and renumber the ''Definitions'' used in § 413.338 by revising paragraphs (a)(1) and (4) through (17) and therefore, we are finalizing the updates as proposed.

B. SNF VBP Program Measures

For background on the measures we have adopted for the SNF VBP Program, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46419), where we finalized the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) that we are currently using for the SNF VBP Program. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), where we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR) that we will use for the SNF VBP Program instead of the SNFRM as soon as practicable, as required by statute. The SNFPPR measure's name is now ''Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure'' (§ 413.338(a)(11)). We intend to submit the SNFPPR measure for NQF endorsement review as soon as practicable, and to assess transition timing of the SNFPPR measure to the SNF VBP Program after NQF endorsement review is complete.

1. Suppression of the SNFRM for the FY 2023 Program Year

a. Background

As discussed in the FY 2023 SNF proposed rule, we remain concerned about the effects of the PHE for COVID–19 on our ability to assess performance on the SNFRM in the SNF VBP Program. As of mid-December 2021, more than 50 million COVID–19 cases and 800,000 COVID–19 deaths have been reported in the United States (U.S.).[151] COVID–19 has overtaken the 1918 influenza pandemic as the deadliest disease in American history.[152] Moreover, the individual and public health ramifications of COVID–19 extend beyond the direct effects of COVID–19 infections. Several studies have

[151] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[152] *https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/.*

demonstrated significant mortality increases in 2020, beyond those attributable to COVID–19 deaths. One paper quantifies the net impact (direct and indirect effects) of the pandemic on the U.S. population during 2020 using three metrics: excess deaths, life expectancy, and total years of life lost. The findings indicate there were 375,235 excess deaths, with 83 percent attributable to direct effects, and 17 percent attributable to indirect effects, of COVID–19. The decrease in life expectancy was 1.67 years, translating to a reversion of 14 years in historical life expectancy gains. Total years of life lost in 2020 was 7,362,555 across the U.S. (73 percent directly attributable, 27 percent indirectly attributable to COVID–19), with considerable heterogeneity at the individual State level.[153]

b. Suppression of the SNFRM for the FY 2023 SNF VBP Program Year

In the FY 2022 SNF PPS final rule (86 FR 42503 through 42505), we adopted a quality measure suppression policy for the duration of the PHE for COVID–19 that enables us to suppress the use of the SNFRM for purposes of scoring and payment adjustments in the SNF VBP Program if we determine that circumstances caused by the PHE for COVID–19 have affected the measure and the resulting performance scores significantly.

We also adopted a series of Measure Suppression Factors to guide our determination of whether to propose to suppress the SNF readmission measure for one or more program years that overlap with the PHE for COVID–19. The Measure Suppression Factors that we adopted are:

- Measure Suppression Factor 1: Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Measure Suppression Factor 2: Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.
- Measure Suppression Factor 3: Rapid or unprecedented changes in:

++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

- Measure Suppression Factor 4: Significant national shortages or rapid or unprecedented changes in:

++ Healthcare personnel.

++ Medical supplies, equipment, or diagnostic tools or materials.

++ Patient case volumes or facility-level case-mix.

We refer readers to the FY 2022 SNF PPS final rule (86 FR 42503 through 42505) for additional details on this policy, including summaries of the public comments that we received and our responses.

Additionally, in the FY 2022 SNF PPS final rule (86 FR 42505 through 42507), we suppressed the SNFRM for the FY 2022 SNF VBP program year under Measure Suppression Factor (4): Significant national shortages or rapid or unprecedented changes in: (iii) Patient case volumes or facility-level case mix. We refer readers to that final rule for additional discussion of the analyses we conducted of SNFRM performance during the PHE for COVID–19, how the measure's reliability changed, how its current risk-adjustment model does not factor in COVID–19, and how the PHE affected different regions of the country at different times, as well as summaries of the public comments that we received on that proposal and our responses.

The PHE for COVID–19 has had direct, significant, and continuing effects on our ability to measure SNFs' performance on the SNFRM. SNFs are experiencing a significant downward trend in admissions compared with their pre-COVID–19 admission rates. For the FY 2021 program year, a total of 1,566,540 SNF admissions were eligible for inclusion in the SNFRM (based on FY 2019 data). We have estimated that approximately 1,069,789 admissions would be eligible for inclusion for the FY 2023 program year (based on currently available data, which ranged from July 1, 2020 through June 30, 2021), representing a volume decrease of approximately 32 percent. Based on this lower number of eligible SNF admissions, we have estimated that only 75.2 percent of SNFs would be eligible to be scored on the SNFRM for FY 2021, compared with 82.4 percent that were eligible to be scored for FY 2019. As discussed in the FY 2023 SNF PPS proposed rule, given the significant decrease in SNF admissions during FY 2021, we remain concerned that using FY 2021 data to calculate SNFRM rates for the FY 2023 program year will have significant negative impacts on the measure's reliability. Our contractor's analysis using FY 2019 data showed that such changes may lead to a 15 percent decrease in the measure reliability, assessed by the intra-class correlation coefficient (ICC).

As discussed in the FY 2023 SNF PPS proposed rule, we also remain concerned that the pandemic's disparate effects on different regions of the country throughout the PHE have presented challenges to our assessments of performance on the SNFRM. According to CDC data,[154] for example, new COVID–19 cases at the beginning of FY 2021 (October 1, 2020) were highest in Texas (3,534 cases), California (3,062 cases), and Wisconsin (3,000 cases). By April 1, 2021, however, new cases were highest in Michigan (6,669 cases), Florida (6,377 cases), and New Jersey (5,606 cases). This variation in COVID–19 case rates throughout the PHE has also been demonstrated in several studies. For example, studies have found widespread geographic variation in county-level COVID–19 cases across the U.S.[155] [156] [157] Specifically, one study found that, across U.S. census regions, counties in the Midwest had the greatest cumulative rate of COVID–19 cases.[158] Another study found that U.S. counties with more immigrant residents, as well as more Central American or Black residents, have more COVID–19 cases.[159] These geographic variations in COVID–19 case rates are often linked to a wide range of county-level

[153] Chan, E.Y.S., Cheng, D., & Martin, J. (2021). Impact of COVID–19 on excess mortality, life expectancy, and years of life lost in the United States. *PloS one, 16*(9), e0256835. *https://pubmed.ncbi.nlm.nih.gov/34469474/.*

[154] ''United States COVID–19 Cases and Deaths by State,'' Centers for Disease Control. Retrieved from *https://data.cdc.gov/Case-Surveillance/United-States-COVID-19-Cases-and-Deaths-by-State-o/9mfq-cb36/data* on March 22, 2022.

[155] Desmet, K., & Wacziarg, R. (2022). JUE Insight: Understanding spatial variation in COVID–19 across the United States. *Journal of Urban Economics, 127,* 103332. *https://doi.org/10.1016/j.jue.2021.103332.*

[156] Messner, W., & Payson, SE (2020). Variation in COVID–19 outbreaks at the US State and county levels. *Public Health, 187,* 15–18. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7396895/pdf/main.pdf.*

[157] Khan, S.S., Krefman, A.E., McCabe, M.E., Petito, L.C., Yang, X., Kershaw, K.N., Pool, L.R., & Allen, N.B. (2022). Association between county-level risk groups and COVID–19 outcomes in the United States: a socioecological study. *BMC Public Health, 22,* 81. *https://doi.org/10.1186/s12889-021-12469-y.*

[158] Khan, S.S., Krefman, A.E., McCabe, M.E., Petito, L.C., Yang, X., Kershaw, K.N., Pool, L.R., & Allen, N.B. (2022). Association between county-level risk groups and COVID–19 outcomes in the United States: a socioecological study. *BMC Public Health, 22,* 81. *https://doi.org/10.1186/s12889-021-12469-y.*

[159] Strully, K., Yang, T-C., & Lui, H. (2021). Regional variation in COVID–19 disparities: connections with immigrant and Latinx communities in U.S. counties. *Annals of Epidemiology, 53,* 56–62. *https://doi.org/10.1016/j.annepidem.2020.08.016.*

characteristics, including sociodemographic and health-related factors.[160] In addition, these studies have found evidence of temporal variation in county-level COVID–19 cases. For example, one study found that while many county-level factors show persistent effects on COVID–19 severity over time, some factors have varying effects on COVID–19 severity over time.[161] The significant variation in COVID–19 case rates across the U.S. can affect the validity of performance data. Therefore, we do not believe it would be fair or equitable to assess SNFs' performance on the measure using FY 2021 data, which has been affected by these variations in COVID–19 case rates.

Increases in the number of COVID–19 cases are typically followed by an increase in the number of COVID–19 related hospitalizations, especially among the unvaccinated. Although COVID–19 vaccines began to come available in December of 2020, it was only readily available in early summer 2021 resulting in less than half of eligible Americans being fully vaccinated by the beginning of the fourth quarter of FY 2021. In addition, the vaccination rates were not evenly distributed across the country. Regions with significantly lower vaccination rates experienced higher hospitalization and ICU rates making them more prone to capacity challenges. Hospital capacity challenges have the potential to influence decisions that impact their downstream post-acute partners. As a result, for the first 3 quarters of FY 2021 performance year, low vaccinated regions' SNFs could have faced care coordination challenges with their partnering hospitals that regions with high vaccination rates did not experience. The continuation of the pandemic into 2021 did not necessarily impact all measures in the post-acute space, but measures related to hospital care may be impacted because of how closely the surge in COVID–19 cases was related to the surge in COVID–19 related hospital cases. Unlike other value-based purchasing programs that have multiple measures, the SNF VBP Program's single-measure requirement, currently the SNFRM, means that suppression of the measure will directly impact the payment adjustment.

The combination of fewer admissions to SNFs, regional differences in the prevalence of COVID–19 throughout the PHE and changes in hospitalization patterns in FY 2021 has impacted our ability to use the SNFRM to calculate payments for the FY 2023 program year.

Based on the significant and continued decrease in the number of patients admitted to SNFs, which likely reflects shifts in utilization patterns due to the risk of spreading COVID–19 in SNFs, we proposed to suppress the SNFRM for the FY 2023 SNF VBP program year under Measure Suppression Factor (4): Significant national shortages or rapid or unprecedented changes in: (iii) Patient case volumes or facility-level case-mix.

As with the suppression policy that we adopted for the FY 2022 SNF VBP Program, we proposed for the FY 2023 SNF VBP Program that we will use the previously finalized performance period (FY 2021) and baseline period (FY 2019) to calculate each SNF's RSRR for the SNFRM. We also proposed to suppress the use of SNF readmission measure data for purposes of scoring and payment adjustments. We further proposed to assign all participating SNFs a performance score of zero in the FY 2023 SNF VBP Program Year. We stated that this assignment would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier.

We proposed to reduce each participating SNF's adjusted Federal per diem rate for FY 2023 by 2 percentage points and award each participating SNF 60 percent of that 2 percent withhold, resulting in a 1.2 percent payback for the FY 2023 SNF VBP Program Year. We continue to believe that this continued application of the 2 percent withhold is required under section 1888(h)(5)(C)(ii)(III) of the Act and that a payback percentage that is spread evenly across all participating SNFs is the most equitable way to reduce the impact of the withhold in light of our proposal to award a performance score of zero to all SNFs.

However, as discussed in the proposed rule, we further proposed to remove the low-volume adjustment policy from the SNF VBP Program beginning with the FY 2023 program year, and instead, implement case and measure minimums that SNFs must meet in order to be eligible to participate in the SNF VBP Program for a program year.

We proposed that SNFs that do not report a minimum of 25 eligible stays for the SNFRM for the FY 2023 program year will not be included in the SNF VBP Program for that program year. As a result, the payback percentage for FY 2023 will remain at 60.00 percent.

For the FY 2023 program year, we also proposed to provide quarterly confidential feedback reports to SNFs and to publicly report the SNFRM rates for the FY 2023 SNF VBP Program Year. However, in the proposed rule, we stated that we will make clear in the public presentation of those data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the PHE for COVID–19 on the data used to calculate the measure (87 FR 22765). We stated in the proposed rule that the public presentation will be limited to SNFs that reported the minimum number of eligible stays. Finally, we proposed to codify these policies for the FY 2023 SNF VBP in our regulation text at § 413.338(i).

As stated in the proposed rule, we continue to be concerned about effects of the COVID–19 PHE but are encouraged by the rollout of COVID–19 vaccinations and treatment for those diagnosed with COVID–19 and believe that SNFs are better prepared to adapt to this virus. Our measure suppression policy focuses on a short-term, equitable approach during this unprecedented PHE, and it was not intended for indefinite application. Additionally, we emphasized the importance of value-based care and incentivizing quality care tied to payment. The SNF VBP Program is an example of our effort to link payments to healthcare quality in the SNF setting. We stated our understanding that the COVID–19 PHE is ongoing and unpredictable in nature; however, we also stated our belief that 2022 presents a more promising outlook in the fight against COVID–19. Over the course of the pandemic, providers have gained experience managing the disease, surges of COVID–19 infection, and supply chain fluctuations.[162] While COVID–19 cases among nursing home staff reached a recent peak in January of 2022, those case counts dropped significantly by the week ending February 6, 2022, to 22,206.[163] COVID–19 vaccinations and boosters have also been taken up by a significant majority of nursing home residents, and according to CDC, by February 6, 2022, more than 68 percent of completely

[160] CDC COVID–19 Response Team. (2020). Geographic Differences in COVID–19 Cases, Deaths, and Incidence—United States, February 12—April 7, 2020. *MMWR Morbidity and Mortality Weekly Report, 69*(15), 465–471. *http://dx.doi.org/10.15585/mmwr.mm6915e4.*

[161] Desmet, K., & Wacziarg, R. (2022). JUE Insight: Understanding spatial variation in COVID–19 across the United States. *Journal of Urban Economics, 127,* 103332. *https://doi.org/10.1016/j.jue.2021.103332.*

[162] McKinsey and Company. (2021). How COVID–19 is Reshaping Supply Chains. Available at *https://www.mckinsey.com/business-functions/operations/our-insights/how-covid-19-is-reshaping-supply-chains.*

[163] ''Nursing Home Covid–19 Data Dashboard.'' Centers for Disease Control, retrieved from *https://www.cdc.gov/nhsn/covid19/ltc-report-overview.html* on February 14, 2022.

vaccinated nursing home residents had received boosters.[164] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits,[165] N–95 masks,[166] and increase COVID–19 testing in schools.[167] In light of this more promising outlook, we stated in the proposed rule that we intend to resume the use of the SNFRM for scoring and payment adjustment purposes beginning with the FY 2024 program year. That is, for FY 2024, for each SNF, we will calculate measure scores in the SNF VBP Program. We will then calculate a SNF performance score for each SNF and convert the SNF performance scores to value-based incentive payments.

We invited public comment on our proposal to suppress the SNFRM for the FY 2023 program year and to codify our scoring and payment proposals for FY 2023 in our regulation text. We received the following comments and provide our responses:

Comment: Many commenters supported our proposal to suppress the SNFRM for FY 2023 and our plans to resume use of the SNFRM beginning with FY 2024 noting the impacts of COVID–19 on readmission rates. One commenter suggested that we consider alternative quality measures in the long term that would encourage providers to use SNFs as a short-term care venue for patients likely to be readmitted. Another commenter recommended that we provide confidential feedback reports to providers rather than publicly reporting SNFRM rates until we end our measure suppression policy and that we delay calculating SNF performance scores in FY 2024 until the end of the PHE.

Response: We appreciate the support for our proposal to suppress the SNFRM for FY 2023 and our plans to resume use of the SNFRM beginning with FY 2024 noting the impacts of COVID–19 on readmission rates. We disagree with the commenter's suggestion to provide only confidential feedback reports to SNFs until we end the suppression policy. We continue to believe that stakeholders benefit immensely from access to quality data, and as we stated in the proposed rule, we will include appropriate caveats on the suppressed measure data when published. We will consider additional quality measurement topics for the Program in future rulemaking.

Comment: Many commenters recommended that we increase the Program's payback percentage to 70 percent while we suppress the SNFRM for FY 2023. One commenter suggested that we return the full 2 percent withheld from SNFs' Medicare payments, while another suggested that we extend suppression through the end of any future PHE.

Response: We did not propose to change the previously finalized payback percentage for the SNF VBP Program in the proposed rule, and we view comments requesting that we change that policy to be beyond the scope of the proposed rule. We believe this continued application of the 2 percent withhold is required under section 1888(h)(5)(C)(ii)(III) of the Act and that a payback percentage that is spread evenly across all qualifying SNFs is the most equitable way to reduce the impact of the withhold in light of our proposal, which we are finalizing in this final rule, to award a performance score of zero to all SNFs. We also do not believe it would be appropriate to preemptively extend the quality measure suppression policy through the end of any future PHE, as the suppression policy focuses on identifying how quality measurement has been affected by a specific PHE.

After considering the public comments, we are finalizing our proposal to suppress the SNFRM for the FY 2023 SNF VBP Program as proposed and codifying it, as well as finalizing the special scoring and payment policies for FY 2023, at § 413.338(i) of our regulations.

2. Technical Updates to the SNFRM To Risk-Adjust for COVID–19 Patients Beginning With the FY 2023 Program Year

The emergence of the COVID–19 PHE, along with the high prevalence of COVID–19 in patients admitted to SNFs, has prompted us to examine whether we should develop an adjustment to the SNFRM that would properly account for COVID–19 patients. As detailed in the proposed rule, we considered four options that such an adjustment could take. After careful examination of each of the four options, we are updating the technical specifications of the SNFRM such that COVID–19 patients (diagnosed at any time within 12 months prior to or during the prior proximal hospitalization [PPH]) will remain in the measure's cohort, but we will add a variable to the risk-adjustment model that accounts for the clinical differences in outcomes for these patients. We stated that we believe this change is technical in nature and does not substantively change the SNFRM.

In order to determine whether and how to update the SNFRM, we first sought to understand the frequency of COVID–19 diagnoses in patients admitted to a SNF between July 1, 2020 and June 30, 2021. Of the 1,069,789 SNF stays included in the year of data, 134,674 (13 percent) had a primary or secondary diagnosis of COVID–19. Of those patients with COVID–19, 108,859 (81 percent) had a primary or secondary COVID–19 diagnosis during the PPH and 25,815 (19 percent) had a COVID–19 diagnosis in their history only (within 12 months of the SNF admission).

We then compared clinical and demographic characteristics between patients with and without COVID–19 between July 1, 2020, and June 30, 2021. When compared to the 30-day readmission rate for patients without COVID–19 (20.2 percent), the observed 30-day readmission rate was noticeably higher for patients with COVID–19 during the PPH (23.4 percent) and patients with a history of COVID–19 (26.9 percent). Both groups also experienced higher 30-day mortality rates compared to patients without COVID–19 (14.9 percent versus 8.8 percent and 10.7 percent versus 8.8 percent, respectively). Admissions for patients with COVID–19 during the PPH or a history of COVID–19 were also much more likely to be for patients who were dual-eligible (40.3 percent versus 28.9 percent and 45.2 percent versus 28.9 percent, respectively) and for patients who were non-white (21.1 percent versus 15.2 percent and 24.4 percent versus 15.2 percent, respectively).

Next, we compared readmission odds ratios for patients with COVID–19 during the PPH and for patients with a history of COVID–19. Patients with COVID–19 during the PPH had significantly higher odds of readmission (1.18), while patients with a history of COVID–19 but no COVID–19 during the PPH had significantly lower odds of readmission (0.84), after adjusting for all

[164] "Nursing Home Covid–19 Data Dashboard." Centers for Disease Control, retrieved from *https://www.cdc.gov/nhsn/covid19/ltc-report-overview.html* on February 14, 2022.

[165] The White House. (2022). Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID–19 Tests to Americans for Free. Available at *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/.*

[166] Miller, Z. 2021. *The Washington Post.* Biden to give away 400 million N95 masks starting next week. Available at *https://www.washingtonpost.com/politics/biden-to-give-away-400-million-n95-masks-starting-next-week/2022/01/19/5095c050-7915-11ec-9dce-7313579de434_story.html.*

[167] The White House. (2022). FACT SHEET: Biden-Harris Administration Increases COVID–19 Testing in Schools to Keep Students Safe and Schools Open. Available at *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/12/fact-sheet-biden-harris-administration-increases-covid-19-testing-in-schools-to-keep-students-safe-and-schools-open/.*

other variables in the SNFRM risk-adjustment model.

Although patients with only a history of COVID–19 had higher observed readmission rates than patients with COVID–19 during the PPH (26.9 percent versus 23.4 percent), they experienced lower readmission odds ratios (0.84 versus 1.18). This is because patients with a history of COVID–19 during the 12 months prior to the SNF admission are generally much sicker and have a substantially higher number of average comorbidities (15) compared to patients with COVID–19 during the PPH (10). We expect unadjusted readmission rates for patients with a history of COVID–19 to be higher because they are suffering from many more comorbidities, making it more likely they will be readmitted to the hospital. After adjusting for all their other comorbidities, we concluded that COVID–19 is not a significant reason for why they return to the hospital. Instead, their other comorbidities are a more significant cause of their readmission; that is, patients with a history of COVID–19 but no COVID–19 during the PPH have lower odds of being readmitted to a hospital once they've been admitted to the SNF. However, we stated in the proposed rule that we believed it was important to keep the history of COVID–19 variable in the model for two reasons: (1) to address any potential concerns with the face validity of the measure if it did not adjust for history of COVID–19; and (2) to account for long COVID–19 and other possible long-term effects of the virus. On the other hand, patients with a COVID–19 diagnosis during the PPH remain at higher odds of readmission even after accounting for their other comorbidities. Even when all other comorbidities are taken into account in the current risk-adjustment model, a COVID–19 diagnosis during the PPH still raises a patient's odds of being readmitted compared to patients who did not have any COVID–19 diagnosis during the PPH.

After having examined the prevalence of COVID–19 in SNF patients and the differences between patients with and without COVID–19, we then evaluated several options for how to account for COVID–19 in the measure. We evaluated four options.

- Under Option 1, we considered and tested whether to add a binary risk-adjustment variable for patients who had a primary or secondary diagnosis of COVID–19 during the PPH.
- Under Option 2, we considered and tested whether to add a binary risk-adjustment variable for patients who had a history of COVID–19 in the 12 months prior to the PPH.
- Under Option 3, we combined the first 2 options into a categorical risk-adjustment variable. The reference category is patients without a history of COVID–19 and no COVID–19 diagnosis during the PPH. The first comparison category is patients who had a history of COVID–19 in the 12 months prior to the PPH and no COVID–19 diagnosis during the PPH. The second comparison category is patients who had a primary or secondary diagnosis of COVID–19 during the PPH. If a patient had both a history of COVID–19 and a COVID–19 diagnosis during the PPH, they would be included in the second comparison category.
- Under Option 4, we considered and tested removing patients with a COVID–19 diagnosis during the PPH from the measure cohort.

We compared how well the model predicted whether patients were readmitted or not (model fit and performance) for these four options to a reference period (FY 2019) that predated COVID–19. Ideally, whichever option we chose would perform as similarly as possible to the reference period, providing us with confidence that the emergence of COVID–19 has not caused the model to perform worse.

The percentage of SNFs that would receive a measure score (75 percent), measure reliability (0.45), and C-statistic (0.66) was identical for the first 3 risk-adjustment options. The percentage of SNFs with a measure score, measure reliability score, and C-statistic values was 71 percent, 0.41, and 0.67 for Option 4 (excluding COVID–19 patients), respectively. The percentage of SNFs with a measure score was lower for the first 3 options than the baseline period (75 percent versus 82 percent), but the measure reliability was nearly identical (0.45 versus 0.46), as was the C-statistic (0.66 versus 0.68).

We also considered removing readmissions from the outcome for patients with a primary or secondary diagnosis of COVID–19 during the readmission hospital stay but decided it would not be appropriate for this measure. Community spread of COVID–19 in SNFs is a possible marker of poor infection control and patients who are admitted to a SNF without any COVID–19 diagnoses but then potentially acquire COVID–19 in a SNF should not be excluded from the readmission outcome.

After careful examination, we selected Option 3 and are modifying the SNFRM beginning with the FY 2023 SNF VBP program year by adding a risk-adjustment variable for both COVID–19 during the PPH and patients with a history of COVID–19. As we stated, this option both maintains the integrity of the model (as demonstrated by nearly identical measure reliability and C-statistic values) and allows the measure to appropriately adjust for SNF patients with COVID–19. In the proposed rule, we stated our belief that this approach will continue to maintain the validity and reliability of the SNFRM. This approach will retain COVID–19 patients in the measure cohort and prevent a further decrease in the sample size, which would harm the measure's reliability.

As discussed in the proposed rule and in section VIII.B.2.c. of this final rule, though we believe risk-adjusting the SNFRM for COVID–19 is an important step in maintaining the validity and reliability of the SNFRM, this risk-adjustment alone is not sufficient for ensuring a reliable SNF performance score in light of the overall decrease in SNF admissions in FY 2021. That is, the risk-adjustment is designed to maintain the scientific reliability of the measure, but it does not mitigate the effects of the PHE on patient case volumes and the resulting impact on the validity of the SNFRM.

We received several public comments on our technical update to the SNFRM to risk-adjust for COVID–19 patients beginning with the FY 2023 program year.

Comment: Some commenters supported our proposal to update the SNFRM to risk-adjust for COVID–19 patients. One commenter agreed with our approach but noted that removing COVID–19 patients from the measure may reduce the sample sizes and result in excluding more facilities from the Program, which may mean missing important indicators of quality performance. Another commenter stated that our proposed risk-adjustment best allows the measure's calculation by removing beneficiaries that were affected directly by a COVID–19 infection. One commenter also recommended that we continue to review COVID–19 data and refine our risk-adjustment policies as we learn more about the impacts and prevalence of ''long'' COVID–19.

Response: We clarify that we selected Option 3, which retains COVID–19 patients in the measure cohort and prevents a decrease in the sample size, while also adjusting for patients with a COVID–19 diagnosis. Furthermore, we decided to risk-adjust for patients with a history of COVID–19 because of the evolving evidence on the impact of ''long'' COVID–19 and the recognition that we still have much to learn about the long-term effects of COVID–19. We will continue to review the impacts of

COVID–19 on the measure's data and will make technical updates to the risk-adjustment methodology for the SNFRM as appropriate.

3. Adoption of Quality Measures for the SNF VBP Expansion Beginning With the FY 2026 Program Year

a. Background

Section 1888(h)(2)(A)(ii) of the Act (as amended by section 111(a)(2)(C) of the Consolidated Appropriations Act, 2021 (Pub. L. 116–120)) allows the Secretary to add up to nine new measures to the SNF VBP Program with respect to payments for services furnished on or after October 1, 2023. These measures may include measures of functional status, patient safety, care coordination, or patient experience. Section 1888(h)(2)(A)(ii) of the Act also requires that the Secretary consider and apply, as appropriate, quality measures specified under section 1899B(c)(1) of the Act.

Currently, the SNF VBP Program includes only a single quality measure, the SNFRM, which we intend to transition to the SNFPPR as soon as practicable. Both the SNFRM and the SNFPPR assess the rate of hospital readmissions. In considering which measures might be appropriate to add to the SNF VBP Program, we requested public comment on potential future measures to include in the expanded SNF VBP Program in the FY 2022 SNF PPS proposed rule (86 FR 20009 through 20011). We refer readers to summaries of input from interested parties in the FY 2022 SNF PPS final rule (86 FR 42507 through 42511). As stated in the proposed rule, we considered this input as we developed our quality measure proposals for this year's proposed rule.

In the FY 2023 SNF PPS proposed rule (87 FR 22767 through 22777), we proposed to adopt three new quality measures for the SNF VBP Program. Specifically, we proposed to adopt two new quality measures for the SNF VBP Program beginning with the FY 2026 program year: (1) Skilled Nursing Facility (SNF) Healthcare Associated Infections (HAI) Requiring Hospitalization (SNF HAI) measure; and (2) Total Nursing Hours per Resident Day Staffing (Total Nurse Staffing) measure. We also proposed to adopt an additional quality measure for the SNF VBP Program beginning with the FY 2027 program year: Discharge to Community (DTC)—Post-Acute Care (PAC) Measure for Skilled Nursing Facilities (NQF #3481). We are finalizing the adoption of these measures, and we discuss each in more detail in the following sections.

We stated in the proposed rule that although none of these quality measures have been specified under section 1899B(c)(1) of the Act, we determined after consideration of those measures that none are appropriate for adoption into the SNF VBP Program until, at a minimum, we have had sufficient time to review their specifications and conduct further analyses to ensure that they are suited for meeting the objectives of the SNF VBP Program. We stated that we are currently reviewing measures of patient falls and functional status, which are both specified under section 1899B(c)(1) of the Act, to determine whether any of them would be appropriate for the SNF VBP Program. We also stated our belief that it is important to cover the full range of SNF services in the SNF VBP Program, which includes measure topics beyond those specified under section 1899B(c)(1) of the Act. Since we have determined that the measures specified under section 1899B(c)(1) of the Act are not yet appropriate for the SNF VBP Program, we proposed to begin the Program expansion with measures that address other important indicators of SNF care quality, including measures that align with the topics listed under section 1888(h)(2)(A)(ii) of the Act and align with HHS priorities.

As proposed, the SNF HAI measure is a patient safety measure, and the DTC PAC SNF measure is a care coordination measure. Regarding the proposed Total Nurse Staffing measure, we stated in the proposed rule that many studies have found that the level of nurse staffing is associated with patient safety,[168] patient functional status,[169] [170] and patient experience.[171] [172] Nursing home staffing, including SNF staffing, is also a high priority for the Department of Health and Human Services (HHS) and the Biden-Harris Administration because of its central role in the quality of care for Medicare beneficiaries.[173]

We stated in the proposed rule that we believe adopting these measures to begin affecting SNF payments in the FY 2026 program year would provide SNFs with sufficient time to prepare and become familiar with the quality measures, as well as with the numerous other programmatic changes that we proposed would take effect in the FY 2023 program year.

As we discussed in the FY 2023 SNF PPS proposed rule (87 FR 22786 through 22787), we also considered and requested public comment on additional quality measures for potential adoption in the SNF VBP Program through future rulemaking.

We received a general comment on the SNF VBP Program's measures.

Comment: One commenter supported the concept of adding new measures to the Program but expressed concern about the increase in estimated savings to Medicare via reduced payments to SNFs. The commenter stated that adding new measures effectively reduces provider reimbursement rates because they must absorb the burden and costs of reporting new measures.

Response: We carefully consider the reporting burden for all quality measures that we propose to adopt in the SNF VBP Program. Specifically, we weigh a measure's reporting burden against the benefits of adopting that measure in the Program. Our goal is to minimize the reporting burdens that we impose on SNFs under the SNF VBP Program and we will continue considering this topic as we explore proposing additional measures for the Program. We also note that the SNF HAI and DTC PAC SNF measures that we are finalizing in this final rule are calculated using Medicare claims data and do not impose any new reporting burdens on SNFs. In addition, the Total Nurse Staffing measure that we are finalizing in this final rule is calculated using information that SNFs already submit to us for the Nursing Home Five-Star Quality Rating System, and therefore, this measure will not impose any new reporting burdens on SNFs.

We proposed to update our regulations at § 413.338(d)(5) to note that, for a given fiscal year, we will specify the measures for the SNF VBP Program. We did not receive any public comments on our proposal to update § 413.338(d)(5) of our regulations, and

[168] Horn S.D., Buerhaus P., Bergstrom N., et al. RN staffing time and outcomes of long-stay nursing home residents: Pressure ulcers and other adverse outcomes are less likely as RNs spend more time on direct patient care. Am J Nurs 2005 6:50–53. *https://pubmed.ncbi.nlm.nih.gov/16264305/.*

[169] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wp-content/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[170] Bostick J.E., Rantz M.J., Flesner M.K., Riggs C.J. Systematic review of studies of staffing and quality in nursing homes. J Am Med Dir Assoc. 2006;7:366–376. *https://pubmed.ncbi.nlm.nih.gov/16843237/.*

[171] *https://www.wolterskluwer.com/en/expert-insights/study-patient-satisfaction-grows-with-nurse-staffing.*

[172] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8522577/.*

[173] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.*

therefore, we are finalizing our proposal as proposed.

b. Adoption of the Skilled Nursing Facility Healthcare-Associated Infections (HAI) Requiring Hospitalization Measure Beginning With the FY 2026 SNF VBP Program Year

As part of the SNF VBP Program expansion authorized under the CAA, we proposed to adopt the SNF HAI measure for the FY 2026 SNF VBP Program and subsequent years. The SNF HAI measure is an outcome measure that estimates the risk-standardized rate of HAIs that are acquired during SNF care and result in hospitalization using 1 year of Medicare fee-for-service (FFS) claims data. As proposed, the SNF HAI measure assesses SNF performance on infection prevention and management, which will align the Program with the Patient Safety domain of CMS's Meaningful Measures 2.0 Framework. In addition, the SNF HAI measure is currently part of the SNF QRP measure set. For more information on this measure in the SNF QRP, please visit *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/skilled-nursing-facility-quality-reporting-program/snf-quality-reporting-program-measures-and-technical-information.* We also refer readers to the SNF HAI Measure Technical Report, available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf,* for the measure specifications, which we proposed to adopt as the SNF HAI measure specifications for the SNF VBP Program.

(1) Background

Healthcare-associated infections (HAIs) are defined as infections acquired while receiving care at a health care facility that were not present or incubating at the time of admission.[174] As stated in the proposed rule, HAIs are a particular concern in the SNF setting, and thus, monitoring the occurrence of HAIs among SNF residents can provide valuable information about a SNF's quality of care. A 2014 report from the Office of the Inspector General (OIG) estimated that one in four adverse events among SNF residents is due to HAIs, and approximately half of all HAIs are potentially preventable.[175] In addition, analyses from FY 2019 found a wide variation in facility-level HAI rates among SNF providers with 25 or more stays, which indicates a performance gap. Specifically, among the 14,102 SNFs included in the sample, the FY 2019 facility-level, risk-adjusted rate of SNF HAIs requiring hospitalization ranged from 2.36 percent to 17.62 percent.[176]

While HAIs are not considered ''never events,'' or serious adverse errors in the provision of health care services that should never occur, most are preventable.[177] HAIs are most often the result of poor processes and structures of care. Specifically, evidence suggests that inadequate patient management following a medical intervention, such as surgery or device implantation, and poor adherence to infection control protocols and antibiotic stewardship guidelines contribute to the occurrence of HAIs.[178] [179] [180] In addition, several provider characteristics relate to the occurrence of HAIs, including staffing levels (for example, low staff-to-resident ratios), facility structure characteristics (for example, high occupancy rates), and adoption, or lack thereof, of infection surveillance and prevention policies.[181] [182] [183] [184] [185] [186]

Inadequate prevention and treatment of HAIs is likely to result in poor health care outcomes for SNF residents, as well as wasteful resource use. Specifically, studies find that HAIs are associated with longer lengths of stay, use of higher-intensity care (for example, critical care services and hospital readmissions), increased mortality, and higher health care costs.[187] [188] [189] [190] Addressing HAIs in SNFs is particularly important as several factors place SNF residents at increased risk for infections, including increased age, cognitive and functional decline, use of indwelling devices, frequent care transitions, and close contact with other residents and healthcare workers.[191] [192] Further, infection prevention and control

[174] World Health Organization. (2010). The burden of health care-associated infections worldwide. Retrieved from *https://www.who.int/news-room/feature-stories/detail/the-burden-of-health-care-associated-infection-worldwide.*

[175] Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

[176] *https://www.cms.gov/files/document/snf-hai-technical-report.pdf.*

[177] CMS. (2006). Eliminating Serious Preventable, and Costly Medical Errors—Never Events. Retrieved from *https://www.cms.gov/newsroom/fact-sheets/eliminating-serious-preventable-and-costly-medical-errors-never-events.*

[178] Beganovic, M. and Laplante, K. (2018). Communicating with Facility Leadership; Metrics for Successful Antimicrobial Stewardship Programs (ASP) in Acute Care and Long-Term Care Facilities. *Rhode Island Medical Journal,* 101(5), 45–49. *http://www.rimed.org/rimedicaljournal/2018/06/2018-06-45-antimicrobial-beganovic.pdf.*

[179] Cooper, D., McFarland, M., Petrilli, F., & Shells, C. (2019). Reducing Inappropriate Antibiotics for Urinary Tract Infections in Long-term Care: A Replication Stud-y. *Journal of Nursing Care Quality,* 34(1), 1621. *https://doi.org/10.1097/NCQ.0000000000000343.*

[180] Feldstein, D., Sloane, P.D., & Feltner, C. (2018). Antibiotic stewardship programs in nursing homes: A systematic review. *Journal of the American Medical Directors Association,* 19(2), 110–116. *http://dx.doi.org/10.1016/j.jamda.2017.06.019.*

[181] Castle, N., Engberg, J.B., Wagner, L.M., & Handler, S. (2017). Resident and facility factors associated with the incidence of urinary tract infections identified in the Nursing Home Minimum Data Set. *Journal of Applied Gerontology,* 36(2), 173–194. *http://dx.doi.org/10.1177/0733464815584666.*

[182] Crnich, C.J., Jump, R., Trautner, B., Sloane, P.D., & Mody, L. (2015). Optimizing antibiotic stewardship in nursing homes: A narrative review and recommendations for improvement. *Drugs & Aging,* 32(9), 699–716. *http://dx.doi.org/10.1007/s40266-015-0292-7.*

[183] Dick, A.W., Bell, J.M., Stone, N.D., Chastain, A.M., Sorbero, M., & Stone, P.W. (2019). Nursing home adoption of the National Healthcare Safety Network Long-term Care Facility Component. *American Journal of Infection Control,* 47(1), 59–64. *http://dx.doi.org/10.1016/j.ajic.2018.06.018.*

[184] Cooper, D., McFarland, M., Petrilli, F., & Shells, C. (2019). Reducing inappropriate antibiotics for urinary tract infections in long-term care: A replication study. *Journal of Nursing Care Quality,* 34(1), 16–21. *http://dx.doi.org/10.1097/NCQ.0000000000000343.*

[185] Gucwa, A.L., Dolar, V., Ye, C., & Epstein, S. (2016). Correlations between quality ratings of skilled nursing facilities and multidrug-resistant urinary tract infections. *American Journal of Infection Control,* 44(11), 1256–1260. *http://dx.doi.org/10.1016/j.ajic.2016.03.015.*

[186] Travers, J.L., Stone, P.W., Bjarnadottir, R.I., Pogorzelska-Maziarz, M., Castle, N.G., & Herzig, C.T. (2016). Factors associated with resident influenza vaccination in a national sample of nursing homes. *American Journal of Infection Control,* 44(9), 1055–1057. *http://dx.doi.org/10.1016/j.ajic.2016.01.019.*

[187] CMS. (2006). Eliminating Serious Preventable, and Costly Medical Errors—Never Events. Retrieved from *https://www.cms.gov/newsroom/fact-sheets/eliminating-serious-preventable-and-costly-medical-errors-never-events.*

[188] Centers for Disease Control and Prevention (2009). The Direct Medical Costs of Healthcare Associated Infections in U.S. Hospitals and the Benefits of Prevention. Retrieved from *https://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf.*

[189] Ouslander, J.G., Diaz, S., Hain, D., & Tappen, R. (2011). Frequency and diagnoses associated with 7- and 30-day readmission of skilled nursing facility patients to a nonteaching community hospital. *Journal of the American Medical Directors Association,* 12(3), 195–203. *http://dx.doi.org/10.1016/j.jamda.2010.02.015.*

[190] Zimlichman, E., Henderson, D., Tamir, O., Franz, C., Song, P., Yamin, C.K., Keohane, C., Denham, C.R., & Bates, D.W. (2013). Health Care-Associated Infections: A Meta-analysis of Costs and Financial Impact on the US Health Care System. *JAMA Internal Medicine,* 173(22), 2039–2046. *https://doi.org/10.1001/jamainternmed.2013.9763.*

[191] Montoya, A., & Mody, L. (2011). Common infections in nursing homes: A review of current issues and challenges. Aging Health, 7(6), 889–899. *http://dx.doi.org/10.2217/ahe.11.80.*

[192] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2013). Chapter 8: Long-Term Care Facilities (p. 194–239) in National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. Retrieved from *https://health.gov/sites/default/files/2019-09/hai-action-plan-ltcf.pdf.*

deficiencies are consistently among the most frequently cited deficiencies in surveys conducted to assess SNF compliance with Federal quality standards.[193] Infection prevention and control deficiencies can include practices directly related to the occurrence and risks of HAIs, such as inconsistent use of hand hygiene practices or improper use of protective equipment or procedures during an infectious disease outbreak, which further underscores the importance of efforts to improve practices to reduce the prevalence of HAIs.

Given the effects of HAIs, preventing and reducing their occurrence in SNFs is critical to delivering safe and high-quality care. As discussed in the proposed rule, we continue to believe the SNF HAI measure, as proposed, aligns with this goal by monitoring the occurrence of HAIs and assessing SNFs on their performance on infection prevention and control efforts. In doing so, we continue to believe the measure may promote patient safety and increase the transparency of care quality in the SNF setting, which aligns the SNF VBP Program with the Patient Safety domain of CMS's Meaningful Measures 2.0 Framework. Prevention and reduction of HAIs has also been a priority at Federal, State, and local levels. For example, the HHS Office of Disease Prevention and Health Promotion has created a National Action Plan to Prevent HAIs, with specific attention to HAIs in LTC facilities. We refer readers to additional information on the National Action Plan available at *https://www.hhs.gov/oidp/topics/health-care-associated-infections/hai-action-plan/index.html.*

Evidence suggests there are several interventions that SNFs may utilize to effectively reduce HAI rates among their residents and thus, improve quality of care. These interventions include adoption of infection surveillance and prevention policies, safety procedures, antibiotic stewardship, and staff education and training programs.[194] [195] [196] [197] [198] [199] [200] In addition, infection prevention and control programs with core components in education, monitoring, and feedback have been found to be successful in reducing HAI rates.[201] The effectiveness of these interventions suggest improvement of HAI rates among SNF residents is possible through modification of provider-led processes and interventions, which supports the overall goal of the SNF VBP Program.

(2) Overview of Measure

The SNF HAI measure, which was finalized for adoption in the SNF QRP in the FY 2022 SNF PPS final rule (86 FR 42473 through 42480), is an outcome measure that estimates the risk-standardized rate of HAIs that are acquired during SNF care and result in hospitalization using 1 year of Medicare FFS claims data. A HAI is defined, for the purposes of this measure, as an infection that is likely to be acquired during SNF care and severe enough to require hospitalization, or an infection related to invasive (not implanted) medical devices (for example, catheters, insulin pumps, and central lines). Several types of infections are excluded from the measure, which we discuss in section VIII.B.2.b.(4). of this final rule. In addition, all SNF stays with an admission date during the 1-year period are included in the measure cohort, except those meeting the exclusion criteria, which we also discuss in section VIII.B.2.b.(4). of this final rule.

Unlike other HAI measures that target specific infections, this measure targets all HAIs serious enough to require admission to an acute care hospital.

The goal of this measure is to identify SNFs that have notably higher rates of HAIs acquired during SNF care, when compared to their peers and to the national average HAI rate.

Validity and reliability testing has been conducted for this measure. For example, split-half testing on the SNF HAI measure indicated moderate reliability. In addition, validity testing showed good model discrimination as the HAI model can accurately predict HAI cases while controlling for differences in resident case-mix. We refer readers to the SNF HAI Measure Technical Report for further details on the measure testing results available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf.*

(a) Measure Applications Partnership (MAP) Review

The SNF HAI measure was included as a SNF VBP measure under consideration in the publicly available ''List of Measures Under Consideration for December 1, 2021.'' [202]

The MAP offered conditional support of the SNF HAI measure for rulemaking, contingent upon NQF endorsement, noting that the measure would add value to the Program due to the addition of an overall measurement of all HAIs acquired within SNFs requiring hospitalization. We refer readers to the final 2021–2022 MAP report available at *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.* We are preparing to submit the SNF HAI measure for NQF endorsement, consistent with the MAP recommendation.

(3) Data Sources

As proposed, the SNF HAI measure uses Medicare FFS claims data to estimate the risk-adjusted rate of HAIs that are acquired during SNF care and result in hospitalization. Specifically, this measure uses data from the Medicare Enrollment Database (EDB), as well as Medicare SNF and inpatient hospital claims from the CMS Common Working File (CWF). HAIs are identified using the principal diagnosis code and the Present on Admission (POA) indicators on the Medicare inpatient rehospitalization claim within a specified incubation window. We refer readers to the SNF HAI Measure Technical Report for further details on

[193] Infection Control Deficiencies Were Widespread and Persistent in Nursing Homes Prior to COVID–19 Pandemic (GAO–20–576R), May, 2020. *https://www.gao.gov/products/gao-20-576r.*

[194] Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

[195] Beganovic, M. and Laplante, K. (2018). Communicating with Facility Leadership; Metrics for Successful Antimicrobial Stewardship Programs (ASP) in Acute Care and Long-Term Care Facilities. *Rhode Island Medical Journal,* 101(5), 45–49. *http://www.rimed.org/rimedicaljournal/2018/06/2018-06-45-antimicrobial-beganovic.pdf.*

[196] Crnich, C.J., Jump, R., Trautner, B., Sloane, P.D., & Mody, L. (2015). Optimizing antibiotic stewardship in nursing homes: A narrative review and recommendations for improvement. *Drugs & Aging,* 32(9), 699–716. *http://dx.doi.org/10.1007/s40266-015-0292-7.*

[197] Freeman-Jobson, J.H., Rogers, J.L., & Ward-Smith, P. (2016). Effect of an Education Presentation On the Knowledge and Awareness of Urinary Tract Infection among Non-Licensed and Licensed Health Care Workers in Long-Term Care Facilities. Urologic Nursing, 36(2), 67–71. Retrieved from *https://pubmed.ncbi.nlm.nih.gov/27281862/.*

[198] Hutton, D.W., Krein, S.L., Saint, S., Graves, N., Kolli, A., Lynem, R., & Mody, L. (2018). Economic Evaluation of a Catheter-Associated Urinary Tract Infection Prevention Program in Nursing Homes. Journal of the American Geriatrics Society, 66(4), 742–747. *http://dx.doi.org/10.1111/jgs.15316.*

[199] Nguyen, H.Q., Tunney, M.M., & Hughes, C.M. (2019). Interventions to Improve Antimicrobial Stewardship for Older People in Care Homes: A Systematic Review. *Drugs & aging,* 36(4), 355–369. *https://doi.org/10.1007/s40266-019-00637-0.*

[200] Sloane, P.D., Zimmerman, S., Ward, K., Kistler, C.E., Paone, D., Weber, D.J., Wretman, C.J., & Preisser, J.S. (2020). A 2-Year Pragmatic Trial of Antibiotic Stewardship in 27 Community Nursing Homes. *Journal of the American Geriatrics Society,* 68(1), 46–54. *https://doi.org/10.1111/jgs.16059.*

[201] Lee, M.H., Lee GA, Lee S.H., & Park Y.H. (2019). Effectiveness and core components of infection prevention and control programs in long-term care facilities: a systematic review. *https://www.journalofhospitalinfection.com/action/showPdf?pii=S0195-6701%2819%2930091-X.*

[202] *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

how these data components are utilized in calculating the SNF HAI measure available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf.* We note that the proposed SNF HAI measure is calculated entirely using administrative data and therefore, it will not impose any additional data collection or submission burden for SNFs.

(4) Inclusion and Exclusion Criteria

The measure's cohort includes all Part A FFS Medicare SNF residents 18 years and older who have a SNF admission date during the 1-year measure period and who do not meet any of the exclusion criteria, which we describe next. Additionally, the hospital admission must occur during the time period which begins on day 4 after SNF admission and ends 3 days after SNF discharge. We note that residents who died during the SNF stay or during the post-discharge window (3 days after SNF discharge), and residents with a missing discharge date (or have ''active'' SNF stays) are included in the measure's cohort.

There are several scenarios in which a SNF stay is excluded from the measure cohort and thus, excluded from the measure denominator. Specifically, any SNF stay that meets one or more of the following criteria is excluded from the cohort and measure denominator:

- Resident is less than 18 years old at SNF admission.
- The SNF length of stay was shorter than 4 days.
- Residents who were not continuously enrolled in Part A FFS Medicare during the SNF stay, 12 months prior to the measure period, and 3 days after the end of the SNF stay.
- Residents who did not have a Part A short-term acute care hospital stay within 30 days prior to the SNF admission date. The short-term stay must have positive payment and positive length of stay.
- Residents who were transferred to a Federal hospital from a SNF as determined by the discharge status code on the SNF claim.
- Residents who received care from a provider located outside the U.S., Puerto Rico, or another U.S. territory as determined from the first 2 characters of the SNF CMS Certification Number.
- SNF stays in which data were missing on any variable used in the measure calculation or risk-adjustment. This also included stays where Medicare did not pay for the stay, which is identified by non-positive payment on the SNF claim.

The measure numerator includes several HAI conditions. We refer readers to Appendix A of the SNF HAI Measure Technical Report, available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf,* for a complete list of the ICD–10 codes that correspond to the HAI conditions included in the measure numerator. There are also several types of HAIs that are excluded from the proposed measure numerator. For example, HAIs reported during emergency department visits and observations stays are excluded from the numerator. In addition, the HAI definition excludes infections that meet any of the following criteria:

- Chronic infections (for example, chronic viral hepatitis B).
- Infections that typically require a long period of time to present (for example, typhoid arthritis).
- Infections that are likely related to the prior hospital stay (for example, postprocedural retroperitoneal abscess).
- Sequela (a condition which is the consequence of a previous disease or injury) and subsequent encounter codes.
- Codes that include ''cause disease classified elsewhere.''
- Codes likely to represent secondary infection, where the primary infection would likely already be coded (for example, pericarditis, myocarditis, or cardiomyopathy).
- Infections likely to be community acquired.
- Infections common in other countries and/or acquired through animal contact.
- Preexisting infections that fall within the CDC's National Healthcare Safety Network (NHSN) Repeat Infection Timeframe (RIT) of 14 days. We refer readers to the SNF HAI Measure Technical Report for additional information on the repeat infection timeframe (RIT) and conditions that are considered preexisting (*https://www.cms.gov/files/document/snf-hai-technical-report.pdf*).

(5) Risk-Adjustment

Risk-adjustment is a statistical process used to account for risk factor differences across SNF residents. By controlling for these differences in resident case-mix, we can better isolate the proposed measure's outcome and its relationship to the quality of care delivered by SNFs. As proposed, the SNF HAI measure's numerator and denominator are both risk-adjusted. Specifically, the denominator is risk-adjusted for resident characteristics excluding the SNF effect. The numerator is risk-adjusted for resident characteristics, as well as a statistical estimate of the SNF effect beyond resident case-mix. The SNF effect, or the provider-specific behaviors that influence a SNF's HAI rates, accounts for clustering of patients within the same SNF and captures variation in the measure outcome across SNFs, which helps isolate differences in measure performance. The risk-adjustment model for this measure includes the following resident characteristic variables:

- Age and sex category.
- Original reason for Medicare entitlement.
- Surgery or procedure category from the prior proximal inpatient (IP) stay.
- Dialysis treatment, but not end-stage renal disease (ESRD) on the prior proximal IP claim.
- Principal diagnosis on the prior proximal IP hospital claim.
- Hierarchical Condition Categories (HCC) comorbidities.
- Length of stay of the prior proximal IP stay.
- Prior intensive care or coronary care utilization during the prior proximal IP stay.
- The number of prior IP stays within a 1-year lookback period from SNF admission.

(6) Measure Calculation

(a) Numerator

The risk-adjusted numerator is the estimated number of SNF stays predicted to have a HAI that is acquired during SNF care and results in hospitalization. This estimate begins with the unadjusted, observed count of the measure outcome, or the raw number of stays with a HAI acquired during SNF care and resulting in hospitalization. The unadjusted, observed count of the measure outcome is then risk-adjusted for resident characteristics and a statistical estimate of the SNF effect beyond resident case-mix, which we discussed in section VIII.B.3.b.(5). of this final rule.

(b) Denominator

The risk-adjusted denominator is the expected number of SNF stays with the measure outcome, which represents the predicted number of SNF stays with the measure outcome if the same SNF residents were treated at an ''average'' SNF. The calculation of the risk-adjusted denominator begins with the total eligible Medicare Part A FFS SNF stays during the measurement period and then applying risk-adjustment for resident characteristics, excluding the SNF effect, as we discussed in section VIII.B.3.b.(5). of this final rule.

The SNF HAI measure rate, which is reported at the facility-level, is the risk-standardized rate of HAIs that are acquired during SNF care and result in

hospitalization. This risk-adjusted HAI rate is calculated by multiplying the standardized risk ratio (SRR) for a given SNF by the national average observed rate of HAIs for all SNFs. The SRR is a ratio that measures excess HAIs and is the predicted number of HAIs (adjusted numerator) divided by the expected number of HAIs (adjusted denominator). A lower measure score for the SNF HAI measure indicates better performance in prevention and management of HAIs. For technical information on the proposed measure's calculation, we refer readers to the SNF HAI Measure Technical Report available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf.*

Because a ''lower is better'' rate could cause confusion among SNFs and the public, we proposed to invert SNF HAI measure rates, similar to the approach used for the SNFRM, for scoring. Specifically, we proposed to invert SNF HAI measure rates using the following calculation:

SNF HAI Inverted Rate = 1 – Facility's SNF HAI rate

This calculation will invert SNFs' HAI measure rates such that higher SNF HAI measure rates will reflect better performance. In the proposed rule, we stated our belief that this inversion is important to incentivize improvement in a clear and understandable manner, so that ''higher is better'' for all measure rates included in the Program.

(7) Confidential Feedback Reports and Public Reporting

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52006 through 52007) for discussion of our policy to provide quarterly confidential feedback reports to SNFs on their measure performance. We also refer readers to the FY 2022 SNF PPS final rule (86 FR 42516 through 42517) for a summary of our two-phase review and corrections policy for SNFs' quality measure data. Furthermore, we refer readers to the FY 2018 SNF PPS final rule (82 FR 36622 through 36623) and the FY 2021 SNF PPS final rule (85 FR 47626) where we finalized our policy to publicly report SNF measure performance information under the SNF VBP Program on the Provider Data Catalog website currently hosted by HHS and available at *https://data.cms.gov/provider-data/.* We proposed to update and redesignate the confidential feedback report and public reporting policies, which are currently codified at § 413.338(e)(1) through (3), to § 413.338(f), to include the SNF HAI measure.

We invited public comment on our proposal to adopt the SNF HAI measure beginning with the FY 2026 SNF VBP program year. We received the following comments and provide our responses:

Comment: Many commenters supported our proposal to adopt the SNF HAI measure beginning with the FY 2026 SNF VBP program year. Commenters noted that the SNF HAI measure is an important quality indicator, that the measure imposes a low reporting burden on SNFs, and that SNFs are already familiar with the measure because it is currently adopted in the SNF QRP.

Response: We agree that the SNF HAI measure is an important quality indicator. Monitoring SNF HAI rates provides valuable information on a SNF's infection prevention and management practices, and the overall quality of care. We also agree that SNFs are already familiar with the SNF HAI measure and that because the measure is calculated using Medicare FFS claims data, the adoption of the measure for the SNF VBP Program would impose no new reporting burden on SNFs.

Comment: Several commenters offered qualified support for our proposal to adopt the SNF HAI measure and offered recommendations for improving the measure. Several commenters noted that the SNF HAI measure has not been endorsed by NQF and a few commenters suggested that we delay finalizing the measure until it has received NQF endorsement. A few commenters also recommended that we update the measure's specifications to exclude hospital- and community-acquired infections, as well as to exclude or risk-adjust for hospitalizations due to COVID–19 infection. One commenter recommended that we collect SNF HAI measure data but not publicly report those data until the PHE for COVID–19 has expired. Another commenter suggested that we develop a better reporting system in CASPER for the measure. Lastly, one commenter recommended that we link SNF HAI measure data to race and ethnicity information to assess care disparities.

Response: We thank the commenters for their recommendations. As part of our routine measure monitoring work, we intend to consider whether any of these recommendations would warrant further analysis or potential updates to the measure's specifications.

We intend to submit the SNF HAI measure to the NQF for consideration of endorsement. However, we also believe that the SNF HAI measure provides valuable quality of care information. For example, the HHS Office of Inspector General estimated that one in four adverse events among SNF residents is due to HAIs with approximately half of all HAIs being potentially preventable.[203] The identification of HAIs by SNFs provides actionable information that SNFs can use to improve their quality of care and prevent their residents from having to be hospitalized. For these reasons, we continue to believe that it is important to include this measure in the SNF VBP Program.

Comment: Several commenters opposed the use of Medicare FFS claims data for calculating the SNF HAI measure and expressed concerns about the validity and accuracy of those claims data. Some commenters recommended that we adopt NHSN-based measures instead of claims-based measures. Another commenter recommended that the measure undergo additional testing before its inclusion in the Program.

Response: As we discussed in the proposed rule (87 FR 22769), validity and reliability testing results showed that the SNF HAI measure has acceptable reliability and validity when calculated from Medicare FFS claims data. In addition, during development of this measure, the TEP considered the appropriateness of using alternative data sources, including NHSN data. The TEP ultimately recommended against using those sources because they would increase the reporting burden on SNFs. We refer commenters to the SNF HAI Final TEP Summary Report, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-HAI-Final-TEP-Report-7-15-19_508C.pdf* for more information.

Comment: One commenter expressed concern that SNFs must rely on hospitals accurately capturing HAIs because the measure is calculated using hospital claims data. Another commenter noted that performance scores may be inaccurate because there is variation in hospital documentation of HAIs.

Response: We use inpatient hospital claims to calculate the SNF HAI measure because the measure's main outcome is HAIs that require hospitalization. In addition, we commissioned a medical record review for the purpose of analyzing the accuracy of hospital coding of Hospital Acquired Conditions (HACs), which include HAIs, and Present on Admission (POA) conditions. This study did not find patterns of

[203] Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

widespread underreporting of HACs or overreporting of POA status.[204] The study found that only 3 percent of HAC cases were underreported and 91 percent of all cases coded POA were accurate. Another medical record review we conducted assessed the accuracy of the principal diagnosis coded on a Medicare claim to identify whether a patient was admitted for a diagnosis included in our list of potentially preventable readmission (PPR) diagnoses.[205] The study analyzed inpatient discharges from October 2015 through September 2017 and found high agreement between principal diagnoses in Medicare claims and corresponding medical records. Specifically, the agreement rate between principal diagnoses in Medicare claims and information in the corresponding medical records ranged from 83 percent to 94 percent by study hospital. Additionally, 91 percent to 97 percent of principal diagnoses from the corresponding medical records were included in our list of PPR diagnoses. Therefore, we disagree with commenters' concerns about the accuracy of hospital inpatient claims data.

Comment: Several commenters opposed our proposal to adopt the SNF HAI measure, stating that SNFs will experience a significant time lag between claims submission and when data derived from those claims are used to measure quality performance. One commenter stated that while measuring HAIs in the SNF setting is ''vital,'' the topic is so important and complex that CMS should develop a measure that delivers more timely, accurate and actionable information. Another commenter was concerned that SNFs have not had time to review their performance data on this measure, thus making improvement plans difficult to implement. One commenter questioned whether providers would be able to use data from this measure to improve the quality of their care.

Response: We understand commenters' concerns regarding the time gap. As we discuss in section VIII.C.3. of this final rule, we are finalizing our proposal to adopt FY 2022 as the baseline period and FY 2024 as the performance period for the SNF HAI measure for the FY 2026 SNF VBP Program. Under section 1888(h)(3)(C) of the Act, we are required to calculate and announce performance standards no later than 60 days prior to the start of the performance period. To meet this statutory requirement, we need sufficient time between the end of the baseline period and the start of the performance period to calculate and announce performance standards, which are derived from baseline period data. Therefore, we continue to believe that a baseline period that occurs 2 fiscal years prior to the start of the performance period is most appropriate for this measure. In addition, under section 1888(h)(7) of the Act, we are required to announce the net results of the Program's adjustments to a SNF's Medicare payment no later than 60 days prior to the fiscal year involved. To meet this statutory requirement, we need sufficient time between the end of the performance period and the applicable fiscal program year to calculate and announce the net results of the Program's adjustments to a SNF's Medicare payment. Therefore, we continue to believe that a performance period that occurs two fiscal years prior to the applicable fiscal program year is most appropriate for this measure We refer readers to section VIII.C.3. of this final rule for further details on the baseline and performance periods for the SNF HAI measure. Given these statutory requirements, and the time needed to calculate valid and reliable measure rates, we have narrowed the time gap to the extent feasible at this time.

We continue to believe that the data provided by the SNF HAI measure will be valuable to SNFs and their efforts to improve care quality. Specifically, a SNF's HAI rate provides information on the effectiveness of its current infection prevention and management practices, as well as provides information regarding opportunities for improvement. As we discussed in the FY 2023 SNF PPS proposed rule (87 FR 22769), evidence suggests that there are several interventions that SNFs may utilize to effectively reduce HAI rates among their residents to improve quality of care, including infection surveillance and prevention policies, safety procedures, antibiotic stewardship, and staff education and training programs. The effectiveness of these interventions suggest that improvement of HAI rates among SNF residents is possible through modification of provider-led processes, which further demonstrates the value in measuring HAI rates among SNF residents.

Comment: One commenter opposed our proposal to adopt the SNF HAI measure because of their belief that the SNF HAI measure only captures HAIs that result in hospitalization and does not prioritize other HAIs and their underlying causes.

Response: We agree with the commenter that detecting all HAIs in the measure definition would provide additional data to SNFs and empower additional quality improvement. However, we decided to include only those HAIs requiring hospitalization in the SNF HAI measure to avoid the risk of overloading SNFs with information on every possible HAI in their SNF HAI measure rate.[206] This decision was consistent with the recommendation of our TEP, which concluded that a concentrated list of severe infections would be more valuable to SNFs and would make the measure more actionable.

Comment: A few commenters expressed concern that the SNF HAI measure does not account for other resident characteristics, including social risk factors, or provider characteristics, such as facility size, location, and teaching status, that influence HAI rates.

Response: We understand commenters' concerns regarding the risk-adjustment model for the SNF HAI measure. As part of our routine measure monitoring work, we intend to continue assessing the appropriateness of the risk-adjustment model. In addition, as described in our RFI in the proposed rule (87 FR 22789), we are considering whether it would be appropriate to incorporate adjustments in the SNF VBP Program, beyond an individual measure's risk-adjustment model, to account for social risk factors as part of our efforts to measure and improve health equity. Further, we note that the risk-adjustment model for the SNF HAI accounts for the following resident characteristic variables: age and sex category; original reason for Medicare entitlement; surgery or procedure category from the prior proximal

[204] Cafardi, S.G., Snow, C.L., Holtzman, L., Waters, H., McCall, N.T., Halpern, M., Newman, L., Langer, J., Eng, T., & Guzman, C.R. (2012). Accuracy of Coding in the Hospital-Acquired Conditions Present on Admission Program Final Report. Retrieved from *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitalacqcond/downloads/accuracy-of-coding-final-report.pdf.*

[205] He, F., Daras, L.C., Renaud, J., Ingber, M., Evans, R., & Levitt, A. (2019, June 3). Reviewing Medical Records to Assess the Reliability of Using Diagnosis Codes in Medicare Claims to Identify Potentially Preventable Readmissions. Retrieved from *https://academyhealth.confex.com/academyhealth/2019arm/meetingapp.cgi/Paper/*31496.

[206] Levitt, A.T., Freeman, C., Schwartz, C.R., McMullen, T., Felder, S., Harper, R., Van, C.D., Li, Q., Chong, N., Hughes, K., Daras, L.C., Ingber, M., Smith, L., & Erim, D. (2019). Final Technical Expert Panel Summary Report: Development of a Healthcare-Associated Infections Quality Measure for the Skilled Nursing Facility Quality Reporting Program. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/NursingHomeQualityInits/Downloads/SNF-HAI-Final-TEP-Report-7-15-19_508C.pdf.*

inpatient (IP) stay; dialysis treatment, but not end-stage renal disease (ESRD) on the prior proximal IP claim; principal diagnosis on the prior proximal IP hospital claim; hierarchical condition categories (HCC) comorbidities; length of stay of the prior proximal IP stay; prior intensive care or coronary care utilization during the prior proximal IP stay; and the number of prior IP stays within a 1-year lookback period from SNF admission. We refer the commenters to section VIII.B.3.b.(5). of this final rule for further discussion of the risk-adjustment model.

Comment: Some commenters opposed our proposal to adopt the SNF HAI measure due to various concerns with the measure specifications. Some commenters expressed validity concerns, stating that the measure's list of exclusion criteria is incomplete. One commenter stated that the inability to define the magnitude of the clinical problem addressed by the SNF HAI measure makes it difficult for SNFs to identify benchmarks and goals. Another commenter suggested that the proposed time window for excluding infections prior to SNF admission is not long enough.

Response: We disagree with commenters' concerns regarding the validity of the measure. As we discussed in the FY 2023 SNF PPS proposed rule (87 FR 22769), the validity testing for this measure showed that the HAI model can accurately predict HAI cases while controlling for differences in resident case-mix.

Our measure contractor developed the exclusion criteria with input from subject matter experts with clinical expertise specific to infectious diseases and the SNF population. We continue to believe the set of exclusion criteria helps ensure that we only capture HAIs requiring hospitalization that can be directly attributed to care during a SNF stay. We also agree with the members of the SNF HAI measure TEP, which found that the exclusion criteria were realistic and comprehensive.[207] With regard to identifying benchmarks and goals for the SNF HAI measure, we note that our analysis of FY 2019 data demonstrated that there is a performance gap in HAI rates across SNFs. Specifically, among the 14,102 SNFs included in the sample, risk-adjusted SNF HAI measure rates ranged from a minimum of 2.36 percent to a maximum of 17.62 percent.[208] In addition, we calculate specific performance standards, based on data gathered from all participating SNFs, that we use as benchmarks and achievement thresholds. We continue to believe each SNF can use this information to set goals for quality improvement that meet the needs of their facility. As we discuss in detail in the next comment response, we have made several resources available to assist SNFs with reducing HAIs and improving their quality of care.

Comment: A few commenters expressed concerns about a lack of resources in SNFs currently. One commenter noted that no new measures should be adopted because of current staffing burdens. Another commenter stated that SNFs may not have the resources for quality improvement efforts and recommended that CMS offer quality improvement support to reduce HAIs.

Response: We note that the SNF HAI measure, as well as the DTC PAC SNF and Total Nurse Staffing measures, will not impose any new reporting burdens on SNFs. In addition, as finalized, the SNF HAI and Total Nurse Staffing measures will not begin affecting SNF payments until the FY 2026 program year, and the DTC PAC SNF measure will not begin affecting SNF payments until the FY 2027 program year. We continue to believe that this provides SNFs with sufficient time to prepare for implementation of these measures.

We also note that we have made several resources available to assist SNFs with reducing HAIs and improving quality of care. These include training in partnership with the CDC and Quality Improvement Organizations (QIOs), many of which are available at *https://www.cdc.gov/longtermcare/prevention/index.html* and *https://www.cdc.gov/longtermcare/prevention/index.html.* Additionally, the CMS Office of Minority Health (OMH) offers a Disparity Impact Statement, which is a tool that all health care stakeholders can use to identify and address health disparities: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.*

After considering the public comments, we are finalizing our proposal to adopt the SNF HAI Requiring Hospitalization Measure beginning with the FY 2026 SNF VBP program year as proposed.

c. Adoption of the Total Nursing Hours per Resident Day Staffing Measure Beginning With the FY 2026 SNF VBP Program Year

We proposed to adopt the Total Nursing Hours per Resident Day Staffing (Total Nurse Staffing) measure for the FY 2026 program year and subsequent years. The Total Nurse Staffing measure is a structural measure that uses auditable electronic data reported to CMS's Payroll Based Journal (PBJ) system to calculate total nursing hours per resident day. Given the well-documented impact of nurse staffing on patient outcomes and quality of care, this measure, as proposed, will align the Program with the Person-Centered Care domain of CMS's Meaningful Measures 2.0 Framework. In addition, the Total Nurse Staffing measure is currently included in the Five-Star Quality Rating System. For more information on the Five-Star Quality Rating System, see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/FSQRS.*

(1) Background

Staffing is a crucial component of quality care for nursing home residents. Numerous studies have explored the relationship between nursing home staffing levels and quality of care. The findings and methods of these studies have varied, but most have found a strong, positive relationship between staffing and quality outcomes.[209] [210] [211] [212] [213] Specifically, studies have shown an association between nurse staffing levels and hospitalizations,[214] [215] pressure

[207] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-HAI-Final-TEP-Report-7-15-19_508C.pdf.*

[208] Acumen LLC & CMS. (2021). Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program: Technical Report. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-FacilityQuality-Reporting-Program/SNF-Quality-ReportingProgram-Measures-and-Technical-Information.*

[209] Bostick J.E., Rantz M.J., Flesner M.K., Riggs C.J. Systematic review of studies of staffing and quality in nursing homes. J Am Med Dir Assoc. 2006;7:366–376. *https://pubmed.ncbi.nlm.nih.gov/16843237/.*

[210] Backhaus R., Verbeek H., van Rossum E., Capezuti E., Hamer J.P.H. Nursing staffing impact on quality of care in nursing homes: a systemic review of longitudinal studies. J Am Med Dir Assoc. 2014;15(6):383– 393. *https://pubmed.ncbi.nlm.nih.gov/24529872/.*

[211] Spilsbury K., Hewitt C., Stirk L., Bowman C. The relationship between nurse staffing and quality of care in nursing homes: a systematic review. Int J Nurs Stud. 2011; 48(6):732–750. *https://pubmed.ncbi.nlm.nih.gov/21397229/https://pubmed.ncbi.nlm.nih.gov/21397229/.*

[212] Castle N. Nursing home caregiver staffing levels and quality of care: a literature review. J Appl Gerontol. 2008;27:375–405. *https://doi.org/10.1177%2F0733464808321596.*

[213] Spilsbury et al.

[214] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wp-*

ulcers,[216 217 218] weight loss,[219 220] functional status,[221 222] and survey deficiencies,[223 224] among other quality and clinical outcomes. The strongest relationships have been identified for registered nurse (RN) staffing; several studies have found that higher RN staffing is associated with better care quality.[225 226] We recognize that the relationship between nurse staffing and quality of care is multi-faceted, with elements such as staff turnover playing a critical role.[227] We refer readers to additional discussion of staffing turnover in section VIII.I.1.a. of this final rule.

The PHE due to COVID–19 has further underscored the critical importance of sufficient staffing to quality and clinical outcomes. Several recent studies have found that higher staffing is associated with lower COVID–19 incidence and fewer deaths.[228 229 230]

Multiple Institute of Medicine (IOM) reports have examined the complex array of factors that influence care quality in nursing homes, including staffing variables such as staffing levels and turnover.[231 232] In the 2004 report, ''Keeping Patients Safe: Transforming the Work Environment of Nurses,'' the IOM's Committee on the Work Environment for Nurses and Patient Safety highlighted the positive relationships between higher nursing staffing levels, particularly RN levels, and better patient outcomes, and recognized the need for minimum staffing standards to support appropriate levels of nursing staff in nursing homes.[233]

Previously published Phase I and Phase II ''Reports to Congress on the Appropriateness of Minimum Staffing Ratios in Nursing Homes'' further studied the relationship between quality and nurse staffing levels and provided compelling evidence of the relationship between staffing ratios and quality of care.[234 235] The Phase II report, completed in 2001, identified staffing thresholds that maximized quality outcomes, demonstrating a pattern of incremental benefits of increased nurse staffing until a threshold was reached. Specifically, the Phase II study used Medicaid Cost Report data from a representative sample of 10 states, including over 5,000 facilities, to identify staffing thresholds below which quality of care was compromised and above which there was no further benefit of additional staffing with respect to quality. The study found evidence of a relationship between higher staffing and better outcomes for total nurse staffing levels up to 4.08 hours per resident day and RN staffing levels up to 0.75 RN hours per resident day. In the 2001 study, minimum staffing levels at any level up to these thresholds were associated with incremental quality improvements, and no significant quality improvements were observed for staffing levels above these thresholds. The findings were also supported by case studies of individual facilities, units, and residents.

We have long identified staffing as one of the vital components of a nursing home's ability to provide quality care and used staffing data to gauge its impact on quality of care in nursing homes more accurately and effectively. In 2003, the National Quality Forum Nursing Home Steering Committee recommended that a nurse staffing quality measure be included in the set of nursing home quality measures that are publicly reported by us. The Total Nurse Staffing measure is currently used in the Nursing Home Five-Star Quality Rating System, as one of two measures that comprise the staffing domain. For more information on the Five-Star Quality Rating System, we refer readers to *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/FSQRS.*

Current Federal requirements for nurse staffing are outlined in the LTC facility requirements for participation (requirements).[236] The regulations at 42 CFR 483.35 specify, in part, that every facility must have sufficient nursing staff with the appropriate competencies and skill sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident

content/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.

[215] Dorr D.A., Horn S.D., Smout R.J. Cost analysis of nursing home registered nurse staffing times. J Am Geriatr Soc. 2005 May;53(5):840–5. doi: 10.1111/j.1532–5415.2005.53267.x. PMID: 15877561. *https://pubmed.ncbi.nlm.nih.gov/15877561/https://pubmed.ncbi.nlm.nih.gov/15877561/.*

[216] Alexander, G.L. An analysis of nursing home quality measures and staffing. Qual Manag Health Care. 2008;17:242–251. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3006165/.*

[217] Horn S.D., Buerhaus P., Bergstrom N., et al. RN staffing time and outcomes of long-stay nursing home residents: Pressure ulcers and other adverse outcomes are less likely as RNs spend more time on direct patient care. Am J Nurs 2005 6:50–53. *https://pubmed.ncbi.nlm.nih.gov/16264305/.*

[218] Bostick et al.

[219] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wp-content/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[220] Bostick et al.

[221] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wp-content/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[222] Bostick et al.

[223] Castle N.G., Wagner L.M., Ferguson-Rome J.C., Men A., Handler S.M. Nursing home deficiency citations for infection control. Am J Infect Control. 2011 May;39(4):263–9. doi: 10.1016/j.ajic.2010.12.010. PMID: 21531271.

[224] Castle N., Wagner L., Ferguson J., Handler S. Hand hygiene deficiency citations in nursing homes. J Appl Gerontol. 2014 Feb;33(1):24–50. doi: 10.1177/0733464812449903. Epub 2012 Aug 1. PMID: 24652942. *https://pubmed.ncbi.nlm.nih.gov/24652942/.*

[225] Backhaus R., Verbeek H., van Rossum E., Capezuti E., Hamer J.P.H. Nursing staffing impact on quality of care in nursing homes: a systemic review of longitudinal studies. J Am Med Dir Assoc. 2014;15(6):383–393. *https://pubmed.ncbi.nlm.nih.gov/24529872/.*

[226] Dellefield M.E., Castle N.G., McGilton K.S., Spilsbury K. The relationship between registered nurses and nursing home quality: an integrative review (2008–2014). Nurs Econ. 2015;33(2):95–108, 116. *https://pubmed.ncbi.nlm.nih.gov/26281280/.*

[227] Bostick et al.

[228] R. Tamara Konetzka, Elizabeth M. White, Alexander Pralea, David C. Grabowski, Vincent Mor, A systematic review of long-term care facility characteristics associated with COVID—19 outcomes, Journal of the American Geriatrics Society, 10.1111/jgs.17434, 69, 10, (2766–2777), (2021). *https://agsjournals.onlinelibrary.wiley.com/doi/10.1111/jgs.17434.*

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[231] Institute of Medicine. 1996. Nursing Staff in Hospitals and Nursing Homes: Is It Adequate? Washington, DC: The National Academies Press. *https://doi.org/10.17226/5151.*

[232] Institute of Medicine 2004. Keeping Patients Safe: Transforming the Work Environment of Nurses. Washington, DC: The National Academies Press. *https://doi.org/10.17226/10851.*

[233] IOM, 2004.

[234] Centers for Medicare and Medicaid Services. Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase I (2000). Baltimore, MD: Centers for Medicare and Medicaid Services. *https://phinational.org/wp-content/uploads/legacy/clearinghouse/Phase_I_VOL_I.pdf.*

[235] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wp-content/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[236] FY 2017 Consolidated Medicare and Medicaid Requirements for Participation for Long-Term Care Facilities Final Rule (81 FR 68688 through 68872). *https://www.govinfo.gov/content/pkg/FR-2016-10-04/pdf/2016-23503.pdf.*

population in accordance with the facility assessment required at § 483.70(e). We adopted this competency-based approach to sufficient staffing to ensure every nursing home provides the staffing levels needed to meet the specific needs of their resident population, including their person-centered care goals. We also note that current regulations require (unless these requirements are waived) facilities to have an RN onsite at least 8 consecutive hours a day, 7 days a week and around-the-clock services from licensed nursing staff under sections 1819(b)(4)(C) and 1919(b)(4)(C) of the Act, and § 483.35(a) and (b).

Section 1128I(g) of the Act requires facilities to electronically submit direct care staffing information (including agency and contract staff) based on payroll and other auditable data. In August 2015, we amended the requirements for LTC facilities at § 483.70(q) to require the electronic submission of payroll-based staffing data, which includes RNs, licensed practical nurses (LPNs) or vocational nurses, certified nursing assistants, and other types of medical personnel as specified by us, along with census data, data on agency and contract staff, and information on turnover, tenure and hours of care provided by each category of staff per resident day.[237] We developed the PBJ system to enable facilities to submit the required staffing information in a format that is auditable to ensure accuracy. Development of the PBJ system built on several earlier studies that included extensive testing of payroll-based staffing measures. The first mandatory PBJ reporting period began July 1, 2016.

We post staffing information publicly to help consumers understand staffing levels and how they differ across nursing homes. See sections 1819(i)(1)(A)(i) and 1919(i)(1)(A)(i) of the Act. However, there are currently no staffing measures in the SNF VBP Program.

Given the strong evidence regarding the relationship between sufficient staffing levels and improved care for residents, inclusion of this measure in the SNF VBP Program adds an important new dimension to provide a more comprehensive assessment of and accountability for the quality of care provided to residents and serves to drive improvements in staffing that are likely to translate into better resident care. PBJ data show that there is variability across SNFs in performance on this measure, and that there is an opportunity and potential for many SNFs to improve their staffing levels. For Q4 CY 2020, average total nurse staffing was 4.09 hours per resident day for the case-mix adjusted Total Nurse Staffing measure, with considerable variability across facilities ranging from 2.81 hours per resident day to 5.93 hours per resident day. Staffing levels increased after April 2018, when we first reported PBJ-based staffing measures on Nursing Home Compare and using them in the Five-Star Quality Rating System. Average nursing staffing hours per resident day increased from 3.85 in Q4 CY 2017 (publicly reported in April 2018) to 4.08 for Q4 CY 2020 (publicly reported in April 2021).

Inclusion of this measure in the SNF VBP Program also aligns with our current priorities and focus areas for the Program and optimizing the use of measures that SNFs are already reporting to us. Because the measure is currently used in the Nursing Home Five-Star Quality Rating System, inclusion of this measure in the Program does not add reporting or administrative burden to SNFs. Recognizing the importance of staffing to supporting and advancing person-centered care needs, this measure will align the Program with the Person-Centered Care domain of CMS's Meaningful Measures 2.0 Framework.

(2) Overview of Measure

The Total Nurse Staffing measure is a structural measure that uses auditable electronic data reported to CMS's PBJ system to calculate total nursing hours, which includes RNs, LPNs, and certified nurse aides (CNA), per resident day. The measure uses a count of daily resident census derived from Minimum Data Set (MDS) resident assessments and is case-mix adjusted based on the distribution of MDS resident assessments by Resource Utilization Groups, version IV (RUG–IV groups). The measure was specified and originally tested at the facility level with SNFs as the care setting. The measure is not currently NQF endorsed; however, we plan to submit it for endorsement in the next 1 to 2 years.

Data on the measure have been publicly reported on the Provider Data Catalog website currently hosted by HHS, available at *https://data.cms.gov/provider-data/,* for many years and have been used in the Nursing Home Five-Star Quality Rating System since its inception in 2008. The data source for the measure changed in 2018, when we started collecting payroll-based staffing data through the PBJ system. Since April 2018, we have been using PBJ and the MDS as the data sources for this measure for public reporting and for use in the Five-Star Quality Rating System. For more information, see the Final Specifications for the SNF VBP Program Total Nursing Hours per Resident Day Measure, at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/Measure.*

The CMS report ''Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II,'' described earlier in this section, showed the relationship between quality and nurse staffing levels using several methods, establishing the face validity of the Total Nurse Staffing measure. The study included an analysis of data from 10 states including over 5,000 facilities and found evidence of a relationship between staffing ratios and the quality of nursing home care.

We note that payroll data are considered the gold standard for nurse staffing measures and a significant improvement over the manual data previously used, wherein staffing information was calculated based on a form (CMS–671) filled out manually by the facility.[238] In contrast, PBJ staffing data are electronically submitted and are auditable back to payroll and other verifiable sources. Analyses of PBJ-based staffing measures show a relationship between higher nurse staffing levels and higher ratings for other dimensions of quality such as health inspection survey results and quality measures.[239]

(a) Interested Parties and TEP Input

In considering whether the total nurse staffing measure would be appropriate for the SNF VBP Program, we looked at the developmental history of the measure in which we employed a transparent process that provided interested parties and national experts the opportunity to provide pre-rulemaking input. We convened meetings with interested parties and offered engagement opportunities at all phases of measure development, from 2004 through 2019. Calls and meetings with interested parties have included patient/consumer advocates and a wide range of facilities throughout the country including large and small, rural and urban, independently owned facilities and national chains. In addition to input obtained through meetings with interested parties, we

[237] 80 FR 46390, Aug. 4, 2015 (*https://www.govinfo.gov/content/pkg/FR-2015-08-04/pdf/2015-18950.pdf*).

[238] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-17-NH.pdf.*

[239] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96520.*

solicited input through a dedicated email address (*NHStaffing@cms.hhs.gov*).

(b) MAP Review

The Total Nurse Staffing measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2021.'' [240] The MAP conditionally supported the Total Nurse Staffing measure for rulemaking, pending NQF endorsement. We refer readers to the final 2021–2022 MAP report available at *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

(3) Data Sources

As proposed, the Total Nurse Staffing measure is calculated using auditable, electronic staffing data submitted by each SNF for each quarter through the PBJ system, along with daily resident census information derived from Minimum Data Set, Version 3.0 (MDS 3.0) standardized patient assessments. We refer readers to the Final Specifications for the SNF VBP Program Total Nursing Hours per Resident Day Measure, at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/Measure.* We noted that the Total Nurse Staffing measure is already reported on the Provider Data Catalog website and used as part of the Five-Star Quality Rating System and thus, there will be no additional data collection or submission burdens for SNFs.

(4) Inclusion and Exclusion Criteria

The target population for the measure is all SNFs to whom the SNF VBP applies and that are not excluded for the reasons listed below. A set of exclusion criteria are used to identify facilities with highly improbable staffing data and these facilities are excluded. The exclusion criteria are as follows:

- Total nurse staffing, aggregated over all days in the quarter that the facility reported both residents and staff is excessively low (<1.5 hours per resident day).
- Total nurse staffing, aggregated over all days in the quarter that the facility reported both residents and staff is excessively high (>12 hours per resident day).
- Nurse aide staffing, aggregated over all days in the quarter that the facility reported both residents and staff is excessively high (>5.25 hours per resident day).

(5) Measure Calculation and Case-Mix Adjustment

We proposed to calculate case-mix adjusted hours per resident day for each facility for each staff type using this formula:

$$\text{Hours}_{\text{Adjusted}} = (\text{Hours}_{\text{Reported}}/\text{Hours}_{\text{Case-Mix}}) * \text{Hours}_{\text{National Average}}$$

The reported hours are those reported by the facility through PBJ. National average hours for a given staff type represent the national mean of case-mix hours across all facilities active on the last day of the quarter that submitted valid nurse staffing data for the quarter.

The measure is case-mix adjusted based on the distribution of MDS assessments by RUG–IV groups. The CMS Staff Time Resource Intensity Verification (STRIVE) Study measured the average number of RN, LPN, and NA minutes associated with each RUG–IV group (using the 66-group version of RUG–IV).[241] We refer to these as ''case-mix hours.'' The case-mix values for each facility are based on the daily distribution of residents by RUG–IV group in the quarter covered by the PBJ reported staffing and estimates of daily RN, LPN, and NA hours from the CMS STRIVE Study. This adjustment is based on the distribution of MDS assessments by RUG–IV groups to account for differences in acuity, functional status, and care needs of residents, and therefore is appropriate for the SNF VBP Program. For more information, see the Final Specifications for the SNF VBP Program Total Nursing Hours per Resident Day Measure, at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/Measure.*

(a) Numerator

The numerator for the measure is total nursing hours (RN + LPN + NA hours). RN hours include the RN director of nursing, RNs with administrative duties, and RNs. LPN hours include licensed practical and licensed vocational nurses with administrative duties and licensed practical and licensed vocational nurses. NA hours include certified nurse aides (CNAs), aides in training, and medication aides/technicians. We noted that the proposed PBJ staffing data include both facility employees (full-time and part-time) and individuals under an organization (agency) contract or an individual contract. The proposed PBJ staffing data do not include ''private duty'' nursing staff reimbursed by a resident or his/her family. Also, hospice staff and feeding assistants are not included.

(b) Denominator

The denominator for the measure is a count of daily resident census derived from MDS resident assessments. It is calculated by: (1) identifying the reporting period (quarter) for which the census will be calculated; (2) extracting MDS assessment data for all residents of a facility beginning 1 year prior to the reporting period to identify all residents that may reside in the facility (that is, any resident with an MDS assessment); and (3) identifying discharged or deceased residents using specified criteria. For any date, residents whose assessments do not meet the criteria for being identified as discharged or deceased prior to that date are assumed to reside in the facility. The count of these residents is the census for that particular day. We refer readers to the Final Specifications for the SNF VBP Program Total Nursing Hours per Resident Day Measure for more information on the calculation of daily resident census used in the denominator of the reported nurse staffing ratios, at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/Measure.*

The currently publicly reported Total Nurse Staffing measure is reported on a quarterly basis. To align with other quality measures for the expanded SNF VBP Program, we proposed to report the measure rate for the SNF VBP Program for each SNF as a simple average rate of total nurse staffing per resident day across available quarters in the 1-year performance period.

(6) Confidential Feedback Reports and Public Reporting

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52006 through 52007) for discussion of our policy to provide quarterly confidential feedback reports to SNFs on their measure performance. We also refer readers to the FY 2022 SNF PPS final rule (86 FR 42516 through 42517) for a summary of our two-phase review and corrections policy for SNFs' quality measure data. Furthermore, we refer readers to the FY 2018 SNF PPS final rule (82 FR 36622 through 36623) and the FY 2021 SNF PPS final rule (85 FR 47626) where we finalized our policy to publicly report SNF measure performance information under the SNF VBP Program on the Provider Data Catalog website currently hosted by HHS and available at *https://data.cms.gov/provider-data/.* We

[240] *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

[241] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/TimeStudy.*

proposed to update and redesignate the confidential feedback report and public reporting policies, which are currently codified at § 413.338(e)(1) through (3) as § 413.338(f), to include the Total Nurse Staffing measure.

We invited public comment on our proposal to adopt the Total Nurse Staffing measure beginning with the FY 2026 SNF VBP program year. We received the following comments and provide our responses:

Comment: Many commenters supported our proposal to adopt a measure of Total Nurse Staffing, citing the strong relationship between higher nurse staffing levels and improved quality of care. Some commenters noted that they supported inclusion of the measure because, although it a structural measure, not an outcome measure, staffing levels are tied to multiple outcomes such as hospitalizations, pressure ulcers, emergency department use, functional improvement, weight loss and dehydration, and COVID–19 infection rates and deaths. Another commenter noted that adding the measure allows for more accountability for SNFs without adding data collection burden.

Response: We agree that there is a strong, positive relationship between nurse staffing levels, quality of care, and patient outcomes and that the adoption of this measure adds an important dimension of quality to the Program. We refer readers to the evidence discussed in our proposed rule (87 FR 22771 through 22772) which demonstrates that nurse staffing levels are associated with various patient outcomes, such as hospitalizations and functional status. We also note that analyses of PBJ-based staffing data show a relationship between higher nurse staffing levels and higher ratings on other dimensions of quality such as health inspection survey results and various quality measures.[242] We agree that the measure allows for more accountability for quality outcomes without adding data reporting or administrative burden, as SNFs already report nurse staffing data on which the measure is based through the PBJ system, and the Total Nurse Staffing measure is currently used in the Nursing Home Five-Star Quality Rating System.

Comment: Many commenters opposed our proposal to adopt a measure of Total Nurse Staffing. Several commenters stated that staff shortages have made it difficult for facilities to operate, potentially impacting SNFs for years to come, and suggested that we delay the measure's implementation in the Program.

Response: We recognize that the COVID–19 PHE has had significant impacts on SNF operations and staffing. We also note that facilities with data indicating excessively low staffing levels are excluded from the measure, and based on the proposed exclusion criteria, facilities with <1.5 nursing hours per resident day will be excluded from the measure on the basis that those data are at high risk for inaccuracy.[243] We refer readers to our proposed rule for further information on the inclusion and exclusion criteria for this measure (87 FR 22773). We also remain committed to the importance of value-based care and incentivizing quality care tied to payment. SNF staffing is a high priority because of its central role in the quality of care for Medicare beneficiaries, and therefore, we continue to believe that this measure will provide a more comprehensive assessment of, and accountability for, the quality of care provided to residents.

Comment: One commenter stated that an operational measure is not appropriate for the SNF VBP Program, while another stated that the Program's purpose to link payments to outcomes is not served by a structural measure.

Response: We recognize that the Total Nurse Staffing measure is a structural measure, not a patient outcome measure. However, numerous studies have shown that higher staffing levels are associated with better patient outcomes, such as fewer hospitalizations[244] [245], fewer pressure ulcers[246] [247] [248], more weight loss[249] [250], and better functional status[251] [252]. As a result, we believe that this measure is a strong indicator of quality of care and is an appropriate and important addition to the Program.

Comment: One commenter noted that the measure is unlikely to provide an accurate assessment of care quality because it simplifies the relationship between staffing levels and improved care. Another commenter stated that we should adopt measures of the clinical outcomes that are associated with nurse staffing and not reward facilities for simply increasing staffing rather than achieving better clinical outcomes. Another commenter stated that there is less evidence of the relationship between patient outcomes and certain types of facility staff, such as LPNs and nurse aides, than there is of the relationship between patient outcomes and RNs.

Response: We recognize the relationship between nurse staffing and quality of care is multi-faceted. We refer commenters to our proposed rule (87 FR 22771 through 22772) where we discussed several studies that emphasize the evidence of a relationship between staffing levels, quality of care, and patient outcomes. We have selected this measure as a first step towards addressing this complex relationship between nurse staffing and quality of care. Furthermore, we are examining additional staffing measures to include in a future Program year to further account for the multi-faceted nature of the relationship between staffing and care quality and outcomes. We refer readers to our RFI on the potential inclusion of a staff turnover measure in section VII.I.1.a. of the

[242] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96520.*

[243] See ''Denominator Exclusions,'' Proposed Specifications for the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program Total Nursing Hours per Resident Day Measure, available at *https://www.cms.gov/files/document/proposed-specifications-skilled-nursing-facility-value-based-purchasing-snf-vbp-program-total.pdf.*

[244] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wpcontent/http://phinational.org/wpcontent/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[245] Dorr D.A., Horn S.D., Smout R.J. Cost analysis of nursing home registered nurse staffing times. J Am Geriatr Soc. 2005 May;53(5):840–5. doi: 10.1111/j.1532–5415.2005.53267.x. PMID: 15877561. *https://pubmed.ncbi.nlm.nih.gov/15877561/.*

[246] Alexander, G.L. An analysis of nursing home quality measures and staffing. Qual Manag Health Care. 2008;17:242–251. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3006165/.*

[247] Horn S.D., Buerhaus P., Bergstrom N., et al. RN staffing time and outcomes of long-stay nursing home residents: Pressure ulcers and other adverse outcomes are less likely as RNs spend more time on direct patient care. Am J Nurs 2005 6:50–53. *https://pubmed.ncbi.nlm.nih.gov/16264305/.*

[248] Bostick et al.

[249] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wpcontent/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[250] Bostick et al.

[251] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wpcontent/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[252] Bostick et al.

proposed rule (87 FR 22786 through 22787). In addition, as we discussed in the proposed rule (87 FR 22771 through 22772), several studies have identified a strong relationship between higher RN staffing and better quality of care. Also, studies support that other nursing staff, including certified nursing assistants and LPNs, play a critical role in providing care to Medicare beneficiaries in SNFs and, therefore, certified nursing assistants and LPNs, in addition to RNs, are also included in our proposed Total Nurse Staffing measure.[253]

Comment: A few commenters recommended that the measure should be endorsed by NQF as soon as possible or prior to its adoption.

Response: We intend to submit the measure for NQF endorsement in the next 1 to 2 years, which we believe is the most feasible timeline. We continue to believe the Total Nurse Staffing measure provides vital quality of care information; as mentioned in the proposed rule (87 FR 22771 through 22772), studies demonstrate a strong relationship between nurse staffing levels, quality of care, and patient outcomes. Given its relationship to quality of care, we believe it is important to include this measure in the Program despite the lack of current NQF endorsement.

Comment: One commenter expressed concern that a staffing measure may exacerbate care disparities because SNFs with larger minority patient populations tend to have lower staffing levels. Another commenter was concerned that the measure could cause SNFs to close, especially if they serve underserved populations and rural communities. The commenter suggested that we reexamine staffing and wage reimbursement levels and economic conditions before implementing the measure.

Response: We recognize the commenters' concerns that this measure could impact disparities in care provided to SNF residents, especially with respect to SNFs that serve large proportions of minority patient populations and other underserved communities. We will monitor and evaluate the measure's impact on health disparities as it is implemented in the SNF VBP Program. Addressing and improving health equity is an important priority for us, and as discussed in our RFI on the Program's approach to measuring and improving health equity (87 FR 22789), we remain committed to examining ways to incorporate health equity measurement and adjustments in our quality reporting and value-based purchasing programs. Further, we share the commenter's concerns about rural health disparities and note that we remain committed to providing support to rural communities in an effort to improve quality of care. We also note that in November 2021, the US Department of Health and Human Services began distributing $7.5 billion in American Rescue Plan (ARP) Rural payments to providers and suppliers who serve rural Medicaid, Children's Health Insurance Program (CHIP), and Medicare beneficiaries.[254] In addition, we will continue to examine staffing and wage reimbursement levels and economic conditions as part of our ongoing evaluation of the Program.

Comment: One commenter recommended that we should only reward facilities with the highest staffing levels. Another commenter noted that literature on the effects of nursing facility staffing incentives is mixed and suggested that incentives may be too small or too complex to administer to motivate behavioral changes. Other commenters suggested that staffing requirements be set based on residents' acuity, stating that facilities that successfully provide quality services without increasing staffing should not be penalized.

Response: We agree that it is important to incentivize staffing levels that foster the highest quality outcomes for SNF residents. As a reminder, the proposed Total Nurse Staffing measure calculates total nursing hours per resident day, and we refer readers to our proposed rule (87 FR 22774) to review the specific measure calculations. We continue to believe that scoring facilities based on their achievement on the Program's quality measures provides strong incentives in this program for those facilities already providing higher quality of care without prescribing specific staffing levels or practices. We believe this type of clinical quality assessment, which allows participating facilities to decide how best to achieve better care outcomes, is an important feature in our quality programs. However, we also believe that it is important to offer SNFs that provide lower levels of care quality in the baseline period with incentives for their successes in substantially improving the quality of care they provide based on their investments in quality improvement. Providing incentives for both achievement and improvement in staffing levels and other quality metrics provides the opportunity for the program to increase the quality of care for all SNF residents, and not only those residents who receive care from higher performing SNFs. We will continue to evaluate the impact on SNFs' behaviors, staffing levels, and quality outcomes as the measure is implemented in the Program. Regarding the commenter's concern that SNFs could be penalized for failing to increase staffing while still providing quality services, we do not believe this measure would penalize those SNFs as long as staffing levels are not low enough to imperil services provided to SNF residents. Finally, we note that the Total Nurse Staffing measure is case-mix adjusted based on resident assessments to account for differences in acuity, functional status, and care needs of residents.

Comment: One commenter suggested that we use targeted surveillance of PBJ staffing data to monitor SNFs' staffing rather than using a broad count of general staff hours, noting that CMS currently monitors PBJ staffing data for trends such as differences in weekend and weekday staffing. Another commenter recommended that we align the Program's staffing requirements with the Five-Star Quality Rating System.

Response: We agree that it is important to align the Program's measures with other quality and public reporting programs and note that the proposed Total Nurse Staffing measure is currently used in the Nursing Home Five-Star Quality Rating System. We agree that targeted oversight and auditing of PBJ staffing data, such as weekend staffing levels and staff turnover, is an important element of our efforts to assure sufficient staffing, and we refer readers to this memorandum for more information on these efforts: *https://www.cms.gov/files/document/qso-22-08-nh.pdf.*

Comment: Several commenters offered technical views on the measure, particularly around the type of staff that are included and excluded. One commenter suggested that nursing hours should exclude RNs with administrative duties, medication aides, technicians, aides in training, or private duty nurses. One commenter recommended that the measure should include only Medicare Part A beneficiaries because the commenter believes that is the scope of the SNF VBP Program. Some

[253] Horn S.D., Buerhaus P., Bergstrom N., Smout R.J. RN staffing time and outcomes of long-stay nursing home residents: pressure ulcers and other adverse outcomes are less likely as RNs spend more time on direct patient care. Am J Nurs. 2005;105(11):58–71. *https://pubmed.ncbi.nlm.nih.gov/16264305/.*

[254] U.S. Department of Health and Human Services. Biden-Harris Administration Begins Distributing American Rescue Plan Rural Funding to Support Providers Impacted by Pandemic. *https://www.hhs.gov/about/news/2021/11/23/biden-admin-begins-distributing-arp-prf-support-to-providers-impacted-by-pandemic.html.* Published November 23, 2021. Accessed July 18, 2022.

commenters recommended that we exclude Temporary Nurse Aides (TNAs) from the measure's calculation, or otherwise measure CNA, LPN, and RN time separately. Some commenters recommended that we weight agency staff lower in the measure.

Response: We refer readers to the proposed rule where we more thoroughly discuss inclusion and exclusion criteria for SNFs under this measure (87 FR 22773). All SNFs to whom the SNF VBP Program applies are included in the measure, except for facilities where total nurse staffing or nurse aide staffing is excessively low or excessively high. As mentioned in our proposed rule (87 FR 22773), facilities where total nurse staffing is <1.5 hours per resident day or >12 hours per resident day are excluded. Also, facilities where nurse aide staffing is >5.25 hours per resident day are excluded. Furthermore, staff included in the measure are RNs, LPNs, and nurse aides, such as certified nurse aides (CNAs), aides in training, and medication aides/technicians. We included a variety of SNF staff in the proposed measure, because as discussed in our proposed rule (87 FR 22771–22772), several studies demonstrate the strong relationship between these types of staff and patient outcomes. Private duty nurses are not included in the measure calculation at this time, because they are not included in PBJ staffing data. We will also take commenters' suggestions around excluding certain types of nurse staffing or calculating CNA, LPN, and RN time separately into account as we monitor implementation of the measure. In response to the commenter suggesting that we limit the measure to Medicare Part A beneficiaries only, we note our continued belief that our quality programs drive quality improvement for all patients, meaning that we do not believe any such limitation is appropriate at this time.

Comment: A few commenters expressed concerns about the measure's case-mix adjustment. One commenter suggested CMS should report both actual staffing levels and case-mix adjusted staffing levels. Another commenter noted that the measure's case-mix adjustment information is outdated and has not been reviewed by a TEP or by NQF.

Response: We note that the proposed case-mix adjustment is consistent with that currently used for the measure in the Nursing Home Five-Star Quality Rating System and was originally reviewed by a TEP (see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/TimeStudy*). The case-mix values for each facility are based on the daily distribution of residents by RUG–IV group in the quarter covered by the PBJ reported staffing and estimates of daily RN, LPN and NA hours from the CMS STRIVE Study. We also believe it is important to include the case-mix adjustment to account for differences in acuity, functional status, and care needs of residents. For more information, we refer commenters to our proposed rule (87 FR 22774). We will consider whether any changes or updates are needed to the case-mix adjustment.

Comment: One commenter expressed concern that PBJ data may not capture salaried individuals who work more than 40 hours per work week and variations in how lunch breaks are captured in the PBJ system. Another commenter recommended that we allow the PBJ system to capture patient care hours provided by other types of professionals such as mental health support service workers, music therapists, or respiratory therapists. One commenter noted that the proposed exclusion criteria are not appropriate for the VBP Program and should be accompanied by an appeals process.

Response: We recognize the importance of various types of professionals in providing care and services to Medicare beneficiaries in SNFs, but we emphasize the strong relationship identified in the literature between nursing professionals and quality of care. For this reason, we proposed to adopt the Total Nurse Staffing measure, which includes the time worked by RNs, LPNs, and nurse aides, in the FY 2026 Program. We intend to assess the impact of other types of professionals on quality of care. We also note that we will continue to assess the measure and if needed, propose measure updates in future rulemaking.

After considering the public comments, we are finalizing our proposal to adopt the Total Nursing Hours per Resident Day Staffing (Total Nurse Staffing) measure beginning with the FY 2026 SNF VBP program year as proposed.

d. Adoption of the DTC—PAC Measure for SNFs (NQF #3481) Beginning With the FY 2027 SNF VBP Program Year

As part of the SNF VBP Program expansion authorized under the CAA, we proposed to adopt the DTC PAC SNF measure for the FY 2027 SNF VBP Program and subsequent years. The DTC PAC SNF measure (NQF #3481) is an outcome measure that assesses the rate of successful discharges to community from a SNF setting, using 2 years of Medicare FFS claims data. As proposed, the measure addresses an important health care outcome for many SNF residents (returning to a previous living situation and avoiding further institutionalization) and will align the Program with the Seamless Care Coordination domain of CMS's Meaningful Measures 2.0 Framework. In addition, the DTC PAC SNF measure is currently part of the SNF QRP measure set.[255] For more information on this measure in the SNF QRP, see *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

(1) Background

As we stated in the proposed rule, we believe it is an important goal in post-acute care settings to return patients to their previous levels of independence and functioning with discharge to community being one of the primary goals for post-acute patients. We also stated our belief that it is important to improve access to community discharge options for SNF residents. Discharge to community is considered a valuable outcome to measure because it provides important information about patient outcomes after being discharged from a SNF and is a multifaceted measure that captures the patient's functional status, cognitive capacity, physical ability, and availability of social support at home.

In 2019, 1.5 million of Medicare's FFS beneficiaries (4 percent of all Medicare FFS beneficiaries) utilized Medicare coverage for a SNF stay.[256] However, almost half of the older adults that are admitted to SNFs are not discharged to the community, and for a significant proportion of those that are discharged back to the community, it may take up to 365 days.[257] [258] In 2017, the SNF QRP and other PAC QRP programs adopted this measure; however, there remains considerable variation in performance on this measure. In 2019, the lowest performing SNFs had risk-adjusted rates of successful discharge to the community at or below 39.5 percent,

[255] We note that the SNF QRP refers to this measure as the ''Discharge to Community—PAC SNF QRP'' measure. Though we are using a different measure short name (''DTC PAC SNF''), we are proposing to adopt the same measure the SNF QRP uses for purposes of the SNF VBP program.

[256] *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch7_sec.pdf.*

[257] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711511/.*

[258] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4706779/.*

while the best performing SNFs had rates of 53.5 percent or higher, indicating considerable room for improvement.[259]

In addition to being an important outcome from a resident and family perspective, residents discharged to community settings, on average, incur lower costs over the recovery episode, compared with those discharged to institutional settings.[260] [261] As stated in the proposed rule, we believe including this measure in the SNF VBP Program will further encourage SNFs to prepare residents for discharge to community, when clinically appropriate, which may have significant cost-saving implications for the Medicare program given the high costs of care in institutional settings. Also, providers have discovered that successful discharge to community is a key factor in their ability to achieve savings, where capitated payments for post-acute care were in place.[262] For residents who require LTC due to persistent disability, discharge to community could result in lower LTC costs for Medicaid and for residents' out-of-pocket expenditures.[263]

Discharge to community is also an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings. Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.[264] [265] [266] [267] Other factors that have shown positive associations with successful discharge to community include patient safety culture within the SNF and availability of home and community-based services.[268] [269] The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care residents is possible through modifying provider-led processes and interventions. Therefore, including the DTC PAC SNF measure in the SNF VBP Program may provide further incentive for providers to continue improving on current interventions or implement new interventions.

(2) Overview of Measure

This measure, which was finalized for adoption under the SNF QRP (81 FR 52021 through 52029), reports a SNF's risk-standardized rate of Medicare FFS residents who are discharged to the community following a SNF stay, do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and remain alive during the 31 days following discharge to community. Community, for this measure, is defined as home or selfcare, with or without home health services. We proposed to adopt this measure beginning with the FY 2027 program year. We note that including this measure in the FY 2027 program year provides advanced notice for facilities to prepare for the inclusion of this measure in the SNF VBP Program. This also provides the necessary time to incorporate the operational processes associated with including this two-year measure in the SNF VBP Program.

(a) Interested Parties and TEP Input

In considering the selection of this measure for the SNF VBP Program, we reviewed the developmental history of the measure, which employed a transparent process that provided interested parties and national experts the opportunity to provide pre-rulemaking input. Our measure development contractor convened a TEP, which was strongly supportive of the importance of measuring discharge to community outcomes and implementing the measure, Discharge to Community PAC SNF QRP in the SNF QRP. The panel provided input on the technical specifications of this measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. We refer readers to the FY 2017 SNF PPS final rule (81 FR 52023), as well as a summary of the TEP proceedings available on the PAC Quality Initiatives Downloads and Videos website available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos* for additional information.

(b) MAP Review

The DTC PAC SNF measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2021,'' [270] and the MAP supported the DTC PAC SNF measure for rulemaking for the SNF VBP Program. We refer readers to the final MAP report available at *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

(3) Data Sources

We proposed to use data from the Medicare FFS claims and Medicare eligibility files to calculate this measure. We will use data from the ''Patient Discharge Status Code'' on Medicare FFS claims to determine whether a resident was discharged to a community setting for calculation of this measure. The eligibility files provide information such as date of birth, date of death, sex, reasons for Medicare eligibility, periods of Part A coverage, and periods in the

[259] March 2021 MedPAC Report to Congress: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf.*

[260] Dobrez D., Heinemann A.W., Deutsch A., Manheim L., Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. American Journal of Physical Medicine & Rehabilitation. 2010;89(3):198–204. *https://doi.org/10.1097/PHM.0b013e3181c9fb40.*

[261] Gage B., Morley M., Spain P., Ingber M.. Examining Post-Acute Care Relationships in an Integrated Hospital System. Final Report. RTI International;2009. *https://aspe.hhs.gov/sites/default/files/private/pdf/75761/report.pdf.*

[262] Doran J.P., Zabinski S.J. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: Bundles in the real world. The journal of arthroplasty. 2015;30(3):353–355. *https://doi.org/10.1016/j.arth.2015.01.035.*

[263] Newcomer R.J., Ko M., Kang T., Harrington C., Hulett D., Bindman A.B. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Medical Care. 2016; 54(3):221–228. *https://doi.org/10.1097/MLR.0000000000000491.*

[264] Kushner D.S., Peters K.M., Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310–1318. *https://doi.org/10.1016/j.apmr.2015.03.011.*

[265] Wodchis W.P., Teare G.F., Naglie G., et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442–448. *https://doi.org/10.1016/j.apmr.2004.06.067.*

[266] Berkowitz R.E., Jones R.N., Rieder R., et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130–1136. *https://doi.org/10.1111/j.1532-5415.2011.03417.*

[267] Kushner D.S., Peters K.M., Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R: The journal of injury, function, and rehabilitation. 2015;7(4):354–364. *https://doi.org/10.1016/j.pmrj.2014.10.010.*

[268] *https://doi.org/10.1111/j.1532-5415.2011.03417* Wenhan Guo, Yue Li, Helena Temkin-Greener, Community Discharge Among Post-Acute Nursing Home Residents: An Association With Patient Safety Culture?, Journal of the American Medical Directors Association, Volume 22, Issue 11, 2021, Pages 2384–2388.e1, ISSN 1525–8610, *https://doi.org/10.1016/j.jamda.2021.04.022.*

[269] *https://doi.org/10.1016/j.pmrj.2014.10.010* Wang, S., Temkin-Greener, H., Simning, A., Konetzka, R.T. and Cai, S. (2021), Outcomes after Community Discharge from Skilled Nursing Facilities: The Role of Medicaid Home and Community-Based Services. Health Serv Res, 56: 16–16. *https://doi.org/10.1111/1475-6773.13737.*

[270] *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

Medicare FFS program. The data elements from the Medicare FFS claims are those basic to the operation of the Medicare payment systems and include data such as date of admission, date of discharge, diagnoses, procedures, indicators for use of dialysis services, and indicators of whether the Part A benefit was exhausted. The inpatient claims data files contain patient-level PAC and other hospital records. SNFs will not need to report additional data for us to calculate this measure.[271]

We refer readers to the FY 2017 SNF PPS final rule where we adopted the DTC measure for use in the SNF QRP (81 FR 52021 through 52029). In that rule, we provided an analysis related to the accuracy of using the ''Patient Discharge Status Code'' in determining discharge to a community setting. Specifically, in all PAC settings, we tested the accuracy of determining discharge to a community setting using the ''Patient Discharge Status Code'' on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the SNF setting, using 2013 data, we found 94.6 percent agreement in discharge to community codes when comparing discharge status codes on claims and the Discharge Status (A2100) on the Minimum Data Set (MDS) 3.0 discharge assessment, when the claims and MDS assessment had the same discharge date. We further examined the accuracy of the ''Patient Discharge Status Code'' on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believe these data support the use of the claims ''Patient Discharge Status Code'' for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the SNF VBP Program because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to us.

[271] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Measure-Specifications-for-FY17-SNF-QRP-Final-Rule.pdf.*

(4) Inclusion and Exclusion Criteria

We proposed that the DTC PAC SNF measure will use the same specifications under the SNF VBP Program as the Discharge to Community—PAC SNF QRP measure used in the SNF QRP, which are available at *https://www.cms.gov/files/zip/snf-qrp-measure-calculations-and-reporting-users-manual-v301-addendum-effective-10-01-2020.zip.* The target population for the measure is the group of Medicare FFS residents who are admitted to a SNF and are not excluded for the reasons listed in this paragraph. The measure exclusion criteria are determined by processing Medicare claims and eligibility data to determine whether the individual exclusion criteria are met. All measure exclusion criteria are based on administrative data. Only SNF stays that are preceded by a short-term acute care stay in the 30 days prior to the SNF admission date are included in the measure. Stays ending in transfers to the same level of care are excluded. The measure excludes residents for which the following conditions are true:

- Age under 18 years;
- No short-term acute care stay within the 30 days preceding SNF admission;
- Discharges to a psychiatric hospital;
- Discharges against medical advice;
- Discharges to disaster alternative care sites or Federal hospitals;
- Discharges to court/law enforcement;
- Residents discharged to hospice and those with a hospice benefit in the post-discharge observation window;
- Residents not continuously enrolled in Part A FFS Medicare for the 12 months prior to the post-acute admission date, and at least 31 days after post-acute discharge date;
- Residents whose prior short-term acute care stay was for non-surgical treatment of cancer;
- Post-acute stays that end in transfer to the same level of care;
- Post-acute stays with claims data that are problematic (for example, anomalous records for stays that overlap wholly or in part, or are otherwise erroneous or contradictory);
- Planned discharges to an acute or LTCH setting;
- Medicare Part A benefits exhausted;
- Residents who received care from a facility located outside of the U.S., Puerto Rico or a U.S. territory; and
- Swing Bed Stays in Critical Access Hospitals.

This measure also excludes residents who had a long-term nursing facility stay in the 180 days preceding their hospitalization and SNF stay, with no intervening community discharge between the long-term nursing facility stay and qualifying hospitalization.

(5) Risk-Adjustment

The measure is risk-adjusted for variables including demographic and eligibility characteristics, such as age and sex, principal diagnosis, types of surgery or procedures from the prior short-term acute care stay, comorbidities, length of stay and intensive care utilization from the prior short-term acute care stay, ventilator status, ESRD status, and dialysis, among other variables. For additional technical information about the measure, including information about the measure calculation, risk-adjustment, and denominator exclusions, we refer readers to the document titled, Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Final-Specifications-for-SNF-QRP-Quality-Measures-and-SPADEs.pdf.* We note that we proposed to use the technical information and specifications found in this document for purposes of calculating this measure in the SNF VBP Program.

(6) Measure Calculation

We proposed to adopt the DTC PAC SNF measure for the SNF VBP Program for FY 2027 and subsequent years. This measure is calculated using 2 years of data. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, SNFs will not be required to report any additional data to us for calculation of this measure.

(a) Numerator

The measure numerator is the risk-adjusted estimate of the number of residents who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. This estimate starts with the observed discharges to community and is risk-adjusted for patient/resident characteristics and a statistical estimate of the facility effect beyond case-mix. A patient/resident who is discharged to the community is considered to have an unfavorable outcome if they have a subsequent unplanned readmission to an acute care hospital or LTCH in the post-discharge

observation window, which includes the day of discharge and the 31 days following day of discharge. Discharge to community is determined based on the ''Patient Discharge Status Code'' from the PAC claim. Discharge to community is defined as discharge to home or self-care with or without home health services, which includes the following Patient Discharge Status Codes: 01 Discharged to home or self-care (routine discharge); 06 Discharged/transferred to home under care of organized home health service organization; 81 Discharged to home or self-care with a planned acute care hospital readmission; and 86 Discharged/transferred to home under care of organized home health service organization with a planned acute care hospital inpatient readmission. Residents who are discharged to the community are also considered to have an unfavorable outcome if they die in the post-discharge window, which includes the day of discharge and the 31 days following day of discharge. Death in the post-discharge window is identified based on date of death from Medicare eligibility files.

(b) Denominator

The denominator for the DTC PAC SNF measure is the risk-adjusted expected number of discharges to community. This estimate includes risk-adjustment for patient/resident characteristics with the facility effect removed. The ''expected'' number of discharges to community is the predicted number of risk-adjusted discharges to community if the same residents were treated at the average facility appropriate to the measure.

(7) Confidential Feedback Reports and Public Reporting

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52006 through 52007) for discussion of our policy to provide quarterly confidential feedback reports to SNFs on their measure performance. We also refer readers to the FY 2022 SNF PPS final rule (86 FR 42516 through 42517) for a summary of our two-phase review and corrections policy for SNFs' quality measure data. Furthermore, we refer readers to the FY 2018 SNF PPS final rule (82 FR 36622 through 36623) and the FY 2021 SNF PPS final rule (85 FR 47626) where we finalized our policy to publicly report SNF measure performance information under the SNF VBP Program on the Provider Data Catalog website currently hosted by HHS and available at *https://data.cms.gov/provider-data/*. We proposed to update and redesignate the confidential feedback report and public reporting policies, which are currently codified at § 413.338(e)(1) through (3) to § 413.338(f), to include the DTC PAC SNF measure.

We invited public comment on this proposal to adopt the DTC PAC SNF measure beginning with the FY 2027 SNF VBP program year. We received the following comments and provide our responses:

Comment: Many commenters supported our proposal to adopt the DTC PAC SNF measure, noting its endorsement by NQF, its use in other quality programs, and its usefulness as an indicator of health outcomes. A few commenters recommended that we modify the measure to include post-discharge ER and observation visits within 31 days because they could be indicators of premature discharge from the SNF. One commenter suggested that we include assisted living and personal care homes as community settings for the measure. One commenter expressed concern about the length of time between baseline, performance, and payment periods and suggested that facilities would benefit from real-time, actionable quality data. Another commenter suggested that we include those nursing home residents discharged back to the same nursing home in the measure's calculation. One commenter also suggested that we monitor how the measure will affect SNFs that care for patients experiencing homelessness.

Response: We agree the measure is an important indicator of quality. We appreciate commenters' recommendations regarding adjustments to the measure specifications and we will take this into consideration in future rulemaking.

Comment: Some commenters opposed our proposal to adopt the DTC PAC SNF measure. One commenter noted that not all Medicare beneficiaries are able to return home, that the measure may disadvantage those residents that continue to need SNF care to maintain functions or slow declines or deterioration in function, and that the measure only captures fee-for-service Medicare beneficiaries. Another commenter recommended that we consider a measure that assesses care coordination between SNFs and post-SNF care, while another commenter worried that the DTC PAC SNF measure may penalize SNFs based on whether a patient complied with discharge instructions and services.

Response: As discussed in the proposed rule (87 FR 22774 through 22776), returning patients to their previous levels of independence and functioning is a key goal of post-acute care and an important indicator for patients and families. When we convened a TEP for this measure's inclusion in the SNF QRP, experts agreed with this assessment. Additionally, as discussed in the proposed rule (87 FR 22775), this measure addresses multiple components including cognitive capacity, physical ability, social support as home, and other actionable elements, incentivizing providers to continue improving care in these various domains. Although we agree that not all residents will be able to return home or will follow all discharge instructions, the variability in current rates of the measure among different SNFs indicate that there is room for improvement. This measure is risk adjusted for several variables, including principal diagnosis. This measure should not disadvantage patients that continue to need SNF care to maintain functioning as it includes readmissions within 30 days of discharge. Thus, providers will not be incentivized to discharge patients inappropriately. Lastly, this measure is calculated using Medicare FFS claims data, which does not require SNFs to report any additional data. Including residents for which claims data is not currently available would add considerable data burden to SNFs. We will consider whether to address care coordination among SNFs for the SNF VBP Program in future rulemaking.

Comment: Some commenters offered technical comments on the measure. One commenter stated that an unplanned readmission post-SNF discharge may not be the best measure of whether a discharge was successful. A few commenters suggested that we consider using the discharge planning process or discharge to a lower level of care instead of discharge to communities, noting that not all admissions are appropriate for community discharge. One commenter also requested clarification on whether we plan to adjust the measure for COVID–19.

Response: As noted above, we recognize that not all admissions are appropriate for community discharge, but discharge to the community is an important goal for residents and families, as well as a key indicator of care. The measure is risk adjusted and has several exclusions to ensure that the appropriate population is being measured. Additionally, this is an NQF endorsed measure and varying performance rates observed among SNFs for this measure suggest that it is actionable. This measure also adjusts for principal diagnosis.

After considering the public comments, we are finalizing our proposal to adopt the DTC PAC SNF measure (NQF #3481) beginning with the FY 2027 SNF VBP program year as proposed.

C. SNF VBP Performance Periods and Baseline Periods

1. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of our considerations for determining performance periods under the SNF VBP Program. In the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), we adopted a policy whereby we will automatically adopt the performance period and baseline period for a SNF VBP Program Year by advancing the performance period and baseline period by 1 year from the previous program year. We also refer readers to the FY 2022 SNF PPS final rule, where we finalized our proposal to use FY 2019 data for the FY 2024 baseline period (86 FR 42512 through 42513).

2. Revised Baseline Period for the FY 2025 SNF VBP Program

Under the policy finalized in the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), the baseline period for the SNFRM for the FY 2025 program year will be FY 2021. However, as more fully described in the proposed rule (87 FR 22764 through 22765), we have determined that the significant decrease in SNF admissions, regional variability in COVID–19 case rates, and changes in hospitalization patterns associated with the PHE for COVID–19 in FY 2021 has impacted SNFRM validity and reliability. Because the baseline period for this measure is used to calculate the performance standards under the SNF VBP Program, we stated that we were concerned about using COVID–19 impacted data for the FY 2025 baseline period for scoring and payment purposes.

Therefore, we proposed to use a baseline period of FY 2019 for the FY 2025 program year. We stated that we believe using data from this period will provide sufficiently valid and reliable data for evaluating SNF performance that can be used for FY 2025 scoring. We also proposed to select this revised data period because it captures a full year of data, including any seasonal effects.

As stated in the proposed rule, we considered using FY 2020 as the baseline period for the FY 2025 program. However, under the ECE, SNF qualifying claims for a 6-month period in FY 2020 (January 1, 2020 through June 30, 2020) are excepted from the calculation of the SNFRM, which means that we will not have a full year of data to calculate the SNFRM for a FY 2020 baseline period.

We also considered using FY 2022 as the baseline period for the FY 2025 program year, which will be the baseline period for the FY 2026 program year for the SNFRM under the previously established policy for adopting baseline periods for future years (83 FR 39277). However, it is operationally infeasible for us to calculate performance standards using a FY 2022 baseline period for the FY 2025 program year because performance standards must be published at least 60 days prior to the start of the performance period, currently planned as FY 2023, as required under section 1888(h)(3)(C) of the Act. We invited public comment on this proposal to update the baseline period for the FY 2025 SNF VBP Program. We received the following comments and provide our responses:

Comment: Some commenters supported the proposal to revise the baseline period for the FY 2025 program year. One commenter recommended that we consider the accuracy of pre- and post-pandemic quality comparisons to ensure that SNFs are not penalized based on factors out of their control, such as lower occupancy levels, patient case-mix, and staffing concerns.

Response: We appreciate the support. We will continue to consider for future rulemaking whether and how to take the lasting impacts of the COVID–19 pandemic into consideration.

After considering the public comments, we are finalizing our proposal to update the baseline period to FY 2019 for the FY 2025 SNF VBP Program.

3. Performance Periods and Baseline Periods for the SNF HAI Measure Beginning With the FY 2026 SNF VBP Program

a. Performance Period for the SNF HAI Measure for the FY 2026 SNF VBP Program and Subsequent Years

As stated in the proposed rule, in considering the appropriate performance period for the SNF HAI measure for the FY 2026 SNF VBP Program, we recognized that we must balance the length of the performance period with our need to calculate valid and reliable performance scores and announce the resulting payment adjustments no later than 60 days prior to the program year involved, in accordance with section 1888(h)(7) of the Act. In our testing of the measure, we found that a 1-year performance period produced moderately reliable performance scores. We refer readers to the SNF HAI Measure Technical Report for further information on measure testing results, available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf.* In addition, we refer readers to the FY 2017 SNF PPS final rule (81 FR 51998 through 51999) for a discussion of the factors we should consider when specifying performance periods for the SNF VBP Program, as well as our stated preference for 1-year performance periods. Based on these considerations, we believed that a 1-year performance period for the SNF HAI measure is operationally feasible for the SNF VBP Program and provides sufficiently accurate and reliable SNF HAI measure rates and resulting performance scores.

We also recognized that we must balance our desire to specify a performance period for a fiscal year as close to the fiscal year's start date as possible to ensure clear connections between quality measurement and value-based payment with our need to announce the net results of the Program's adjustments to Medicare payments not later than 60 days prior to the fiscal year involved, in accordance with section 1888(h)(7) of the Act. In considering these constraints, and in alignment with the SNFRM, we believed that a performance period that occurs 2 fiscal years prior to the applicable fiscal program year is most appropriate for the SNF HAI measure.

For these reasons, we proposed to adopt a 1-year performance period for the SNF HAI measure. In addition, we proposed to adopt FY 2024 (October 1, 2023 through September 30, 2024) as the performance period for the SNF HAI measure for the FY 2026 SNF VBP Program.

In alignment with the current Program measure, we also proposed that, for the SNF HAI measure, we would automatically adopt the performance period for a SNF VBP program year by advancing the beginning of the performance period by 1 year from the previous program year's performance period.

We invited public comment on these proposals related to the performance period for the SNF HAI measure for the FY 2026 program year and subsequent years. We received one public comment related to the performance periods for the SNF HAI measure. We summarized that comment and provide our response below in section VIII.C.3.b. of this final rule. As stated in that section, we are finalizing our proposal to adopt FY 2024

(October 1, 2023 through September 30, 2024) as the performance period for the SNF HAI measure for the FY 2026 program year and finalizing our proposal to adopt performance periods for the SNF HAI measure for subsequent program years by advancing the beginning of the performance period by 1 year from the previous program year's performance period.

b. Baseline Period for the SNF HAI Measure for the FY 2026 SNF VBP Program and Subsequent Years

We discussed in the FY 2016 SNF PPS final rule (80 FR 46422) that, as with other Medicare quality programs, we generally adopt a baseline period for a fiscal year that occurs prior to the performance period for that fiscal year to establish measure performance standards. In the FY 2016 SNF PPS final rule (80 FR 46422), we also discussed our intent to adopt baseline periods that are as close as possible in duration as the performance period for a fiscal year as well as our intent to seasonally align baseline periods with the performance period to avoid any effects on quality measurement that may result from tracking SNF performance during different times in a year. Therefore, to align with the proposed performance period length for the SNF HAI measure, we believed a 1-year baseline period is most appropriate for the SNF HAI measure.

We also recognized that we are required to calculate and announce performance standards no later than 60 days prior to the start of the performance period, as required by section 1888(h)(3)(C) of the Act. Therefore, in alignment with the SNFRM baseline period, we believed that a baseline period that occurs 4 fiscal years prior to the applicable fiscal program year, and 2 fiscal years prior to the performance period, is most appropriate for the SNF HAI measure and provides sufficient time to calculate and announce performance standards prior to the start of the performance period.

For these reasons, we proposed to adopt a 1-year baseline period for the SNF HAI measure. In addition, we proposed to adopt FY 2022 (October 1, 2021 through September 30, 2022) as the baseline period for the SNF HAI measure for the FY 2026 SNF VBP Program.

In alignment with the current Program measure, we also proposed that for the SNF HAI measure, we would automatically adopt the baseline period for a SNF VBP program year by advancing the beginning of the baseline period by 1 year from the previous program year's baseline period.

We invited public comment on these proposals related to the baseline period for the SNF HAI measure for the FY 2026 program year and subsequent years. We received the following comment related to the SNF HAI measure performance and baseline periods and provide our response:

Comment: One commenter supported the performance and baseline periods for the SNF HAI measure as proposed.

Response: We thank the commenter for its support of the proposed performance and baseline periods for the SNF HAI measure.

After considering the public comment, we are finalizing our proposal to adopt FY 2024 (October 1, 2023 through September 30, 2024) as the performance period for the SNF HAI measure for the FY 2026 program year and finalizing our proposal to adopt performance periods for the SNF HAI measure for subsequent program years by advancing the beginning of the performance period by 1 year from the previous program year's performance period. Additionally, we are finalizing our proposal to adopt FY 2022 (October 1, 2021 through September 30, 2022) as the baseline period for the SNF HAI measure for the FY 2026 program year and finalizing our policy to adopt baseline periods for the SNF HAI measure for subsequent program years by advancing the beginning of the baseline period by 1 year from the previous program year's baseline period.

4. Performance Periods and Baseline Periods for the Total Nursing Hours per Resident Day Staffing Measure Beginning With the FY 2026 SNF VBP Program

a. Performance Period for the Total Nursing Hours per Resident Day Staffing Measure for the FY 2026 SNF VBP Program and Subsequent Years

As stated in the proposed rule, in considering the appropriate performance period for the Total Nurse Staffing measure for the FY 2026 SNF VBP Program, we recognized that we must balance the length of the performance period with our need to calculate valid and reliable performance scores and announce the resulting payment adjustments no later than 60 days prior to the program year involved, in accordance with section 1888(h)(7) of the Act. The Total Nurse Staffing measure is currently reported on a quarterly basis for the Nursing Home Five-Star Quality Rating System. For purposes of inclusion in the SNF VBP Program, we proposed that the measure rate would be calculated on an annual basis. To do so, we proposed to aggregate the quarterly measure rates using a simple mean of the available quarterly case-mix adjusted scores in a 1-year performance period. We conducted testing of the measure and found that the quarterly measure rate and resident census are stable across quarters. Further, an unweighted yearly measure aligns the SNF VBP Program rates with rates reported on the Provider Data Catalog website currently hosted by HHS, available at *https://data.cms.gov/provider-data/.* It can also be easily understood by, and is transparent to, the public. In addition, we refer readers to the FY 2017 SNF PPS final rule (81 FR 51998 through 51999) for discussion of the factors we should consider when specifying performance periods for the SNF VBP Program as well as our preference for 1-year performance periods. Based on these considerations, we believed that a 1-year performance period for the Total Nurse Staffing measure is operationally feasible under the SNF VBP Program and provides sufficiently accurate and reliable Total Nurse Staffing measure rates and resulting performance scores.

We also recognized that we must balance our desire to specify a performance period for a fiscal year as close to the fiscal year's start date as possible to ensure clear connections between quality measurement and value-based payment with our need to announce the net results of the Program's adjustments to Medicare payments not later than 60 days prior to the fiscal year involved, in accordance with section 1888(h)(7) of the Act. In considering these constraints, and in alignment with the SNFRM, we believed that a performance period that occurs 2 fiscal years prior to the applicable fiscal program year is most appropriate for the Total Nurse Staffing measure.

For these reasons, we proposed to adopt a 1-year performance period for the Total Nurse Staffing measure. In addition, we proposed to adopt FY 2024 (October 1, 2023 through September 30, 2024) as the performance period for the Total Nurse Staffing measure for the FY 2026 SNF VBP program year.

In alignment with the current Program measure, we also proposed that, for the Total Nurse Staffing measure, we would automatically adopt the performance period for a SNF VBP program year by advancing the beginning of the performance period by 1 year from the previous program year's performance period.

We invited public comment on these proposals related to the performance period for the Total Nurse Staffing

measure for the FY 2026 program year and subsequent years. We received the following comment and provide our response:

Comment: One commenter recommended that we use the calendar year rather than the fiscal year for the Total Nurse Staffing measure's performance period. The commenter stated that because data for this measure are collected and reported quarterly starting 45 days after the end of the quarter, a calendar year schedule provides CMS with enough time to announce the Program's adjustments to Medicare payments not later than 60 days prior to the fiscal year involved.

Response: We believe that using the fiscal year as the performance period for the Total Nurse Staffing measure is important to maintain consistency with our other measures in the SNF VBP Program that use fiscal year performance and baseline periods. All of the measures proposed thus far for the SNF VBP program rely on fiscal year measurement periods, and we intend to use measures relying on fiscal year periods in the Program in the future to the extent such alignment is feasible and practical. We believe that this type of alignment, where possible, helps stakeholders understand their quality measurement obligations and reporting periods more easily.

After considering the public comments, we are finalizing our proposal to adopt FY 2024 (October 1, 2023 through September 30, 2024) as the performance period for the Total Nurse Staffing measure for the FY 2026 program year. We are also finalizing our proposal to adopt 1-year performance periods for the Total Nurse Staffing measure for subsequent program years as proposed by advancing the beginning of the performance period by 1 year from the previous program year's performance period.

b. Baseline Period for the Total Nursing Hours per Resident Day Staffing Measure for the FY 2026 SNF VBP Program and Subsequent Years

We discussed in the FY 2016 SNF PPS final rule (80 FR 46422) that, as with other Medicare quality programs, we generally adopt a baseline period for a fiscal year that occurs prior to the performance period for that fiscal year to establish measure performance standards. In the FY 2016 SNF PPS final rule (80 FR 46422), we also discussed our intent to adopt baseline periods that are as close as possible in duration as the performance period for a fiscal year, as well as our intent to seasonally align baseline periods with the performance period to avoid any effects on quality measurement that may result from tracking SNF performance during different times in a year. Therefore, to align with the proposed performance period length for the Total Nurse Staffing measure, we believed a 1-year baseline period is most appropriate.

We also recognized that we are required to calculate and announce performance standards no later than 60 days prior to the start of the performance period, as required by section 1888(h)(3)(C) of the Act. Therefore, in alignment with the SNFRM baseline period, we believed that a baseline period that occurs 4 fiscal years prior to the applicable fiscal program year, and 2 fiscal years prior to the performance period, is most appropriate for the Total Nurse Staffing measure and provides sufficient time to calculate and announce performance standards prior to the start of the performance period.

For these reasons, we proposed to adopt a 1-year baseline period for the Total Nurse Staffing measure. In addition, we proposed to adopt FY 2022 (October 1, 2021 through September 30, 2022) as the baseline period for the Total Nurse Staffing measure for the FY 2026 SNF VBP Program.

In alignment with the current Program measure, we also proposed that for the Total Nurse Staffing measure, we would automatically adopt the baseline period for a SNF VBP program year by advancing the beginning of the baseline period by 1 year from the previous program year's baseline period.

We invited public comment on these proposals related to the baseline period for the Total Nurse Staffing measure for the FY 2026 program year and subsequent years. We received the following comments and provide our responses:

Comment: One commenter supported our proposal to use FY 2022 as the baseline period for the Total Nurse Staffing measure.

Response: We thank the commenter for their support of the proposed baseline period for the Total Nurse Staffing measure.

Comment: One commenter expressed concern about using any FY 2021 data for the Total Nurse Staffing measure, stating that during the PHE for COVID–19, many nursing facilities reported severe staffing shortages. The commenter suggested that we adopt a different baseline period focusing on the year with the highest staffing levels nationally, on average.

Response: We clarify that we proposed to adopt FY 2022 as the baseline period for the Total Nurse Staffing measure for the FY 2026 SNF VBP Program. We also believe that adopting a baseline period for a fiscal year that occurs prior to the performance period for that fiscal year gives us enough time to establish the measure's performance standards in our quality programs. Further, we note that we are required to calculate and announce performance standards no later than 60 days prior to the start of the performance period, as required by section 1888(h)(3)(C) of the Act.

Comment: One commenter opposed our proposal to use FY 2022 as the baseline period for the Total Nurse Staffing measure, stating that we should instead use FY 2019 to assess performance from prior to the COVID–19 pandemic.

Response: We believe that additional policies we adopted in response to the challenges presented by the COVID–19 pandemic, including quality measure suppression, sufficiently mitigate the effects of the PHE on quality measurements and allow us to adopt FY 2022 as the baseline period.

After considering the public comments, we are finalizing our proposal to adopt FY 2022 (October 1, 2021 through September 30, 2022) as the baseline period for the Total Nurse Staffing measure for the FY 2026 program year. We are also finalizing our proposal to adopt 1-year baseline periods for the Total Nurse Staffing measure for subsequent program years as proposed by advancing the beginning of the baseline period by 1 year from the previous program year's baseline period.

5. Performance Periods and Baseline Periods for the DTC PAC Measure for SNFs for the FY 2027 SNF VBP Program and Subsequent Years

a. Performance Period for the DTC PAC SNF Measure for the FY 2027 SNF VBP Program and Subsequent Years

Under the SNF QRP, The Discharge to Community—PAC SNF QRP measure has a reporting period that uses 2 consecutive years to calculate the measure (83 FR 39217 through 39272). In alignment with the reporting period that applies to the measure under the SNF QRP, we proposed to adopt a 2-year performance period for the DTC PAC SNF measure under the SNF VBP Program.

We proposed to align our performance period with the performance period for the measure used by the SNF QRP to maintain streamlined data requirements and reduce any confusion for participating SNFs. In addition, we proposed to adopt FY 2024 through FY 2025 (October 1, 2023 through September 30, 2025) as the performance

period for the DTC PAC SNF measure for the FY 2027 SNF VBP Program.

We also proposed that for the DTC PAC SNF measure, we would automatically adopt the performance period for a SNF VBP program year by advancing the beginning of the performance period by 1 year from the previous program year's performance period.

We invited public comment on our proposals related to the performance period for the DTC PAC SNF measure for FY 2027 program year and subsequent years. We received the following comment and provide our response:

Comment: One commenter supported the proposed performance period for the DTC PAC SNF measure.

Response: We thank the commenter for their support of the proposed performance period for the DTC PAC SNF measure.

After considering the public comment, we are finalizing our proposal to adopt FY 2024 through FY 2025 (October 1, 2023 through September 30, 2025) as the performance period for the DTC PAC SNF measure for the FY 2027 program year. We are also finalizing our proposal to adopt performance periods for the DTC PAC SNF measure for subsequent program years by advancing the beginning of the performance period by 1 year from the previous program year's performance period.

b. Baseline Period for the DTC PAC SNF Measure for the FY 2027 SNF VBP Program Year and Subsequent Years

We discussed in the FY 2016 SNF PPS final rule (80 FR 46422) that, as with other Medicare quality programs, we generally adopt a baseline period for a fiscal year that occurs prior to the performance period for that fiscal year to establish measure performance standards. In the FY 2016 SNF PPS final rule (80 FR 46422), we also discussed our intent to adopt baseline periods that are as close as possible in duration as the performance period for a fiscal year, as well as our intent to seasonally align baseline periods with the performance period to avoid any effects on quality measurement that may result from tracking SNF performance during different times in a year. Therefore, to align with the proposed performance period length for the DTC PAC SNF measure, we believed a 2-year baseline period is most appropriate for this measure.

We also recognized that we are required to calculate and announce performance standards no later than 60 days prior to the start of the performance period, as required by section 1888(h)(3)(C) of the Act. Therefore, we believed that a baseline period that begins 6 fiscal years prior to the applicable fiscal program year, and 3 fiscal years prior to the performance period, is most appropriate for the DTC PAC SNF measure and provides sufficient time to calculate and announce performance standards prior to the start of the performance period.

For these reasons, we proposed to calculate the performance period for the DTC PAC SNF measure using 2 consecutive years of data. In addition, we proposed to adopt FY 2021 through FY 2022 (October 1, 2020 through September 30, 2022) as the baseline period for the DTC PAC SNF measure for the FY 2027 SNF VBP Program.

In alignment with the current Program measure, we also proposed that for the DTC PAC SNF measure, we would automatically adopt the baseline period for a SNF VBP program year by advancing the beginning of the baseline period by 1 year from the previous program year's baseline period.

We invited public comment on these proposals related to the baseline period for the DTC PAC SNF measure for FY 2027 program year and subsequent years. We received the following comment and provide our response:

Comment: One commenter expressed concern about adopting a baseline period for the DTC PAC SNF measure that includes FY 2021 through FY 2022 data, stating that many beneficiaries discharged during those years may have been discharged early due to COVID–19 fears. The commenter noted that the associated census declines compared to pre-PHE practices may adversely affect facilities' outcomes. The commenter also encouraged us to delay implementation of the DTC PAC SNF measure until the baseline period does not include quality data from other measures that have been suppressed.

Response: We continue to believe that using FY 2021 through FY 2022 as the baseline period for the DTC PAC SNF measure for the FY 2027 program year is most appropriate and would help ensure clear connections between the quality measurement and value-based incentive payments. As stated in the proposed rule, we note that the continuation of the PHE for COVID–19 did not necessarily impact all measures in the SNF setting specifically, but measures related to hospital care, including the SNFRM, may be impacted because of how closely the surge in COVID–19 cases was related to the surge in COVID–19 related hospital admissions. We do not believe the DTC PAC SNF measure data has been affected in this way. In addition, we believe the additional policies we adopted in response to the challenges presented by the PHE for COVID–19, including quality measure suppression, sufficiently mitigate the effects of the PHE on quality measurement. As we have done with the SNFRM, we will continue to assess whether the PHE has impacted the DTC PAC SNF measure data. Further, we note that SNFs that do not meet the case minimum for the DTC PAC SNF measure during the baseline period due to potential census declines associated with the PHE for COVID–19 will continue to have the opportunity to be scored on achievement during the applicable performance period.

After considering the public comment, we are finalizing our proposal to adopt FY 2021 through FY 2022 (October 1, 2020 through September 30, 2022) as the baseline period for the DTC PAC SNF measure for the FY 2027 program year. We are also finalizing our proposal to adopt baseline periods for the DTC PAC SNF measure for subsequent program years by advancing the beginning of the baseline period by 1 year from the previous program year's baseline period.

D. Performance Standards

1. Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for a summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy. We adopted the final numerical values for the FY 2023 performance standards in the FY 2021 SNF PPS final rule (85 FR 47625) and adopted the final numerical values for the FY 2024 performance standards in the FY 2022 SNF PPS final rule (86 FR 42513). We also adopted a policy allowing us to correct the numerical values of the performance standards in the FY 2019 SNF PPS final rule (83 FR 39276 through 39277).

We did not propose any changes to these performance standard policies in the proposed rule.

2. SNF VBP Performance Standards Correction Policy

In the FY 2019 SNF PPS final rule (83 FR 39276 through 39277), we finalized a policy to correct numerical values of performance standards for a program year in cases of errors. We also finalized that we will only update the numerical values for a program year one time, even if we identify a second error, because we believe that a one-time correction will allow us to incorporate new information into the calculations

without subjecting SNFs to multiple updates. We stated that any update we make to the numerical values based on a calculation error will be announced via the CMS website, listservs, and other available channels to ensure that SNFs are made fully aware of the update. In the FY 2021 SNF PPS final rule (85 FR 47625), we amended the definition of ''Performance standards'' at § 413.338(a)(9), consistent with these policies finalized in the FY 2019 SNF PPS final rule, to reflect our ability to update the numerical values of performance standards if we determine there is an error that affects the achievement threshold or benchmark. To improve the clarity of this policy, we proposed to amend the definition of ''Performance standards'' and redesignate it as § 413.338(a)(12), then add additional detail about the correction policy at § 413.338(d)(6).

We invited public comment on our changes to the text at § 413.338(a)(12) and (d)(6). However, we did not receive any public comments on this topic. Accordingly, we are finalizing our proposal to update the performance standards correction policy in our regulations.

3. Performance Standards for the FY 2025 Program Year

As discussed in section VIII.C.2. of this final rule, we are finalizing our proposal to use FY 2019 data as the baseline period for the FY 2025 program year. Based on this updated baseline period and our previously finalized methodology for calculating performance standards (81 FR 51996 through 51998), the final numerical values for the FY 2025 program year performance standards are shown in Table 17.

TABLE 17: Final FY 2025 SNF VBP Program Performance Standards

Measure ID	Measure Description	Achievement Threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79139	0.82912

E. SNF VBP Performance Scoring

1. Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52000 through 52005) for a detailed discussion of the scoring methodology that we have finalized for the Program. We also refer readers to the FY 2018 SNF PPS final rule (82 FR 36614 through 36616) for discussion of the rounding policy we adopted. We also refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39281), where we adopted: (1) a scoring policy for SNFs without sufficient baseline period data, (2) a scoring adjustment for low-volume SNFs, and (3) an ECE policy. Finally, we refer readers to the FY 2022 SNF PPS final rule (86 FR 42513 through 42515), where we adopted for FY 2022 a special scoring and payment policy due to the impact of the PHE for COVID–19.

2. Special Scoring Policy for the FY 2023 SNF VBP Program Due to the Impact of the PHE for COVID–19

In the FY 2023 SNF PPS proposed rule, we proposed to suppress the SNFRM for the FY 2023 program year due to the impacts of the PHE for COVID–19. Specifically, for FY 2023 scoring, we proposed that, for all SNFs participating in the FY 2023 SNF VBP Program, we will use data from the previously finalized performance period (FY 2021) and baseline period (FY 2019) to calculate each SNF's RSRR for the SNFRM. Then, we will assign all SNFs a performance score of zero. This will result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We also proposed that SNFs that do not meet the case minimum for the SNFRM for FY 2023 (see VIII.E.3.b. of this final rule) will be excluded from the Program for FY 2023. SNFs will not be ranked for the FY 2023 SNF VBP Program. We also proposed to update our regulation text at § 413.338(i) to codify this scoring policy for FY 2023. As we noted in section VIII.B.1. of this final rule, our goal is to continue the use of measure data for scoring and payment adjustment purposes beginning with the FY 2024 program year.

We invited public comment on our proposal to use a special scoring policy for the FY 2023 Program year. We received the following comments and provide our responses:

Comment: Some commenters supported our proposals to adopt special scoring and payment policies for FY 2023.

Response: We thank the commenters for their support.

Comment: Some commenters opposed our proposal to adopt a special scoring and payment policy for FY 2023. Some commenters noted that awarding all SNFs a performance score of zero does not create a value-based incentive payment as required by statute and further stated that CMS is required to rank SNFs for the fiscal year. Another commenter stated that the special scoring and payment policy will cause all SNFs to experience a payment reduction, which they believed is inconsistent with the statute. One commenter recommended that we give all SNFs an exemption from the payment reduction for FY 2023, while other commenters recommended that we adopt a 70 percent payback percentage for the FY 2023 Program year. One commenter suggested that we grant a full exemption from the adjusted Federal per diem rate reduction required by section 1888(h)(6) of the Act.

Response: We stated in the proposed rule our belief that for purposes of scoring and payment adjustments under the SNF VBP Program, the SNFRM as impacted by the COVID–19 PHE should not be attributed to the participating facility positively or negatively. We believe that using SNFRM data that has been impacted by the PHE due to COVID–19 could result in performance scores that do not accurately reflect SNF performance for making national comparisons and ranking purposes. Due to the SNFRM being the only quality measure currently authorized for use in the FY 2023 SNF VBP, suppression of the SNFRM would mean we would not be able to calculate SNF performance scores for any SNF nor to differentially rank SNFs. Therefore, we are finalizing a change to the scoring methodology to assign all SNFs a performance score of zero and effectively rank all SNFs equally in the FY 2023 SNF VBP program year.

After considering the public comments, we are finalizing our proposal to adopt a special scoring policy for the FY 2023 program year as proposed and codifying it at § 413.338(i) of our regulations.

3. Case Minimum and Measure Minimum Policies

a. Background

Section 111(a)(1) of Division CC of the CAA amended section 1888(h)(1) of the Act by adding paragraph (h)(1)(C), which established criteria for excluding SNFs from the SNF VBP Program. Specifically, with respect to payments for services furnished on or after October 1, 2022, paragraph (h)(1)(C) precludes the SNF VBP Program from applying to a SNF for which there are not a minimum number of cases (as determined by the Secretary) for the measures that apply to the SNF for the performance period for the applicable fiscal year, or a minimum number of measures (as determined by the Secretary) that apply to the SNF for the performance period for the applicable fiscal year.

To implement this provision, we proposed to establish case and measure minimums that SNFs must meet to be included in the Program for a given program year. These case and measure minimum requirements will serve as eligibility criteria for determining whether a SNF is included in, or excluded from, the Program for a given program year. Inclusion in the Program for a program year means that a SNF would receive a SNF performance score and would be eligible to receive a value-based incentive payment. Exclusion from the Program for a program year means that, for the applicable fiscal year, a SNF would not be subject to the requirements under § 413.338 and would also not be subject to a payment reduction under § 413.337(f). Instead, the SNF would receive its full Federal per diem rate under § 413.337 for the applicable fiscal year.

We proposed to establish a case minimum for each SNF VBP measure that SNFs must meet during the performance period for the program year. We also proposed that SNFs must have a minimum number of measures during the performance period for the applicable program year in order to be eligible to participate in the SNF VBP Program for that program year. We proposed to codify these changes to the applicability of the SNF VBP Program beginning with FY 2023 at § 413.338(b).

We proposed that the case and measure minimums would be based on statistical accuracy and reliability, such that only SNFs that have sufficient data are included in the SNF VBP Program for a program year. The purpose of these restrictions is to apply program requirements only to SNFs for which we can calculate reliable measure rates and SNF performance scores.

Because the case and measure minimum policies will ensure that SNFs participate in the Program for a program year only if they have sufficient data for calculating accurate and reliable measure rates and SNF performance scores, we do not believe there is a continuing need to apply the low-volume adjustment (LVA) policy beginning with FY 2023. Accordingly, in the FY 2023 SNF PPS proposed rule (87 FR 22783), we proposed to remove the LVA policy from the Program beginning with the FY 2023 program year. As discussed further in section VIII.E.5. of this final rule, we are finalizing our proposal to remove the LVA policy.

We did not receive any public comments on our proposal to codify the changes to the applicability of the SNF VBP Program beginning with FY 2023 at § 413.338(b), and therefore, we are finalizing this proposal.

b. Case Minimum During a Performance Period for the SNFRM Beginning With the FY 2023 SNF VBP Program Year

We proposed that beginning with the FY 2023 program year, SNFs must have a minimum of 25 eligible stays for the SNFRM during the applicable 1-year performance period in order to be eligible to receive a score on that measure in the SNF VBP Program.

As stated in the proposed rule, we believed this case minimum requirement for the SNFRM is appropriate and consistent with the findings of reliability tests conducted for the SNFRM, and it is also consistent with the case threshold we have applied under the LVA policy. The reliability testing results, which combined CY 2014 and 2015 SNFRM files, indicated that a minimum of 25 eligible stays for the SNFRM produced sufficiently reliable measure rates. In addition, the testing results found that approximately 85 percent of all SNFs met the 25 eligible stay minimum during the CY 2015 testing period. While excluding 15 percent of SNFs may seem high, we continue to believe that the 25 eligible stay minimum for the SNFRM appropriately balances quality measure reliability with our desire to allow as many SNFs as possible to participate in the Program. For further details on the measure testing, we refer readers to the minimum eligible stay threshold analysis for the SNFRM available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNFRM-Reliability-Testing-Memo.pdf.*

We also believed this case minimum requirement for the SNFRM ensures that those SNFs included in the Program receive a sufficiently accurate and reliable SNF performance score. However, we also proposed changes to our scoring and payment policies for the FY 2023 SNF VBP Program in the proposed rule. If finalized, beginning with the FY 2023 SNF VBP program year, any SNF that does not meet this case minimum requirement for the SNFRM during the applicable performance period will be excluded from the Program for the affected program year, provided there are no other measures specified for the affected program year. Those SNFs will not be subject to any payment reductions under the Program and instead will receive their full Federal per diem rate.

We invited public comment on our proposal to adopt a case minimum requirement for the SNFRM beginning with the FY 2023 SNF VBP program year. We received the following comments and provide our responses:

Comment: One commenter supported the proposed case minimum for the SNFRM based on the evidence and rationale provided.

Response: We thank the commenter for support of the case minimum for the SNFRM.

Comment: Some commenters urged CMS to increase the case minimums adopted in the Program to reach a reliability standard of 0.7, which they stated could be achieved with a case minimum of 60. The commenters stated that adopting longer performance and baseline periods would mitigate the effects of this recommendation on excluded SNFs based on the higher minimum number of cases.

Response: Our reliability testing results demonstrated that increasing the case minimum threshold to 50 eligible stays would slightly increase the measure's reliability but would approximately double the number of SNFs that would not meet this higher case minimum.[272] Therefore, we continue to believe that a 25-eligible stay minimum for the SNFRM best balances quality measure reliability with our desire to allow as many SNFs as possible to participate in the Program. As we discussed in the FY 2023 SNF PPS proposed rule (87 FR 22781), reliability testing for the SNFRM indicated that a 25 eligible stay minimum produces sufficiently reliable measure rates. In addition, our analyses found that approximately 85 percent of all SNFs met the 25 eligible stay

[272] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNFRM-Reliability-Testing-Memo.pdf.*

minimum during the CY 2015 testing period.

We also disagree with the commenters' suggestion to adopt longer performance and baseline periods as a method for increasing measure reliability. As we discussed in the FY 2016 SNF PPS final rule (80 FR 46422) and the FY 2017 SNF PPS final rule (81 FR 51998 through 51999), we continue to believe that 1-year performance and baseline periods provide sufficient levels of data accuracy and reliability for scoring performance on the SNFRM, while also allowing us to link SNF performance on the measure as closely as possible to the payment year to ensure clear connections between quality measurement and value-based payment. We also believe that adopting longer performance and baseline periods would create a time gap that would hinder our ability to clearly connect the quality data with SNFs' value-based payment, as well as limit the actionability of such quality data for SNFs to make quality improvements.

After considering the public comments, we are finalizing our proposal to adopt a 25 eligible stay minimum requirement during a performance period for the SNFRM beginning with the FY 2023 program year.

c. Case Minimums During a Performance Period for the SNF HAI, Total Nurse Staffing, and DTC PAC SNF Measures

In the FY 2023 SNF PPS proposed rule (87 FR 22767 through 22777), we proposed to adopt the SNF HAI and Total Nurse Staffing measures beginning with the FY 2026 program year, as well as the DTC PAC SNF measure beginning with the FY 2027 program year.

For the SNF HAI measure, we proposed that SNFs must have a minimum of 25 eligible stays during the applicable 1-year performance period in order to be eligible to receive a score on the measure. As stated in the proposed rule, we believed this case minimum requirement for the SNF HAI measure is appropriate and consistent with the findings of measure testing analyses. For example, testing results indicated that a 25 eligible stay minimum produced moderately reliable measure rates for purposes of public reporting under the SNF QRP. In addition, testing results found that 85 percent of SNFs met the 25 eligible stay minimum for public reporting under the SNF QRP. We believed these case minimum standards for public reporting purposes are also appropriate standards for establishing a case minimum for this measure under the SNF VBP Program. In addition, we believed these testing results for the 25 eligible stay minimum support our objective, which is to establish case minimums that appropriately balance quality measure reliability with our continuing desire to score as many SNFs as possible on this measure. For further details on SNF HAI measure testing for the SNF QRP, we refer readers to the SNF HAI Measure Technical Report available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf.*

For the Total Nurse Staffing measure, we proposed that SNFs must have a minimum of 25 residents, on average, across all available quarters during the applicable 1-year performance period in order to be eligible to receive a score on the measure. As discussed in the proposed rule, we tested three potential case minimums for this measure: a 25-resident minimum, a minimum of one quarter of PBJ data, and a minimum of two quarters of PBJ data. Over 94 percent of SNFs satisfied the case minimum under all three alternatives tested. There were very minimal differences observed between the case minimums tested, and this finding held for most subgroups tested as well, including rural SNFs, large SNFs, and those SNFs serving the highest proportion of dually eligible beneficiaries. The only notable observed difference occurred within small SNFs, defined as those with fewer than 46 beds as a proxy for size. About 90 percent of small SNFs reported two quarters of PBJ data, and about 92 percent of small SNFs reported one quarter of PBJ data, but only about 63 percent of small SNFs satisfied the 25-resident minimum, indicating that even after two quarters of successful PBJ reporting there was a substantial proportion of small SNFs (about 27 percent) reporting minimal numbers of residents, calling into question the utility of their limited staffing data. After considering these alternatives, we determined that the proposed 25-resident minimum best balances quality measure reliability with our desire to score as many SNFs as possible on this measure. We also noted that the 25-resident minimum for this measure aligns with the case minimums we are proposing for the other proposed measures.

Further, for the DTC PAC SNF measure, we proposed that SNFs must have a minimum of 25 eligible stays during the applicable 2-year performance period in order to be eligible to receive a score on the measure. As stated in the proposed rule, we believed this case minimum requirement for the DTC PAC SNF measure is appropriate and consistent with the findings of measure testing analyses. Analyses conducted by CMS contractors found that a 25 eligible stay minimum produced good to excellent measure score reliability. In addition, analyses using 2015 through 2016 Medicare FFS claims data found that 94 percent of SNFs met the 25 eligible stay minimum during the 2-year performance period. We believed these testing results for the 25 eligible stay minimum support our objective, which is to establish case minimums that appropriately balance quality measure reliability with our continuing desire to score as many SNFs as possible on this measure. The complete measure testing results conducted by our contractors that we included as part of the documentation supporting our request for NQF to endorse the measure are available at *https://www.qualityforum.org/QPS/3481.*

We invited public comment on our proposal to adopt case minimums for the SNF HAI, Total Nurse Staffing, and DTC PAC SNF measures. We received the following comments and provide our responses:

Comment: One commenter supported the proposed case minimums for the SNF HAI, DTC PAC SNF, and Total Nurse Staffing measures as proposed.

Response: We thank the commenter for support of the case minimums for the SNF HAI, DTC PAC SNF, and Total Nurse Staffing measures.

Comment: One commenter recommended increasing the proposed minimum number of stays to at least 60 to mitigate the effects of a larger Medicare Advantage population and nursing homes that have had to limit or reduce admissions due to staff shortages.

Response: We continue to believe that a 25 eligible stay minimum for the SNF HAI measure; a 25-resident minimum, on average, across all available quarters for the Total Nurse Staffing measure; and a 25 eligible stay minimum for the DTC PAC SNF measure best balance quality measure reliability with our desire to score as many SNFs as possible on these measures. We recognize the growing Medicare Advantage population as well as the impact of staff shortages on the ability of a SNF to admit residents and we intend to continue assessing these topics in the future.

After considering the public comments, we are finalizing our proposal to adopt a 25 eligible stay minimum for the SNF HAI measure; a 25-resident minimum, on average, across all available quarters for the Total Nurse Staffing measure; and a 25

eligible stay minimum for the DTC PAC SNF measure.

d. Measure Minimums for the FY 2026 and FY 2027 Program Years

We proposed to adopt measure minimums for the FY 2026 and FY 2027 program years. Under these policies, only SNFs that have the minimum number of measures applicable to the program year would be eligible for inclusion in the Program for that program year.

In the proposed rule, we proposed to adopt two new quality measures (SNF HAI and Total Nurse Staffing measures) beginning with the FY 2026 Program. If finalized, the SNF VBP Program would consist of three quality measures in FY 2026 (SNF Readmission Measure, SNF HAI, and Total Nurse Staffing measures). We proposed that for FY 2026, SNFs must have the minimum number of cases for two of these three measures during the performance period to receive a performance score and value-based incentive payment. SNFs that do not meet these minimum requirements will be excluded from the FY 2026 program and will receive their full Federal per diem rate for that fiscal year. Under these minimum requirements, we estimated that approximately 14 percent of SNFs would be excluded from the FY 2026 Program. Alternatively, if we required SNFs to have the minimum number of cases for all three measures during the performance period, approximately 21 percent of SNFs would be excluded from the FY 2026 Program. We also assessed the consistency of value-based incentive payment adjustment factors, or incentive payment multipliers (IPMs), between time periods as a proxy for performance score reliability under the different measure minimum options. The testing results indicated that the reliability of the SNF performance score would be relatively consistent across the different measure minimum requirements. Based on these testing results, we believed the minimum of two out of three measures for FY 2026 best balances SNF performance score reliability with our desire to ensure that as many SNFs as possible can receive a performance score and value-based incentive payment.

We also proposed to adopt an additional quality measure (DTC PAC SNF measure) beginning with the FY 2027 Program. If finalized, the SNF VBP Program would consist of four quality measures in FY 2027 (SNF Readmission Measure, SNF HAI, Total Nurse Staffing, and DTC PAC SNF measures). We proposed that for FY 2027, SNFs must have the minimum number of cases for three of the four measures during a performance period to receive a performance score and value-based incentive payment. SNFs that do not meet these minimum requirements will be excluded from the FY 2027 program and will receive their full Federal per diem rate for that fiscal year. Under these minimum requirements, we estimated that approximately 16 percent of SNFs would be excluded from the FY 2027 Program. Alternatively, if we required SNFs to have the minimum number of cases for all four measures, we estimated that approximately 24 percent of SNFs would be excluded from the FY 2027 Program. We also assessed the consistency of incentive payment multipliers (IPMs) between time periods as a proxy for performance score reliability under the different measure minimum options. The testing results indicated that the reliability of the SNF performance score for the FY 2027 program year would be relatively consistent across the different measure minimum requirements. Based on these testing results, we believed the minimum of three out of four measures for FY 2027 best balances SNF performance score reliability with our desire to ensure that as many SNFs as possible can receive a performance score and value-based incentive payment.

Under these measure minimums, we estimated that 14 percent of SNFs would be excluded from the Program for the FY 2026 program year, but that the excluded SNFs would, as a whole, provide care to approximately 2 percent of the total number of eligible SNF stays. Similarly, for the FY 2027 Program, we estimated that 16 percent of SNFs would be excluded from the Program, but that the excluded SNFs, as a whole, provide care to approximately 2 percent of the total number of eligible SNF stays.

We invited public comment on our proposal to adopt measure minimums for the FY 2026 and FY 2027 SNF VBP program years. We received the following comment and provide our response:

Comment: One commenter supported the measure minimums for FY 2026 and FY 2027 as proposed.

Response: We thank the commenter for support of the measure minimums for the FY 2026 and FY 2027 program years.

After considering the public comment, we are finalizing our proposal for FY 2026 that SNFs must have the minimum number of cases for two of the three measures during the performance period to receive a performance score and value-based incentive payment, and finalizing our proposal for FY 2027 that SNFs must have the minimum number of cases for three of the four measures during a performance period to receive a performance score and value-based incentive payment.

4. Updated Scoring Policy for SNFs Without Sufficient Baseline Period Data Beginning With the FY 2026 Program Year

In the FY 2019 SNF PPS final rule (83 FR 39278), we finalized a policy to score SNFs based only on their achievement during the performance period for any program year for which they do not have sufficient baseline period data, which we defined as SNFs with fewer than 25 eligible stays during the baseline period for a fiscal year. We codified this policy at § 413.338(d)(1)(iv) of our regulations.

We continue to be concerned that measuring SNF performance on a given measure for which the SNF does not have sufficient baseline period data may result in unreliable improvement scores for that measure and, as a result, unreliable SNF performance scores. However, the current policy was designed for a SNF VBP Program with only one measure. As we continue to add measures to the Program, we aim to maintain the reliability of our SNF performance scoring. Therefore, we proposed to update our policy beginning with the FY 2026 program year. Under this updated policy, we will not award improvement points to a SNF on a measure for a program year if the SNF has not met the case minimum for that measure during the baseline period that applies to the measure for the program year. That is, if a SNF does not meet a case minimum threshold for a given measure during the applicable baseline period, that SNF will only be eligible to be scored on achievement for that measure during the performance period for that measure for the applicable fiscal year.

For example, if a SNF has fewer than the minimum of 25 eligible stays during the applicable 1-year baseline period for the SNF HAI measure for FY 2026, that SNF would only be scored on achievement during the performance period for the SNF HAI measure for FY 2026, so long as that SNF meets the case minimum for that measure during the applicable performance period.

We proposed to codify this update in our regulation text at § 413.338(e)(1)(iv).

We invited public comment on this proposal to update the policy for scoring SNFs that do not have sufficient baseline period data. We received the following comment and provide our response:

Comment: One commenter supported our proposal to not award improvement points to SNFs that do not meet the case minimums during the applicable baseline periods.

Response: We thank the commenter for support of this proposal.

After considering the public comment, we are finalizing our proposal to update the policy for scoring SNFs that do not have sufficient baseline period data such that we would not award improvement points to a SNF on a measure for a program year if that SNF does not meet the case minimum for that measure during the baseline period that applies to the measure for the program year. We are also finalizing our proposal to codify this update at § 413.338(e)(1)(iv) of our regulations.

5. Removal of the LVA Policy From the SNF VBP Program Beginning With the FY 2023 Program Year

In the FY 2019 SNF PPS final rule (83 FR 39278 through 39280), we finalized our LVA policy, which provides an adjustment to the Program's scoring methodology to ensure low-volume SNFs receive sufficiently reliable performance scores for the SNF readmission measure. In that final rule, we also codified the LVA policy in § 413.338(d)(3) of our regulations. As we discussed in the FY 2019 SNF PPS final rule, we found that the reliability of the SNFRM measure rates and resulting performance scores were adversely affected if SNFs had fewer than 25 eligible stays during the performance period for a program year (83 FR 39279). Therefore, we believed that assigning a performance score that results in a value-based incentive payment amount that is equal to the adjusted Federal per diem rate that the SNF would have received in the absence of the Program, to any SNF with fewer than 25 eligible stays for the SNFRM during the performance period, was the most appropriate adjustment for ensuring reliable performance scores.

However, as discussed in the proposed rule, we no longer believe the LVA policy is necessary because we are now required under the statute to have case and measure minimum policies for the SNF VBP Program, and those policies will achieve the same payment objective as the LVA policy. Therefore, we proposed to remove the LVA Policy from the SNF VBP Program's scoring methodology beginning with the FY 2023 program year. With the removal of the LVA policy, the total amount available for a fiscal year will no longer be increased as appropriate for each fiscal year to account for the assignment of a performance score to low-volume SNFs. We proposed to update the total amount available for a fiscal year to 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by us, in our regulations at§ 413.338(c)(2)(i). We proposed to update the LVA policy at § 413.338(d)(3) to reflect its removal from the Program.

We invited public comment on our proposal to remove the LVA policy from the SNF VBP Program beginning with the FY 2023 program year. We received the following comment and provide our response:

Comment: One commenter supported our proposed removal of the LVA policy.

Response: We thank the commenter for their support of this proposal.

After considering the public comment, we are finalizing our proposal to remove the LVA policy from the SNF VBP Program beginning with the FY 2023 program year and finalizing our proposal to update our regulations at § 413.338(d)(3) to reflect its removal from the Program.

6. Updates to the SNF VBP Scoring Methodology Beginning in the FY 2026 Program Year

a. Background

In the FY 2017 SNF PPS final rule (81 FR 52000 through 52005), we adopted a scoring methodology for the SNF VBP Program where we score SNFs on their performance on the SNFRM, award between zero and 100 points to each SNF (with up to 90 points available for improvement) and award each SNF a SNF performance score consisting of the higher of its scores for achievement and improvement. The SNF performance score is then translated into a value-based incentive payment multiplier that can be applied to each SNF's Medicare claims during the SNF VBP Program year using an exchange function. Additionally, in the FY 2018 SNF PPS final rule (82 FR 36615), we adopted a clarification of our rounding policy in SNF VBP scoring to award SNF performance scores that are rounded to the nearest ten-thousandth of a point, or with no more than five significant digits to the right of the decimal point. We have also codified numerous aspects of the SNF VBP Program's policies in our regulations at § 413.338, and our scoring policies appear in paragraph (d) of that section.

We refer readers to the FY 2017 rule cited above for a detailed discussion of the SNF VBP Program's scoring methodology, public comments on the proposed policies, and examples of our scoring calculations.

b. Measure-Level Scoring Update

We proposed to update our achievement and improvement scoring methodology to allow a SNF to earn a maximum of 10 points on each measure for achievement, and a maximum of nine points on each measure for improvement. For purposes of determining these points, we proposed to define the benchmark as the mean of the top decile of SNF performance on a measure during the baseline period and the achievement threshold as the 25th percentile of national SNF performance on a measure during the baseline period.

We proposed to award achievement points to SNFs based on their performance period measure rate for each measure according to the following:

- If a SNF's performance period measure rate was equal to or greater than the benchmark, the SNF would be awarded 10 points for achievement.
- If a SNF's performance period measure rate was less than the achievement threshold, the SNF would receive zero points for achievement.
- If a SNF's performance period measure rate was equal to or greater than the achievement threshold, but less than the benchmark, we would award between zero and 10 points according to the following formula:

$$Achievement\ Score = \left(\left[9 \times \left(\frac{Performance\ Period\ Rate - Achievement\ Threshold}{Benchmark - Achievement\ Threshold}\right)\right] + 0.5\right)$$

We also proposed to award improvement points to SNFs based on their performance period measure rate according to the following:

- If a SNF's performance period measure rate was equal to or lower than its baseline period measure rate, the SNF would be awarded zero points for improvement.
- If a SNF's performance period measure rate was equal to or higher than the benchmark, the SNF would be awarded nine points for improvement.
- If a SNF's performance period measure rate was greater than its baseline period measure rate but less than the benchmark, we would award between zero and nine points according to the following formula:

$$Improvement\ Score = \left(\left[10 \times \left(\frac{Performance\ Period\ Rate - Baseline\ Period\ Rate}{Benchmark - Baseline\ Period\ Rate}\right)\right] - 0.5\right)$$

As proposed, we will score SNFs' performance on achievement and improvement for each measure and award them the higher of the two scores for each measure to be included in the SNF performance score, except in the instance that the SNF does not meet the case minimum threshold for the measure during the applicable baseline period, in which case we proposed that the SNF would only be scored on achievement, as discussed in section VIII.E.4. of this final rule. As discussed in the following section of this final rule, we will then sum each SNFs' measure points and normalize them to arrive at a SNF performance score that ranges between zero and 100 points. We believe that this policy appropriately recognizes the best performers on each measure and reserves the maximum points for their performance levels while also recognizing that improvement over time is important and should also be rewarded.

We further proposed that this change would apply beginning with the FY 2026 SNF VBP program year. As proposed, all measures in the expanded SNF VBP Program would be weighted equally, as we believe that an equal weighting approach is simple for participating SNFs to understand and assigns significant scoring weight (that is, 33.33 percentage points if a SNF has sufficient data on all three measures proposed for FY 2026) to each measure topic covered by the expanded SNF VBP Program. However, as we consider whether we should propose to adopt additional measures, we also intend to consider whether we should group the measures into domains and weight them, similar to what we do under the Hospital VBP Program scoring methodology.

We view this change to the measure-level scoring as a necessary update to the SNF VBP Program's scoring methodology to incorporate additional quality measures and to allow us to add more measures in the future. We also proposed to codify these updates to our scoring methodology in our regulation text by revising the heading for paragraph (d) and adding paragraph (e)(1) at § 413.338.

We invited public comment on this proposal. We received the following comments and provide our responses:

Comment: Some commenters supported our proposed measure-level scoring updates. One commenter recommended adding decimal gradations to the nine and 10-point scales to allow additional variation and ensure that providers are not being disadvantaged by the scoring methodology.

Response: We did not propose to round the measure-level scores that result from use of the scoring formulas specified earlier in this section, and we will award measure-level scores with decimal gradations as the commenter suggested.

Comment: One commenter opposed the use of the mean of the top decile of SNFs' performance during the baseline period as the benchmark, stating that only about 5 percent of SNFs can meet such performance levels. The commenter argued that this methodology discriminates against certain types of SNFs, such as urban SNFs and those that provide care to larger minority populations. The commenter recommended placing the benchmark at the 10th decile of SNFs' performance and presenting analytical findings to a TEP for review and connection to clinical goals.

Response: We thank the commenter for this feedback. While the commenter is correct that only a small percentage of SNFs are likely to qualify for the maximum number of points available on any given measure in a SNF VBP Program year, we believe this policy appropriately rewards top performers on the Program's quality measures. In our view, a value-based purchasing program correctly provides incentives to all participating providers to achieve the best performance possible on the Program's measures. We note further that all SNFs whose performance on a quality measure exceeds the 25th percentile of performance from the baseline period can receive achievement points on a quality measure under the Program's scoring methodology. Further, all SNFs whose performance improves between the baseline and performance period can quality for improvement points under the Program's methodology. We therefore do not agree with the commenter's view that our performance standards policy discriminates against any SNFs, and we continue to believe that the performance standards policy, including the definition of the term ''benchmark,'' appropriately balances our desire to reward top performers while also recognizing SNFs whose performance improves over time.

Comment: One commenter stated that we should consider adopting a form of risk-adjustment for SNF VBP scores, noting that some facilities do not have enough data to calculate some quality measures.

Response: We thank the commenter for this suggestion. However, we are finalizing policies in this final rule that are designed to accommodate SNFs that do not have enough data to calculate some quality measures, specifically including a minimum number of measures required to receive a SNF performance score. We believe that this policy appropriately balances our desire to allow as much participation in the Program as possible while ensuring that those SNFs' performance scores are based on sufficiently reliable data.

Comment: One commenter stated that we should review adjustments and incentives for clinically complex residents, stating that capturing multiple diagnoses and residents' overarching socioeconomic needs is important for care coordination.

Response: We agree with the commenter that clinically complex residents may present challenges to SNFs attempting to provide the best possible care, and we will continue

examining this topic as part of our monitoring and evaluation efforts. However, we would like to clarify that we already incorporate clinical risk adjustment and certain exclusions in the specifications for many of our quality measures. The SNFRM accounts for variation across SNFs in both case mix and patient characteristics.[273] The SNF HAI measure incorporates risk adjustment that estimates both the average predictive effect of resident characteristics across all SNFs, and the degree to which each SNF has an effect on the outcome that differs from that of the average SNF.[274] Finally, the DTC PAC measure includes a statistical model for risk adjustment that estimates both the average predictive effect of the resident characteristics across all facilities and the degree to which each facility has an effect on discharge to community that differs from that of the average facility, as well as exclusions from the measure's calculations for situations where discharge to the community may not be clinically appropriate.[275] We also refer readers to the FY 2023 SNF PPS proposed rule for our discussion of risk-adjustments for the SNF HAI measure (87 FR 22770), the DTC PAC SNF measure (87 FR 22776), and case-mix adjustment for the Total Nurse Staffing measure (87 FR 22774).

After considering the public comments, we are finalizing our proposal to adopt a measure-level scoring policy beginning with the FY 2026 program year as described above, and to update our regulations at § 413.338 to reflect the new policy.

c. Normalization Policy

We continue to believe that awarding SNF performance scores out of a total of 100 points helps interested parties more easily understand the performance evaluation that we provide through the SNF VBP Program. Therefore, we believe that continuing to award SNF performance scores out of 100 points would help interested parties understand the revised scoring methodology and would allow the scoring methodology to accommodate additional measures in the future without more methodological changes.

Therefore, we considered how we could construct the SNF performance score such that the scores continue to range between zero and 100 points. We considered our past experience in our VBP programs, specifically including our experience with the Hospital VBP Program, where we award between zero and 10 points to participating providers for their performance on each measure, and to arrive at a Total Performance Score that ranges between zero and 100 points regardless of the number of measures on which the hospital has sufficient data, we normalize hospitals' scores. We believe the Hospital VBP Program's success in comprehensible measure-level scoring provides a strong model for the expanded SNF VBP Program.

We proposed to adopt a ''normalization'' policy for SNF performance scores under the expanded SNF VBP Program, effective in the FY 2026 program year and subsequent years. As proposed, we will calculate a raw point total for each SNF by adding up the SNF's score on each of the measures. For example, a SNF that met the case minimum to receive a score on three quality measures would receive a score between zero to 30 points, while a SNF that met the case minimum to receive a score on two quality measures would receive a score between zero to 20 points. We will then normalize the raw point totals by converting them to a 100-point scale, with the normalized values being awarded as the SNF performance score. For example, we would normalize a SNF's raw point total of 27 points out of 30 by converting that total to a 100-point scale, with the result that the SNF would receive a SNF performance score of 90.

In addition to allowing us to maintain a 100-point total performance score scale, this policy enables us to adopt additional quality measures for the program without making further changes to the scoring methodology. If, for example, we proposed to adopt a total of seven quality measures in the future, the normalization policy would enable us to continue to award SNF performance scores on a 100-point scale, even though the maximum raw point total would be 70 points.

We view this normalization policy as a useful update to the SNF VBP Program's scoring methodology to accommodate additional quality measures and to ensure that the public understands the SNF performance scores that we award. We also proposed to codify these updates to our scoring methodology by adding paragraph (e)(2) to our regulation text at § 413.338.

We invited public comment on our proposal. However, we did not receive any comments specific to the normalization policy. Therefore, we are finalizing our proposal to adopt a normalization policy for SNF performance scores under the SNF VBP Program beginning with the FY 2026 program year, and to update our regulations at § 413.338 to reflect the new policy.

F. Adoption of a Validation Process for the SNF VBP Program Beginning With the FY 2023 Program Year

Section 1888(h)(12) of the Act (as added by Division CC, section 111(a)(4) of the Consolidated Appropriations Act, 2021 (Pub. L. 116–120)), requires the Secretary to apply a process to validate SNF VBP program measures and data, as appropriate. We proposed to adopt a validation process for the Program beginning with the FY 2023 program year.

For the SNFRM, we proposed that the process we currently use to ensure the accuracy of the SNFRM satisfies this statutory requirement. Information reported through claims for the SNFRM are validated for accuracy by Medicare Administrative Contractors (MACs) to ensure accurate Medicare payments. MACs use software to determine whether billed services are medically necessary and should be covered by Medicare, review claims to identify any ambiguities or irregularities, and use a quality assurance process to help ensure quality and consistency in claim review and processing. They conduct pre-payment and post-payment audits of Medicare claims, using both random selection and targeted reviews based on analyses of claims data. We proposed to codify these proposals for the FY 2023 SNF VBP in our regulation text at § 413.338(j).

We are considering additional validation methods that may be appropriate to include in the future for the SNF HAI, DTC PAC SNF, and Total Nurse Staffing measures, as well as for other new measures we may consider for the program, and for other SNF quality measures and assessment data. In the FY 2023 SNF PPS proposed rule (87 FR 22788 through 22789), we requested public comment on potential future approaches for data validation in the Request for Information on the Validation of SNF Measures and Assessment Data.

[273] See Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) NQF #2510: All-Cause Risk-Standardized Readmission Measure Technical Report Supplement—2019 Update. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/Downloads/SNFRM-TechReportSupp-2019-.pdf.*

[274] See Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program Technical Report, available at: *https://www.cms.gov/files/document/snf-hai-technical-report.pdf-0.*

[275] See Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements (SPADEs), available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Final-Specifications-for-SNF-QRP-Quality-Measures-and-SPADEs.pdf.*

We invited public comment on our proposal to adopt a validation process for the SNF VBP Program beginning with the FY 2023 program year. We received the following comment and provide our response:

Comment: One commenter supported our proposed approach to SNFRM validation.

Response: We thank the commenter for their support.

After considering the public comment, we are finalizing our proposal to adopt a validation process for the SNF VBP Program beginning with the FY 2023 program year as proposed and codifying it at § 413.338(j) of our regulations.

G. SNF Value-Based Incentive Payments for FY 2023

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36616 through 36621) for discussion of the exchange function methodology that we have adopted for the Program, as well as the specific form of the exchange function (logistic, or S-shaped curve) that we finalized, and the payback percentage of 60 percent. We adopted these policies for FY 2019 and subsequent fiscal years.

We also discussed the process that we undertake for reducing SNFs' adjusted Federal per diem rates under the Medicare SNF PPS and awarding value-based incentive payments in the FY 2019 SNF PPS final rule (83 FR 39281 through 39282).

As discussed in the FY 2023 SNF PPS proposed rule, we proposed to suppress the SNFRM for the FY 2023 program year and assign all SNFs a performance score of zero, which will result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We also proposed that we will not rank SNFs for FY 2023. We also proposed to reduce each participating SNF's adjusted Federal per diem rate for FY 2023 by 2 percentage points and to award each participating SNF 60 percent of that 2 percent withhold, resulting in a 1.2 percent payback for the FY 2023 program year. We believe this continued application of the 2 percent withhold is required under section 1888(h)(5)(C)(ii)(III) of the Act and that a payback percentage that is spread evenly across all SNFs is the most equitable way to reduce the impact of the withhold considering our proposal to award a performance score of zero to all SNFs. We also proposed that those SNFs that do not meet the proposed case minimum for the SNFRM for FY 2023 will be excluded from the Program for FY 2023. We proposed to update § 413.338(i) to reflect that this special scoring and payment policy will apply for FY 2023 in addition to FY 2022. As noted in section VIII.B.1. of this final rule, our goal is to resume use of the scoring methodology we finalized for the program prior to the PHE beginning with the FY 2024 program year.

We invited public comment on this proposed change to the SNF VBP Program's payment policy for the FY 2023 program year. However, we did not receive any public comments on this policy. We are therefore finalizing our proposal to adopt a special payment policy for the FY 2023 program year and codifying it at § 413.338(i) of our regulations.

H. Public Reporting on the Provider Data Catalog Website

1. Background

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make SNFs' performance information on SNF VBP Program measures available to the public on the Nursing Home Compare website or a successor website, and to provide SNFs an opportunity to review and submit corrections to that information prior to its publication. We began publishing SNFs' performance information on the SNFRM in accordance with this directive and the statutory deadline of October 1, 2017. In December 2020, we retired the Nursing Home Compare website and are now using the Provider Data Catalog website (*https://data.cms.gov/provider-data/*) to make quality data available to the public, including SNF VBP performance information.

Additionally, section 1888(h)(9)(A) of the Act requires the Secretary to make available to the public certain information on SNFs' performance under the SNF VBP Program, including SNF performance scores and their ranking. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the Program, including the range of SNF performance scores and the number of SNFs receiving value-based incentive payments, and the range and total amount of those payments.

In the FY 2017 SNF PPS final rule (81 FR 52009), we discussed the statutory requirements governing public reporting of SNFs' performance information under the SNF VBP Program. In the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), we finalized our policy to publish SNF VBP Program performance information on the Nursing Home Compare or successor website after SNFs have had an opportunity to review and submit corrections to that information under the two-phase Review and Correction process that we adopted in the FY 2017 SNF PPS final rule (81 FR 52007 through 52009) and for which we adopted additional requirements in the FY 2018 SNF PPS final rule. In the FY 2018 SNF PPS final rule, we also adopted requirements to rank SNFs and adopted data elements that we will include in the ranking to provide consumers and interested parties with the necessary information to evaluate SNF's performance under the Program (82 FR 36623).

As discussed in section VIII.B.1. of this final rule, we are finalizing our proposal to suppress the SNFRM for the FY 2023 program year due to the impacts of the PHE for COVID–19. Under this finalized policy, for all SNFs participating in the FY 2023 SNF VBP Program, we will use the performance period (FY 2021, October 1, 2020 through September 30, 2021) we adopted in the FY 2021 SNF PPS final rule (85 FR 47624), as well as the previously finalized baseline period (FY 2019, October 1, 2018 through September 30, 2019) to calculate each SNF's RSRR for the SNFRM. We are also finalizing our proposal to assign all SNFs a performance score of zero. This will result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier.

While we will publicly report the SNFRM rates for the FY 2023 program year, we will make clear in the public presentation of those data that we are suppressing the use of those data for purposes of scoring and payment adjustments in the FY 2023 SNF VBP Program given the significant changes in SNF patient case volume and facility-level case-mix described earlier.

2. Changes to the Data Suppression Policy for Low-Volume SNFs Beginning With the FY 2023 SNF VBP Program Year

In the FY 2020 SNF PPS final rule (84 FR 38823 through 38824), we adopted a data suppression policy for low-volume SNF performance information. Specifically, we finalized that we will suppress the SNF performance information available to display as follows: (1) if a SNF has fewer than 25 eligible stays during the baseline period for a program year, we will not display the baseline risk-standardized readmission rate (RSRR) or improvement score, although we will still display the performance period RSRR, achievement score, and total performance score if the SNF had sufficient data during the performance period; (2) if a SNF has fewer than 25

eligible stays during the performance period for a program year and receives an assigned SNF performance score as a result, we will report the assigned SNF performance score and we will not display the performance period RSRR, the achievement score, or improvement score; and (3) if a SNF has zero eligible cases during the performance period for a program year, we will not display any information for that SNF. We codified this policy in the FY 2021 SNF PPS final rule (85 FR 47626) at § 413.338(e)(3)(i) through (iii).

As discussed in section VIII.B.1. of this final rule, we are finalizing our proposal to suppress the SNFRM for the FY 2023 program year, and we are finalizing a special scoring and payment policy for FY 2023. In addition, as discussed in section VIII.E.3.b. of this final rule, we are finalizing our proposal to adopt a new case minimum that will apply to the SNFRM beginning with FY 2023, new case minimums that will apply to the SNF HAI and Total Nurse Staffing measures and a measure minimum that will apply beginning with FY 2026, a new case minimum that will apply to the DTC PAC SNF measure and a new measure minimum that will apply beginning with FY 2027. As a result of these policies, and in order to implement them for purposes of clarity and transparency in our public reporting, we proposed revising the data suppression policy as follows:

(1) If a SNF does not have the minimum number of cases during the baseline period that applies to a measure for a program year, we would publicly report the SNF's measure rate and achievement score if the SNF had minimum number of cases for the measure during the performance period for the program year;

(2) If a SNF does not have the minimum number of cases during the performance period that applies to a measure for a program year, we would not publicly report any information on the SNF's performance on that measure for the program year;

(3) If a SNF does not have the minimum number of measures during the performance period for a program year, we would not publicly report any data for that SNF for the program year.

We proposed to codify this policy at § 413.338(f)(4).

We invited public comment on these proposals. However, we did not receive any public comments on this topic. We are therefore finalizing our proposal to revise our data suppression policy and codify those revisions at § 413.338(f)(4) of our regulations.

I. Requests for Comment Related to Future SNF VBP Program Expansion Policies

1. Requests for Comment on Additional SNF VBP Program Measure Considerations for Future Years

a. Request for Comment on Including a Staffing Turnover Measure in a Future SNF VBP Program Year

In the FY 2022 SNF PPS final rule (86 FR 42507 through 42511), we summarized feedback from interested parties on our RFI related to potential future measures for the SNF VBP Program, including a specific RFI on measures that focus on staffing turnover. Specifically, we noted that we have been developing measures of staff turnover with data that are required to be submitted under section 1128I(g)(4) of the Act, with the goal of making the information publicly available. We stated that, through our implementation of the PBJ staffing data collection program, we will be reporting rates of employee turnover in the future (for more information on this program, see CMS memorandum QSO–18–17–NH [276]). We refer readers to the FY 2022 SNF PPS final rule for additional details on this RFI and a summary of the public comments we received (86 FR 42507 through 42511).

Nursing staff turnover has long been identified as a meaningful factor in nursing home quality of care.[277] Studies have shown a relationship between staff turnover and quality outcomes; for example, higher staff turnover is associated with an increased likelihood of receiving an infection control citation.[278] The collection of auditable payroll-based daily staffing data through the PBJ system has provided an opportunity to calculate, compare, and publicly report turnover rates; examine facility characteristics associated with higher or lower turnover rates; and further measure the relationship between turnover and quality outcomes. For example, a recent study using PBJ data found that nursing staff turnover is higher than previously understood, variable across facilities, and correlated with organizational characteristics such as for-profit status, chain ownership, and higher Medicaid census.[279] In addition, we have found that higher overall star ratings are associated with lower average staff turnover rates, suggesting that lower staff turnover rates are associated with higher overall nursing home quality.[280]

In January of 2022, we began publicly reporting a staffing turnover measure on the Compare tool currently hosted by HHS, available at *https://www.medicare.gov/care-compare,* and this information will be included in the Nursing Home Five-Star Quality Rating System in July 2022. We refer readers to the Nursing Home Staff Turnover and Weekend Staffing Levels Memo for additional information related to this measure at *https://www.cms.gov/files/document/qso-22-08-nh.pdf.* We believe staffing turnover is an important indicator of quality of care provided in nursing homes and SNFs. Additionally, in response to our RFI on a staffing turnover measure, interested parties strongly recommended that we consider measures of staffing turnover to assess patterns and consistency in staffing levels. As a part of our goals to build a robust and comprehensive measure set for the SNF VBP Program and in alignment with recommendations from interested parties, we stated our intent to propose to adopt a staffing turnover measure in the SNF VBP Program in the FY 2024 SNF PPS proposed rule. Specifically, the measure we intend to include in the SNF VBP Program is the percent of total nurse staff that have left the facility over the last year. Total nurse staff include RNs, LPNs, and nurse aides. More information on this measure, can be found in the Five-Star Rating Technical Users' Guide at *https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/usersguide.pdf.*

The Biden-Harris Administration is committed to improving the quality of care in nursing homes. As stated in a fact sheet entitled ''Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes,'' we are committed to strengthening the SNF VBP Program and have begun to measure and publish staff turnover and weekend staffing levels, metrics which

[276] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-17-NH.pdf.*

[277] Centers for Medicare and Medicaid Services. 2001 Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II. Baltimore, MD: Centers for Medicare and Medicaid Services. *http://phinational.org/wp-content/uploads/legacy/clearinghouse/PhaseIIVolumeIofIII.pdf.*

[278] Lacey Loomer, David C. Grabowski, Ashvin Gandhi, Association between Nursing Home Staff Turnover and Infection Control Citations, SSRN Electronic Journal, 10.2139/ssrn.3766377, (2020). *https://onlinelibrary.wiley.com/doi/abs/10.1111/1475-6773.13877.*

[279] Gandhi, A., Yu, H., & Grabowski, D., ''High Nursing Staff Turnover in Nursing Homes Offers Important Quality Information'' (2021) Health Affairs, 40(3), 384–391. doi:10.1377/hlthaff.2020.00957. *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00957.*

[280] *https://www.cms.gov/files/document/qso-22-08-nh.pdf.*

closely align with the quality of care provided in a nursing home. We stated our intent to propose new measures based on staffing adequacy, the resident experience, as well as how well facilities retain staff. Accordingly, we seek commenters' feedback on including the staff turnover measure that captures the percent of total nurse staff that have left the facility over the last year for the SNF VBP Program as currently specified or whether the measure should be revised before being proposed for inclusion in the SNF VBP Program.

In addition, we are interested in whether we should explore the development of a composite measure that would capture multiple aspects of staffing, including both total nurse hours and the staff turnover measure rather than having separate but related measures related to nursing home staffing, such a measure could potentially replace the initial measure we intend to propose to include in SNF VBP for FY 2024. Preliminary analyses using the staff turnover data on the *Medicare.gov* Care Compare website have indicated that as the lower average staff turnover decreases, the overall star ratings for facilities increases, suggesting that lower turnover is associated with higher overall quality,[281] and research has indicated that staff turnover has been linked with increased infection control issues.[282] We believe it is important to capture and tie aspects of both staffing levels and staffing turnover to quality payment and welcome commenter's feedback for how to balance those goals under the SNF VBP Program. We are also interested to hear about actions SNFs may take or have taken to reduce staff turnover in their facilities, and for SNFs that did reduce staff turnover, the reduction's observed impact on quality of care. In particular, we are interested in best practices for maintaining continuity of staffing among both nursing and nurse aide staff. Finally, we are interested in commenters feedback on any considerations we should take into account related to the impact that including a Nursing Home Staff Turnover measure may have on health equity. Before proposing to include this measure in the SNF VBP Program in the FY 2024 SNF PPS proposed rule, we would include the measure on a list of measures under consideration, as described in section 1890A of the Act.

We welcomed public comment on the potential future adoption of a staffing turnover measure. The following is a summary of the public comments we received on this RFI.

Comment: Many commenters supported a staffing turnover measure in the SNF VBP Program, citing growing evidence that staffing turnover affects quality of care for residents. One commenter suggested that we consider using a turnover measure from the Five-Star rating system rather than developing a new measure and suggested that we limit the Program's incentive payments to those facilities that achieve the lowest turnover rates. One commenter stated that we should assess both total nurse staff turnover and RN staff turnover and suggested that only nurses providing direct care should be included in the measure. Another commenter suggested that the measure make a distinction between voluntary and involuntary turnover, such as termination of staff that do not meet expectations. The commenter also suggested examining facility turnover by characteristics such as size and ownership. Some commenters suggested that CMS focus more on staff retention rather than turnover. Some commenters stated that facilities able to achieve lower levels of staff turnover have higher overall star ratings and better performance on Medicare's claims-based quality measures. One commenter noted that successfully reducing turnover is important to implementation of minimum staffing standards.

Some commenters opposed a staffing turnover measure on the basis that facilities face challenges when mitigating turnover. Some commenters stated that facilities have trouble maintaining staff due to the COVID–19 pandemic. Additionally, one commenter stated that cases where agency staff work assignments or where specialized teams travel to multiple facilities should not be counted as turnover. Another commenter similarly stated that short-term agency staff should not be included in a measure of staffing turnover and suggested that extended leaves of absence should also be excluded. The commenter also suggested that the resulting turnover does not indicate low quality of care and that measuring staffing turnover would result in payment cuts to facilities that are already struggling with staffing costs. Another commenter stated that many factors outside of SNFs' control affect turnover. Another commenter stated that all health care providers are struggling with staffing and suggested that we limit the number of staffing agencies that contribute to the problem. Another commenter stated that not all turnover is detrimental and that it may be beneficial to dismiss staff that do not have the patience or disposition to work in a nursing facility. One commenter suggested that we add administrative and facility turnover to reduce management turnover, which the commenter believed contributes to lower quality of care.

Some commenters expressed concern that a staffing turnover measure could impact the financial situation of SNFs with higher minority populations, which they believed tend to have higher turnover rates. One commenter worried that a staffing turnover measure would cause SNFs to focus narrowly on staff retention rather than care quality. One commenter recommended against a composite measure, stating that separate measures will provide consumers with clearer information and allow more stratification by facility type, staff members, and resident characteristics. One commenter expressed concern that the resources necessary for measure validation for the Total Nurse Staffing measure may shift facilities' efforts to those reviews rather than beneficiary care. The commenter also stated that both PBJ and MDS data are already reviewed for accuracy during health inspections.

Response: We will take this feedback into consideration as we develop our policies for the FY 2024 SNF PPS proposed rule. In addition, as previously indicated, we have been posting measures of staff turnover since January 2022 and including SNF employee turnover information as part of the staffing domain of the Nursing Home Five Star Quality Rating System on the *Medicare.gov* Care Compare website since July 2022.

b. Request for Comment on Including the National Healthcare Safety Network (NHSN) COVID–19 Vaccination Coverage Among Healthcare Personnel Measure in a Future SNF VBP Program Year

In addition to the staffing turnover measure and the other potential future measures listed in the FY 2022 SNF PPS final rule, we are also considering the inclusion of the NHSN COVID–19 Vaccination Coverage among Healthcare Personnel measure, which measures the percentage of healthcare personnel who receive a complete COVID–19 vaccination course. This measure data is collected by the CDC NHSN and the measure was finalized for use in the SNF QRP in the FY 2022 SNF PPS final

[281] To Advance Information on Quality of Care, CMS Makes Nursing Home Staffing Data Available, available at: *https://www.cms.gov/newsroom/press-releases/advance-information-quality-care-cms-makes-nursing-home-staffing-data-available.*

[282] Lacey Loomer, David C. Grabowski, Ashvin Gandhi, Association between Nursing Home Staff Turnover and Infection Control Citations, SSRN Electronic Journal, 10.2139/ssrn.3766377, (2020). *https://onlinelibrary.wiley.com/doi/abs/10.1111/1475-6773.13877.*

rule (86 FR 42480 through 42489). We seek commenters' feedback on whether to propose to include this measure in a future SNF VBP program year. Before proposing to include any such measure, we would include the measure on a list of measures under consideration, as required by section 1890A of the Act.

We welcomed public comment on the potential future adoption of the NHSN COVID–19 Vaccination Coverage among Healthcare Personnel measure. The following is a summary of the public comments received on this RFI.

Comment: Some commenters supported a COVID–19 vaccination measure for healthcare personnel in the SNF VBP Program. One commenter stated that the measure is an important safety measure for beneficiaries and families. Another commenter suggested that the measure is best placed in the SNF QRP until long-term vaccination needs can be assessed.

Some commenters expressed concerns about a future COVID–19 vaccination measure for healthcare personnel in the SNF VBP Program. One commenter noted that the measure uses CDC processes and believed that may create interagency barriers and challenges. Another commenter stated that the measure specifications are likely to change as the definition of a completed COVID–19 vaccination course may change. One commenter stated that vaccination decisions are made by staffs' personal preferences, not the SNF. Another commenter noted that CMS already requires LTC facilities to report residents' and staffs' COVID–19 vaccination rates and suggested that such a measure in the SNF VBP Program would be duplicative. Another commenter stated that exemptions create variation in vaccination rates. One commenter stated that the measure is not a patient outcome measure and thus does not align with the Program's purpose.

Response: We will take this feedback into consideration as we develop our policies for future rulemaking.

2. Request for Comment on Updating the SNF VBP Program Exchange Function

In the FY 2018 SNF PPS final rule (82 FR 36616 through 36619), we adopted an exchange function methodology for translating SNFs' performance scores into value-based incentive payments. We illustrated four possibilities for the functional forms that we considered—linear, cube, cube root, and logistic—and discussed how we assessed how each of the four possible exchange function forms would affect SNFs' incentive payments under the Program. We also discussed several important factors that we considered when adopting an exchange function, including the numbers of SNFs that receive more in value-based incentive payments in each scenario compared to the number of SNFs for which a reduction is applied to their Medicare payments, as well as the resulting incentives for SNFs to reduce hospital readmissions. We also evaluated the distributions of value-based incentive payment adjustments and the functions' results for compliance with the Program's statutory requirements. We found that the logistic function maximized the number of SNFs with positive payment adjustments among SNFs measured using the SNFRM. We also found that the logistic function best fulfilled the requirement that SNFs in the lowest 40 percent of the Program's ranking receive a lower payment rate than would otherwise apply, resulted in an appropriate distribution of value-based incentive payment percentages, and otherwise fulfilled the Program's requirements specified in statute.

Additionally, we published a technical paper describing the analyses of the SNF VBP Program exchange function forms and payback percentages that informed the policies that we adopted in the FY 2018 SNF PPS final rule. The paper is available on our website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP-exchange-function-analysis.pdf.*

As discussed earlier, we proposed numerous policy changes to expand the SNF VBP Program's measure set based on authority provided by the Consolidated Appropriations Act, 2021, including additional quality measures and adjustments to the Program's scoring methodology to accommodate the presence of more than one quality measure. We are also considering whether we should propose a new form for the exchange function or modify the logistic exchange function in future years.

When we adopted the logistic function for the SNF VBP Program, we focused on that function's ability, coupled with the 60 percent payback percentage, to provide net-positive value-based incentive payments to as many top-performing SNFs as possible. We believed that structuring the Program's incentive payments in this manner enabled us to reward the Program's top-performing participants and provide significant incentives for SNFs that were not performing as well to improve over time.

We continue to believe that these considerations are important and that net-positive incentive payments help drive quality improvement in the SNF VBP Program. However, in the context of a value-based purchasing program employing multiple measures, we are considering whether a new functional form or modifications to the existing logistic exchange function may provide the best incentives to SNFs to improve on the Program's measures.

If finalized, the additional measures that we are proposing for the SNF VBP Program would align the Program more closely with the Hospital VBP Program, on which some of SNF VBP's policies, like the exchange function methodology, are based. The Hospital VBP Program employs a linear exchange function to translate its Total Performance Scores into value-based incentive payment percentages that can be applied to hospitals' Medicare claims. A linear exchange function is somewhat simpler for interested parties to understand but presents less of an opportunity to reward top performers than the logistic form that we currently employ in the SNF VBP Program at *https://data.cms.gov/provider-data/* or *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/SNF-VBP-Page.*

We requested feedback from interested parties on whether we should consider proposing either a new functional form or modified logistic exchange function for the SNF VBP Program. Specifically, we requested comments on whether the proposed addition of new quality measures in the Program should weigh in favor of a new exchange function form, a modified logistic exchange function, or no change to the existing exchange function, whether interested parties believe that the increased incentive payment percentages for top performers offered by the logistic function should outweigh the simplicity of the linear function, and whether we should further consider either the cube, cube root, or other functional forms.

We welcomed public comment on potential future updates to the Program exchange function. The following is a summary of the public comments we received on this RFI.

Comment: One commenter recommended providing more information to SNFs on how their value-based incentive payments would change with an updated exchange function. The commenter also noted that the current system may disadvantage smaller SNFs, as well as those that treat sicker patients and a higher proportion of dual-eligible

patients. The commenter requested that CMS explore how the SNF VBP Program could ensure more equitable opportunity for these SNFs to achieve a positive value-based incentive payment, including utilizing peer groups. One commenter recommended that any change to the exchange function should be consistent with the rationale used for adopting the logistic function. The commenter also recommended that all options be further evaluated to ensure a potential exchange function does not create incentives at the higher end of performance to deny needed care. One commenter stated that, based on quality measures' typical distribution in a bell curve, the Program's exchange function methodology prevents many facilities from reaching top performance. The commenter stated that every facility should have the opportunity to be a top performer if they meet measure requirements.

Response: We will take this feedback into consideration as we develop our policies for future rulemaking.

3. Request for Comment on the Validation of SNF Measures and Assessment Data

We have proposed to adopt measures for the SNF VBP Program that are calculated using data from a variety of sources, including Medicare FFS claims, the minimum data set (MDS), and the PBJ system, and we are seeking feedback on the adoption of additional validation procedures. In addition, section 1888(h)(12) of the Act requires the Secretary to apply a process to validate SNF VBP program measures, quality measure data, and assessment data as appropriate. MDS information is transmitted electronically by nursing homes to the national MDS database at CMS. The data set was updated in 2010 from MDS 2.0 to MDS 3.0 to address concerns about the quality and validity of the MDS 2.0 data. Final testing of MDS 3.0 showed strong results, with the updated database outperforming MDS 2.0 in terms of accuracy, validity for cognitive and mood items, and clinical relevance.[283] Research has also shown that MDS 3.0 discharge data match Medicare enrollment and hospitalization claims data with a high degree of accuracy.[284]

Although the MDS data sets are assessed for accuracy, as described above, we are interested in ensuring the validity of the data reported by skilled nursing facilities because use of this data would have payment implications under the SNF VBP Program. Accordingly, we requested feedback from interested parties on the feasibility and need to select SNFs for validation via a chart review to determine the accuracy of elements entered into MDS 3.0 and PBJ. Additionally, we requested feedback on data validation methods and procedures that could be utilized to ensure data element validity and accuracy.

We noted that other programs, including the Hospital IQR (85 FR 58946) and Hospital OQR programs (76 FR 74485), have developed validation processes for chart-abstracted measures and electronic clinical quality measures (eCQMs), data sources not utilized for the SNF VBP Program. However, there are other elements of existing programs' validation procedures that may be considered for a future SNF VBP Program validation effort. For example, we request feedback on the volume of facilities to select for validation under the SNF VBP Program. We estimate that 3,300 hospitals report data under the Hospital OQR (86 FR 63961) and Hospital IQR (86 FR 45508) Programs. We estimate that over 15,000 SNFs are eligible for the SNF VBP Program. The Hospital OQR Program randomly selects the majority of hospitals (450 hospitals) for validation and additionally select a subset of targeted hospitals (50 hospitals) (86 FR 63872). Under the Hospital IQR Program, 400 hospitals are selected randomly and up to 200 hospitals are targeted for chart-abstracted data validation and up to 200 hospitals are randomly selected for eCQM data validation (86 FR 45424). We sample approximately 10 records from 300 randomly selected facilities under the ESRD QIP Program (82 FR 50766).

We also requested feedback from interested parties on the use of both random and targeted selection of facilities for validation. The Hospital OQR program identifies hospitals for targeted validation based on whether they have previously failed validation or have reported an outlier value deviating markedly from the measure values for other hospitals (more than 3 standard deviations of the mean) (76 FR 74485). Validation targeting criteria utilized by the Hospital IQR Program include factors such as: (1) abnormal, conflicting or rapidly changing data patterns; (2) facilities which have joined the program within the previous 3 years, and which have not been previously validated or facilities which have not been randomly selected for validation in any of the previous 3 years; and (3) any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent (85 FR 58946).

Finally, we requested feedback from interested parties on the implementation timeline for additional SNF VBP Program validation processes, as well as validation processes for other quality measures and assessment data. We believe it may be feasible to implement additional validation procedures beginning with data from the FY 2026 program year, at the earliest. Additionally, we may consider the adoption of a pilot of additional data validation processes; such an approach would be consistent with the implementation of the ESRD QIP data validation procedures, which began with a pilot in CY 2014 (82 FR 50766).

We welcomed public comments on the data validation considerations for the SNF VBP Program discussed previously in this section. The following is a summary of the public comments we received on this RFI.

Comment: Some commenters supported adopting a chart review process for SNF VBP validation. One commenter specifically recommended that we assess how MDS coding is equated with medical review. Another commenter noted MDS reviews could be included in a SNF VBP validation program structured similarly to hospital validation processes. Another commenter recommended that we consider the burden placed on SNFs, particularly chart reviews, that may take staff away from patient care. One commenter recommended that we consider the HVBP Program's experience with validation. The commenter also urged us to involve patients and families when developing validation to ensure that results are meaningful to consumers. Another commenter recommended that we adopt a pilot validation program first. One commenter suggested that we adopt the same types of validation procedures for the DTC and HAI measures as we proposed for the SNFRM. Another commenter requested that we work with relevant interested parties to develop and make available evidence-based practices on validation processes. Another commenter requested that we confirm whether a multidisciplinary care team can participate in MDS completion. Some commenters stated that additional validation processes are unnecessary because measures or data

[283] RAND MDS 3.0 Final Study Report: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/MDS30FinalReport-Appendices.zip.*

[284] Rahman M., Tyler D., Acquah J.K., Lima J., Mor V.. Sensitivity and specificity of the Minimum Data Set 3.0 discharge data relative to Medicare claims. J Am Med Dir Assoc. 2014;15(11):819–824. doi:10.1016/j.jamda.2014.06.017: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4731611/.*

collection processes already include methods to ensure their accuracy.

One commenter supported additional validation of SNF VBP measures, including auditing measures based on MDS data. The commenter was concerned that facilities may report inaccurate or inflated MDS data to increase their Five-Star measure ratings. One commenter stated that MDS data have already been shown to be accurate. One commenter suggested that we consider a mix of random and targeted selection of providers in the validation process, and one commenter supported both random and targeted facility selection for validation. One commenter supported implementing a validation program beginning with FY 2026 data.

Response: We will take this feedback into consideration as we develop our policies for future rulemaking.

4. Request for Comment on a SNF VBP Program Approach To Measuring and Improving Health Equity

Significant and persistent inequities in healthcare outcomes exist in the U.S. Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; being a member of a religious minority; or being near or below the poverty level, is often associated with worse health outcomes.[285] [286] [287] [288] [289] [290] [291] [292] [293] In accordance with Executive Order 13985 of January 20, 2021 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, equity is defined as consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality (86 FR 7009). In February 2022, we further expanded on this definition by defining health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, sex, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive. Over the past decade we have enacted a suite of programs and policies aimed at reducing health care disparities including the CMS Mapping Medicare Disparities Tool,[294] the CMS Innovation Center's Accountable Health Communities Model,[295] the CMS Disparity Methods stratified reporting program,[296] and efforts to expand social risk factor data collection, such as the collection of Standardized Patient Assessment Data Elements in the post-acute care setting.[297]

As we continue to leverage our value-based purchasing programs to improve quality of care across settings, we are interested in exploring the role of health equity in creating better health outcomes for all populations in these programs. As the March 2020 ASPE Report to Congress on Social Risk Factors and Performance in Medicare's VBP Program notes, it is important to implement strategies that cut across all programs and health care settings to create aligned incentives that drive providers to improve health outcomes for all beneficiaries.[298] Therefore, in the proposed rule, we requested feedback from interested parties on guiding principles for a general framework that could be utilized across our quality programs to assess disparities in healthcare quality in a broader RFI in section VI.E. of the proposed rule. We refer readers to this RFI titled, ''Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—A Request for Information,'' which includes a complete discussion on the key considerations that we intend to consider when determining how to address healthcare disparities and advance health equity across all of our quality programs. Additionally, we are interested in feedback from interested parties on specific actions the SNF VBP Program can take to align with other value-based purchasing and quality programs to address healthcare disparities and advance health equity.

As we continue assessing the SNF VBP Program's policies in light of its operation and its expansion as directed by the CAA, we requested public comments on policy changes that we should consider on the topic of health equity. We specifically requested comments on whether we should consider incorporating adjustments into the SNF VBP Program to reflect the varied patient populations that SNFs serve around the country and tie health equity outcomes to SNF payments under the Program. These adjustments could occur at the measure level in forms such as stratification (for example, based on dual status or other metrics) or including measures of social determinants of health (SDOH). These adjustments could also be incorporated at the scoring or incentive payment level in forms such as modified benchmarks, points adjustments, or modified incentive payment multipliers (for example, peer comparison groups based on whether the facility includes a

[285] Joynt K.E., Orav E., Jha A.K. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[286] Lindenauer P.K., Lagu T., Rothberg M.B., et al. (2013). Income inequality and 30-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. *British Medical Journal,* 346.

[287] Trivedi A.N., Nsa W., Hausmann L.R.M., et al. (2014). Quality and equity of care in U.S. hospitals. *New England Journal of Medicine,* 371(24):2298–2308.

[288] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. *Health Affairs,* 40(2): 307–316.

[289] Rural Health Research Gateway. (2018). Rural communities: age, income, and health status. *Rural Health Research Recap. https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-incomehealth-status-recap.pdf.*

[290] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[291] *http://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[292] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians Health Psychol. 2016 Apr; 35(4): 351–355.

[293] Poteat T.C., Reisner S.L., Miller M., Wirtz A.L. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. *medRxiv.* 2020;2020.07.21. 20159327. doi:10.1101/2020.07.21.20159327.

[294] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[295] *https://innovation.cms.gov/innovation-models/ahcm.*

[296] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.*

[297] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/-IMPACT-Act-Standardized-Patient-Assessment-Data-Elements.*

[298] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. *https://aspe.hhs.gov/social-risk-factors-and-medicares-value-basedpurchasing-programs.*

high proportion of dual eligible beneficiaries or other metrics). We requested commenters' views on which of these adjustments, if any, would be most effective for the SNF VBP Program at accounting for any health equity issues that we may observe in the SNF population.

We welcomed public comment on potential approaches to measuring and improving health equity in the SNF VBP Program. The following is a summary of the public comments we received on this RFI.

Comment: Many commenters supported our commitment to health equity for SNF residents. Some commenters suggested that we examine factors that may lead to care inequities and suggested that we incorporated patient-reported outcomes and experiences in shaping our equity strategies. Another commenter suggested that we consider balancing short-stay and long-stay residents' needs when developing equity adjustments. Some commenters recommended that we report quality data stratified by race and ethnicity to assess health equity issues in the SNF sector. Another commenter suggested that we adopt a risk-adjustment or incentive payment policy for facilities that accept residents that other facilities will not. Another commenter recommended that we engage with interested parties throughout any health equity policy development so that facilities can implement proper data collection. One commenter recommended that we pair clinical data measures with social risk metrics to help providers deliver more comprehensive care. One commenter recommended against tying quality measures involving race and ethnicity to payment, stating that such policies may be unconstitutional and could lead to ineffective or biased clinical care. The commenter stated that categories such as dual eligibility status or social determinants of health would be better ways to stratify measures than racial or ethnic categories. One commenter supported measures emphasizing and incorporating social determinants of health but recommended delaying their implementation on the basis that additional administrative burden on providers is inappropriate at this time.

Response: We will take this feedback into consideration as we develop our policies for future rulemaking.

IX. Changes to the Requirements for the Director of Food and Nutrition Services and Physical Environment Requirements in Long-Term (LTC) Facilities and Summary of Public Comments and Responses to the Request for Information on Revising the Requirements for Long-Term Care Facilities To Establish Mandatory Minimum Staffing Levels

A. Changes to the Requirements for the Director of Food and Nutrition Services and Physical Environment Requirements in Long-Term (LTC) Facilities

On July 18, 2019, we published a proposed rule entitled, ''Requirements for Long-Term Care (LTC) Facilities: Provisions to Promote Efficiency and Transparency'' (84 FR 34737). In combination with our internal review of the existing regulations, we used feedback from interested parties to inform our policy decisions about the proposals we set forth. We specifically considered how each recommendation could potentially reduce burden or increase flexibility for providers without impinging on the health and safety of residents. In the proposed rule, we included a detailed discussion regarding interested parties' response to our solicitations for suggestions to reduce provider burden. In response to the proposed rule, we received a total of 1,503 public comments. In this final rule, we are finalizing two of the proposals, which we believe will have a significant impact on a facility's ability to recruit and retain qualified staff as well as, allowing older existing nursing homes to remain in compliance without having to completely rebuild their facility or have to use the Fire Safety Evaluation System (FSES). On July 14, 2022, we published a notice to extend the timeframe allowed to finalize the remaining proposals in the July 18, 2019 rule (87 FR 42137). We are continuing to evaluate those proposals and will issue an additional final rule if we choose to proceed with further rulemaking.

Responses to Public Comments and Provisions of the Final Rule

1. Food and Nutrition Services (§ 483.60)

Dietary standards for residents of LTC facilities are critical to both quality of care and quality of life. LTC interested parties have shared concerns regarding the current requirement that existing dietary staff include certified dietary managers or food service managers. Specifically, interested parties have concerns regarding the need for existing dietary staff, who are experienced in the duties of a dietary manager and currently operate in the position, to obtain new or additional training to become qualified under the current regulatory requirements. We believe that effective management and oversight of the food and nutrition service is critical to the safety and well-being of all residents of a nursing facility. Therefore, we continue to believe that it is important that there are standards for the individuals who will lead this service. However, to address concerns from interested parties we proposed to revise the standards at § 483.60(a)(2) to increase flexibility, while providing that the director of food and nutrition services is an individual who has the appropriate competencies and skills necessary to oversee the functions of the food and nutrition services. Specifically, we proposed to revise the standards at § 483.60(a)(2)(i) and (ii) to provide that at a minimum an individual designated as the director of food and nutrition services would have 2 or more years of experience in the position of a director of food and nutrition services, or have completed a minimum course of study in food safety that would include topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving. We are retaining the existing requirement at § 483.60(a)(2)(iii) which specifies that the director of food and nutrition services must receive frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional. We noted in the proposed rule that these revisions will maintain established standards for the director of food and nutrition services given the critical aspects of their job function, while addressing concerns related to costs associated with training existing staff and the potential need to hire new staff.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the proposal stating that the changes would increase flexibility for providers to be able to recruit and retain important staff members, and also allow experienced professionals to remain in their roles. Other commenters had significant concerns and stated that the proposed qualification requirements were insufficient since some knowledge necessary for the position could not be gained through experience alone. For example, commenters noted that the knowledge and expertise received during the Certified Dietary Manager

(CDM) certification required courses are not necessarily skills staff would learn from experience. These commenters encouraged CMS to retain the current requirements for the director of food and nutrition services.

Response: We appreciate the feedback and agree that increased flexibility for recruitment and staff retention is important. However, we also acknowledge that some knowledge obtained through education may not be easily gained through experience alone. We agree with the commenters that certain training/education should be required for anyone seeking to qualify as the director of food and nutrition services, including those experienced staff. Therefore, we are revising the proposal to allow a person who has 2 or more years of experience in the position *and* has completed a minimum course of study in food safety to meet the requirement by October 1, 2023, to qualify. These modifications to the requirements at § 483.60 will allow for more flexibility and will help providers with recruiting and retaining qualified staff, while also providing for an adequate minimum standard of education for the position. We believe that there are many paths to obtaining the knowledge and skills necessary to meet these requirements. Therefore, the experience qualifier is only one option for meeting the requirements for the director of food and nutrition services.

Therefore, the director of food and nutrition services must meet the following requirements, some of which remain unchanged from our current regulations:

- In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers (existing § 483.60(a)(2)(ii)); and
- Receive frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional (existing § 483.60(a)(2)(iii)).

In addition, the director will need to meet the conditions of one of the following five options, four of which are retained from the existing rule:

- Have 2 or more years of experience in the position of a director of food and nutrition services, *and* have completed a minimum course of study in food safety, by no later than 1 year following the effective date of this rule, that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, food purchasing/receiving, etc. (new § 483.60(a)(2)(i)(E)) (we note that this would essentially be the equivalent of a ServSafe Food Manager certification); or
- Be a certified dietary manager (existing § 483.60(a)(2)(i)(A)); or
- Be a certified food service manager (existing § 483.60(a)(2)(i)(B)); or
- Have similar national certification for food service management and safety from a national certifying body(existing § 483.60(a)(2)(i)(C)); or
- Have an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning (existing § 483.60(a)(2)(i)(D)).

We believe that maintaining qualified and trained food and nutrition personnel is critical to the health and safety of residents in LTC facilities. We note that issues with food and nutrition requirements are the 3rd most frequently cited deficiencies in LTC facilities. We believe that these requirements will help ensure resident safety while also allowing facilities the flexibility to staff according to their unique needs and resources.

Comment: Many commenters recommended this requirement be phased in over 3 years to allow providers and professionals the time they need to obtain the necessary certifications, which require 15 to 18 months and an investment of more than $2,000 for the course, textbooks, fees, and to sit for the exam.

Response: We do not agree that a phase-in is necessary. As discussed in detail in the previous response, we have revised the requirements to allow 1 year for an experienced director of food and nutrition services to obtain training necessary to qualify for the position. Experience plus a minimum course of study is one of five ways to qualify for the position of the director of food and nutrition services. Given the many options available to qualify as well as the importance of food and safety in nursing homes, we do not believe that a 3-year delay in implementing the requirements is necessary or in the best interest of resident health and safety. We believe that all required staff will be able to meet the requirements.

After consideration of public comments, we are finalizing our proposal with the following changes—

- We are withdrawing our proposal at § 483.60(a)(2) to replace the existing qualifications for the director of food and nutrition services with an experience qualification and minimum course of study exclusively.
- We are revising § 483.60(a)(2)(i), to add experience in the position as one of the ways to qualify for the position of the director of food and nutrition services. Specifically, an individual who, on the effective date of this final rule, has 2 or more years of experience in the position of director of food and nutrition services in a nursing facility setting and has completed a course of study in food safety and management by no later than October 1, 2023, along with the other requirements set out at § 483.60(a)(2), is qualified to be the director of food and nutrition services.

2. Physical Environment (§ 483.90)

a. Life Safety Code

On May 4, 2016, we published a final rule entitled, ''Medicare and Medicaid; Fire Safety Requirements for Certain Health Care Facilities,'' adopting the 2012 edition of the National Fire Protection Association (NFPA) 101 (81 FR 26871), also known as the Life Safety Code (LSC). One of the references in the LSC is NFPA 101A, Guide on Alternative Approaches to Life Safety, also known as the Fire Safety Evaluation System (FSES). The FSES was developed as a means of achieving and documenting an equivalent level of life safety without requiring literal compliance with the Life Safety Code. The FSES is a point score system which establishes the general overall level of fire safety for health care facilities as compared to explicit conformance to individual requirements outlined in the Life Safety Code. The system uses combinations of widely accepted fire safety systems and arrangements to provide a level of fire safety which has been judged to be at least equivalent to the level achieved through strict compliance with the Life Safety Code. Some LTC facilities that utilized the FSES in order to determine compliance with the containment, extinguishment and people movement requirements of the LSC were no longer able to achieve a passing score, on the FSES, because of a change in scoring.

To address this need, in the July 2019 rule, we proposed to allow those existing LTC facilities (those that were Medicare or Medicaid certified before July 5, 2016) that have previously used the FSES to determine equivalent fire protection levels, to use an alternate scoring methodology to meet the requirements. Specifically, we proposed to have facilities use the mandatory values provided in the proposed regulations text at § 483.90(a)(1)(iii) when determining compliance for containment, extinguishment and people movement requirements. In the proposed rule, we noted that allowing the use of the provided mandatory scoring values will continue to provide the same amount of safety for residents

and staff as has been provided since we began utilizing the score values set out in the FSES. We also indicated that the proposed values would allow existing LTC facilities that previously met the FSES requirements to continue to do so without incurring great expense to change their construction types. We proposed to use the mandatory scoring values as shown in Table 18.

TABLE 18: Final Mandatory Values—Nursing Homes

	Containment (Sa)		Extinguishment (Sb)		People Movement (Sc)	
Zone Location	New	Exist.	New	Exist.	New	Exist.
1st story	11	5	**15(12)***	4	**8(5)***	1
2nd or 3rd story	15	9	**17(14)***	6	**10(7)***	3
4th story or higher	18	9	**19(16)***	6	**11(8)***	3

* Use ( ) in zones that do not contain patient sleeping rooms.

We proposed to include Table 18 at § 483.90(a)(1)(iii).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed changes to allow LTC facilities to use the provided mandatory values found at § 483.90(a)(1)(iii) when determining compliance for containment, extinguishment and people movement requirements, especially the LTC facilities that are currently affected by this issue. Commenters stated that using the 2013 NFPA 101A (FSES) values create substantial and unnecessary hardships for providers, residents and staff. Since the adoption of the 2013 NFPA 101A several nursing homes have struggled to remain in compliance, and using the provided mandatory values is a much-needed change. Many facilities stated that they meet the 2001 FSES, but the 2013 FSES would require retrofitting and essentially put them out of business due to financial hardship. Using the FSES mandatory values would allow existing facilities that previously met the FSES requirements to continue to do so without incurring great expense to change construction type that will not substantially improve the safety of residents.

Response: We agree that using the proposed mandatory values at § 483.90(a)(1)(iii) would allow existing facilities to continue to operate without incurring additional expenses that might otherwise be necessary to achieve compliance. All of the affected facilities are completely sprinklered and would not be lowering their safety standards at all. We agree that using the mandatory values set forth in the chart at § 483.90(a)(1)(iii) would allow us to resolve the scoring issue immediately for the affected providers. Therefore, this fix will remain in place until CMS adopts a newer version of the LSC.

Comment: One commenter stated that revisions to the construction limits for existing nursing homes were proposed for the 2021 edition of NFPA 101 based on input from the long-term care industry and believe that the effectiveness and dependability of automatic sprinkler systems could allow facilities to continue to operate. The commenter stated that existing facilities installed automatic sprinklers in good faith to compensate for construction deficiencies and demonstrate equivalency via NFPA 101A–2001 prior to the adoption of the 2012 edition of the NFPA 101. The commenters stated that since facilities would be in compliance with the revised construction requirements of the 2021 edition of the NFPA 101, equivalency would not need to be demonstrated via an FSES. The commenter suggested that we not finalize this proposal, and instead institute a categorical waiver process for the affected facilities until CMS incorporated by reference the standards of the 2021 edition of the NFPA 101.

Response: We are aware that revisions to the NFPA 101 were finalized and issued August 11, 2021. We will need to go through notice and comment rulemaking in order to adopt the 2021 edition or a newer edition of the LSC, which could take up to 3 additional years. Using the values found in the chart at § 483.90(a)(1)(iii) will allow us to address the problem immediately and will remain in place until we adopt a newer version of the LSC.

Comment: Many commenters agreed that the FSES chart resulting from adoption of the 2012 Life Safety Code has created a huge unanticipated negative effect on certain types of existing building construction, which may result in such buildings being forced to relocate residents and close within the next 2 years without any reduction in the overall fire safety features such as smoke detectors, sprinklers, fire alarm systems and building construction. Modifying the FSES mandatory scoring values as proposed by CMS solves this problem.

Response: We do not want any facilities to potentially have to close or completely reconstruct their building because of the scoring system for the FSES. LTC facilities are currently required to meet the required health and safety standards based on the 2012 edition of the LSC and Health Care Facilities Code (NFPA 99). By using the FSES these facilities can demonstrate that although they may not meet a certain requirement such as the construction type for the current LSC requirements, they are able to demonstrate that they have other measures in place to provide the same or higher level of safety for residents and staff. We also know that all LTC facilities are fully sprinklered, which helps them maintain this higher level of safety. We are finalizing this provision as proposed to avoid any facility closures or displacement for residents and to avoid significant facility expenditures that may not be necessary.

After consideration of public comments, we are finalizing our proposed changes without modifications.

B. Summary of Public Comments and Responses to the Request for Information on Revising the Requirements for Long-Term Care Facilities To Establish Mandatory Minimum Staffing Levels

The COVID–19 Public Health Emergency has highlighted and exacerbated longstanding concerns with inadequate staffing in long-term care (LTC) facilities. The Biden-Harris Administration is committed to improving the quality of U.S. nursing

homes so that seniors and others living in nursing homes get the reliable, high-quality care they deserve. As a result, we intend to propose in future rulemaking the minimum standards for staffing adequacy that nursing homes would be required to meet. We will conduct a new research study to help inform policy decisions related to determining the level and type of staffing needed to ensure safe and quality care and expect to issue proposed rules within one year. In the Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2023; Request for Information on Revising the Requirements for Long-Term Care Facilities To Establish Mandatory Minimum Staffing Levels proposed rule (87 FR 22720), we solicited public comments on opportunities to improve our health and safety standards to promote thoughtful, informed staffing plans and decisions within LTC facilities that aim to meet resident needs, including maintaining or improving resident function and quality of life. We stated that such an approach is essential to effective person-centered care and that we are considering policy options for future rulemaking to establish specific minimum direct care staffing standards and are seeking stakeholder input to inform our policy decisions.

Specifically, we solicited stakeholder input on options for future rulemaking regarding adequate staffing levels and we asked questions that we should consider as we evaluate future policy options (87 FR 22794 through 22795).

Comment: We received 3,129 comments from a variety of interested parties involved in long-term care issues, including advocacy groups, long-term care ombudsmen, industry associations (providers), labor unions and organizations, nursing home staff and administrators, industry experts and other researchers, family members and caretakers of nursing home residents. Overall, commenters were generally supportive of establishing a minimum staffing requirement, whereas other commenters were opposed. Commenters supporting the establishment of a minimum staffing requirement voiced safety concerns regarding residents not receiving adequate care due to chronic understaffing in facilities. Commenters offered examples of residents going entire shifts without receiving toileting assistance, which can lead to an increase in falls or presence of pressure ulcers. Other commenters shared stories of residents wearing the same outfit for a week without a change of clothing or a shower. These commenters highlighted the contributions of facility staff and greatly attributed these incidences and lack of quality care to insufficient staffing levels. Commenters offered recommendations for implementing minimum staffing requirements, with some commenters suggesting that CMS focus on implementing an acuity staffing model per shift instead of a minimum staffing requirement, while others recommended that minimum staffing levels be established for residents with the lowest care needs, assessed using the MDS 3.0 assessment forms, citing concerns that acuity-based minimums will be more susceptible to gaming. Commenters also provided information on several resident and facility factors for consideration when assessing a facility's ability to meet any mandated staffing standard, including whether or not the facility may have a higher Medicaid census, larger bed size, for profit ownership, higher county SNF competition, and, for staffing RNs specifically, higher community poverty and lower Medicare census. Other commenters stated that resident acuity should be a primary determinant in establishing minimum staffing standards, noting that CMS pays nursing homes based on resident acuity level.

We also received comments on factors impacting facilities' ability to recruit and retain staff, with most commenters in support of creating avenues for competitive wages for nursing home staff to address issues of recruitment and retention and other commenters suggesting that skilled nursing facility payments are continuing to be cut, complicating facilities ability to increase staff wages and benefits.

Finally, we received comments on the cost impacts of establishing staffing standards, payment, and study design. Some commenters pointed to the variability of Medicaid labor reimbursement amounts and how many States' Medicaid rates do not keep pace with rising labor costs while others noted that evidence shows most facilities have adequate resources to increase their staffing levels without additional Medicaid resources and pointed to a recent study documenting that most major publicly traded nursing home companies were highly profitable, even during the COVID pandemic. Commenters provided robust feedback on the action design and method for implementing a nurse staffing requirement, with some noting that resident acuity could change on a daily basis and recommended that CMS establish benchmarks rather than absolute values in staffing requirements. Other commenters recommended using both minimum nursing hours per resident day (hprd) and nurse to resident ratios.

Response: We appreciate the robust response we received on this RFI. As noted, staff levels in nursing homes have a substantial impact on the quality of care and outcomes residents experience. The input received will be used in conjunction with a new research study being conducted by CMS to determine the level and type of nursing home staffing needed to ensure safe and quality care. CMS intends to issue proposed rules on a minimum staffing level measure within one year. We will consider the feedback that we have received on this RFI for the upcoming rulemaking and changes to the LTC facility requirements for participation. This feedback from a wide range of interested parties will help to establish minimum staffing requirements that ensure all residents are provided safe, quality care, and that workers have the support they need to provide high-quality care.

X. Collection of Information Requirements

As explained below, this final rule will not impose any new or revised ''collection of information'' requirements or burden. Consequently, this final rule is not subject to the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). For the purpose of this section, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

With regard to the SNF QRP, in section VI.C.1. of this final rule, we are finalizing our proposal that SNFs submit data on the Influenza Vaccination Coverage among HCP measure beginning with the FY 2024 SNF QRP. We noted in the proposed rule that the CDC has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act (NCVIA) (Pub. L. 99–660, enacted November 14, 1986).[299] Since the burden is exempt from the requirements of the PRA, we set out such burden under the economic analysis section (see section X.A.5.) of the proposed rule. While the waiver is specific to the

[299] Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S.C., but can be found in a note at 42 U.S.C. 300aa–1.

PRA's requirements (''Chapter 35 of Title 44, United States Code''), our economic analysis requirements are not waived by any such statutes. We refer readers to section X.A.5. of the proposed rule, where we provided an estimate of the burden to SNFs.

In section VI.C.2. of this final rule, we are finalizing our proposal to revise the compliance date for certain SNF QRP reporting requirements including the Transfer of Health information measures and certain standardized patient assessment data elements (including race, ethnicity, preferred language, need for interpreter, health literacy, and social isolation). The finalized change in compliance date will have no impact on any requirements or burden estimates; both proposals are active and accounted for under OMB control number 0938–1140 (CMS–10387). Consequently, we did not finalize any changes under that control number.

In section VI.C.3. of this final rule, we are finalizing our proposed revisions to the regulatory text. The finalized revisions will have no collection of information implications.

With regard to the SNF VBP Program, in section VIII.B.1.b. of this final rule, we are finalizing our proposal to suppress the SNFRM for scoring and payment purposes for the FY 2023 SNF VBP program year. This measure is calculated using Medicare FFS claims data, and our suppression of data on this measure for the FY 2023 program year will not create any new reporting burden for SNFs. We will publicly report the SNFRM rates for the FY 2023 program year, and we will make clear in the public presentation of those data that we are suppressing the use of those data for purposes of scoring and payment adjustments in the FY 2023 SNF VBP Program given the significant changes in SNF patient case volume and facility-level case mix, as described in section VIII.H.1. of this final rule. In sections VIII.B.3.b. and VIII.B.3.c. of this final rule, we are finalizing the adoption of two additional measures (the SNF Healthcare-Associated Infections (HAI) Requiring Hospitalization and the Total Nursing Hours per Resident Day/Payroll-Based Journal (Total Nurse Staffing) measures) beginning with the FY 2026 Program. The SNF HAI measure is calculated using Medicare FFS claims data, therefore, this measure will not create any new reporting burden for SNFs. The Total Nurse Staffing measure is calculated using data that SNFs currently report to CMS under the Nursing Home Five-Star Quality Rating System, and therefore, this will not create new reporting burden for SNFs.

In section VIII.B.3.d. of this final rule, we are finalizing the adoption of the DTC PAC Measure for SNFs beginning with the FY 2027 Program. The DTC PAC SNF measure is calculated using Medicare FFS claims data; therefore, this measure will not create a new reporting burden for SNFs.

The aforementioned FFS-related claims submission requirements and burden are active and approved by OMB under control number 0938–1140 (CMS–10387). This rule's changes will have no impact on the requirements and burden that are currently approved under that control number.

XI. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

a. Statutory Provisions

This final rule updates the FY 2023 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted Federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. These are statutory provisions that prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, and we do not have the discretion to adopt an alternative approach on these issues.

With respect to the SNF QRP, this final rule updates the FY 2024 SNF QRP requirements. Section 1888(e)(6) of the Act authorizes the SNF QRP and applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-critical access hospital (CAH) swing-bed rural hospitals. We finalize one new measure which we believe will encourage healthcare personnel to receive the influenza vaccine, resulting in fewer cases, less hospitalizations, and lower mortality associated with the virus. We finalize a revision to the compliance date for certain SNF QRP reporting requirements to improve data collection to allow for better measurement and reporting on equity across post-acute care programs and policies. For consistency in our regulations, we are also finalizing conforming revisions to the Requirements under the SNF QRP at § 413.360.

With respect to the SNF VBP Program, this final rule updates SNF VBP Program requirements for FY 2023 and subsequent years, including a policy to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for the FY 2023 SNF VBP Program Year for scoring and payment adjustment purposes. In addition, section 1888(h)(3) of the Act requires the Secretary to establish and announce performance standards for SNF VBP Program measures no later than 60 days before the performance period, and this final rule finalizes numerical values of the performance standards for the all-cause, all-condition hospital readmission measure. Section 1888(h)(2)(A)(ii) of the Act (as amended by section 111(a)(2)(C) of the Consolidated Appropriations Act, 2021 (Pub. L. 116–120)) allows the Secretary to add up to nine new measures to the SNF VBP Program, and in this final rule we are also adding two new measures to the SNF VBP Program beginning with the FY 2026 SNF VBP program year and one new measure beginning with the FY 2027 program year and finalizing several updates to the scoring methodology beginning with the FY 2026 program year. We have updated regulations at § 413.338 in accordance with these updates.

With respect to LTC physical environment changes and the changes to the requirements for the Director of Food and Nutrition Services in LTC facilities, sections 1819 and 1919 of the Act, authorize the Secretary to issue requirements for participation in Medicare and Medicaid, including such regulations as may be necessary to protect the health and safety of residents (sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act). Such regulations are codified in the implementing regulations at 42 CFR part 483, subpart B.

b. Discretionary Provisions

In addition, this final rule includes the following discretionary provisions:

(1) Recalibrating the Patient Driven Payment Model (PDPM) Parity Adjustment

As a policy decision to ensure on-going budget neutral implementation of the new case mix system, the PDPM, we proposed a recalibration of the PDPM parity adjustment. Since October 1, 2019, we have been monitoring the implementation of PDPM and our analysis of FY 2020 and FY 2021 data reveals that the PDPM implementation led to an increase in Medicare Part A SNF spending, even after accounting for the effects of the COVID–19 PHE. We noted that recalibrating the PDPM parity adjustment and reducing SNF spending by 4.6 percent, or $1.7 billion, in FY 2023 with no delayed implementation

or phase-in period would allow for the most rapid establishment of payments at the appropriate level. This would work to ensure that PDPM will be budget-neutral as intended and prevent continuing accumulation of excess SNF payments, which we cannot recoup. However, while we received few comments on the methodology used to calculate the PDPM parity adjustment, we received a significant number of comments recommending that CMS use a phased approach in implementing the recalibration of the parity adjustment. These comments, and our responses, are discussed in section VI.C of this final rule. Considering these comments, in this final rule, we are finalizing the proposed recalibration of the PDPM parity adjustment with a 2-year phase-in, resulting in a reduction in FY 2023 of 2.3 percent, or $780 million, and a reduction in FY 2024 of 2.3 percent.

(2) SNF Forecast Error Adjustment

Each year, we evaluate the market basket forecast error for the most recent year for which historical data is available. The forecast error is determined by comparing the projected market basket increase in a given year with the actual market basket increase in that year. In evaluating the data for FY 2021, we found that the forecast error for FY 2021 was 1.5 percentage point, exceeding the 0.5 percentage point threshold we established in regulation for proposing adjustments to correct for forecast error. Given that the forecast error exceeds the 0.5 percentage threshold, current regulations require that the SNF market basket percentage change for FY 2023 be increased by 1.5 percentage point.

(3) Proposed Permanent Cap on Wage Index Decreases

The Secretary has broad authority to establish appropriate payment adjustments under the SNF PPS, including the wage index adjustment. As discussed earlier in this section, the SNF PPS regulations require us to use an appropriate wage index based on the best available data. For the reasons discussed earlier in this section, we believe that a 5-percent cap on wage index decreases would be appropriate for the SNF PPS. Therefore, for FY 2023 and subsequent years, we proposed to apply a permanent 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. In this final rule, we are finalizing this proposed cap, as proposed.

(4) Technical Updates to ICD–10 Mappings

Each year, the ICD–10 Coordination and Maintenance Committee, a Federal interdepartmental committee that is chaired by representatives from the National Center for Health Statistics (NCHS) and by representatives from CMS, meets biannually and publishes updates to the ICD–10 medical code data sets in June of each year. These changes become effective October 1 of the year in which these updates are issued by the committee. The ICD–10 Coordination and Maintenance Committee also has the ability to make changes to the ICD–10 medical code data sets effective on April 1 of each year. In the proposed rule, we proposed several changes to the ICD–10 code mappings and lists. In this final rule, we are finalizing these proposed changes to the PDPM ICD–10 mappings, as proposed.

2. Introduction

We have examined the impacts of this final 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 Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below.

3. Overall Impacts

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2022 (86 FR 42424). We estimated in the proposed rule that the aggregate impact would be a decrease of approximately $320 million (0.9 percent) in Part A payments to SNFs in FY 2023. This reflected a $1.4 billion (3.9 percent) increase from the proposed update to the payment rates and a $1.7 billion (4.6 percent) decrease from the proposed reduction to the SNF payment rates to account for the recalibrated parity adjustment. We noted in the proposed rule that these impact numbers do not incorporate the SNF VBP Program reductions that we estimated would total $185.55 million in FY 2023. We noted in the proposed rule that events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to events that may occur within the assessed impact time period.

For this final rule, as noted in section IV.B. of this final rule, we have updated the productivity-adjusted market basket increase factor for FY 2023 based on a more recent forecast. Additionally, as discussed in section VI.C of this final rule, we are finalizing a 2-year phase-in for recalibrating the PDPM parity adjustment. As a result, we estimate that the aggregate impact of the provisions in this final rule will result in an estimated net increase in SNF payments of 2.7 percent, or $904 million, for FY 2023. This reflects a 5.1 percent increase from the final update to the payment rates and a 2.3 percent decrease from the reduction to the SNF payment rates to account for the recalibrated parity adjustment, using the formula to multiply the percentage change described in section X.A.4. of this final rule.

In accordance with sections 1888(e)(4)(E) and (e)(5) of the Act and implementing regulations at § 413.337(d), we are updating the FY 2022 payment rates by a factor equal to the market basket index percentage change increased by the forecast error adjustment and reduced by the productivity adjustment to determine the payment rates for FY 2023. The impact to Medicare is included in the total column of Table 19. When we proposed the SNF PPS rates for FY 2023, we proposed a number of standard annual revisions and clarifications as mentioned in the proposed rule.

The annual update in this rule applies to SNF PPS payments in FY 2023. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish

a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2023 SNF PPS payment impacts appear in Table 19. Using the most recently available data, in this case FY 2021 we apply the current FY 2022 CMIs, wage index and labor-related share value to the number of payment days to simulate FY 2022 payments. Then, using the same FY 2021 data, we apply the FY 2023 CMIs, wage index and labor-related share value to simulate FY 2023 payments. We noted in the proposed rule that, given that this same data is being used for both parts of this calculation, as compared to other analyses discussed in the proposed rule which compare data from FY 2020 to data from other fiscal years, any issues discussed throughout this rule with regard to data collected in FY 2020 will not cause any difference in this economic analysis. We tabulate the resulting payments according to the classifications in Table 19 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2022 payments to the simulated FY 2023 payments to determine the overall impact. The breakdown of the various categories of data in Table 19 is as follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various proposed changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the proposed parity adjustment recalibration discussed in section V.C. of this final rule.
- The fourth column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available as well as accounts for the 5 percent cap on wage index transitions, discussed in section VI.A. of this final rule. The total impact of this change is 0.0 percent; however, there are distributional effects of the proposed change.
- The fifth column shows the effect of all of the changes on the FY 2023 payments. The update of 5.1 percent is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments would increase by 5.1 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 19, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this final rule, rural providers would experience a 2.5 percent increase in FY 2023 total payments.

In this chart and throughout the rule, we use a multiplicative formula to derive total percentage change. This formula is:

(1 + Parity Adjustment Percentage) * (1 + Wage Index Update Percentage) * (1 + Payment Rate Update Percentage) − 1 = Total Percentage Change

For example, the figures shown in Column 5 of Table 19 are calculated by multiplying the percentage changes using this formula. Thus, the Total Change figure for the Total Group Category is 2.7 percent, which is (1 − 2.3%) * (1 + 0.0%) * (1 + 5.1%) − 1.

As a result of rounding and the use of this multiplicative formula based on percentage, derived dollar estimates may not sum.

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TABLE 19: Impact to the SNF PPS for FY 2023

Impact Categories	Number of Facilities	Parity Adjustment Recalibration	Update Wage Data	Total Change
Group				
Total	15,541	-2.3%	0.0%	2.7%
Urban	11,216	-2.3%	0.0%	2.7%
Rural	4,325	-2.2%	-0.3%	2.5%
Hospital-based urban	378	-2.3%	0.3%	3.0%
Freestanding urban	10,847	-2.3%	0.0%	2.7%
Hospital-based rural	410	-2.2%	-0.5%	2.3%
Freestanding rural	3,906	-2.2%	-0.3%	2.5%
Urban by region				
New England	753	-2.3%	-0.7%	2.0%
Middle Atlantic	1,492	-2.4%	0.3%	2.9%
South Atlantic	1,948	-2.3%	-0.4%	2.3%
East North Central	2,155	-2.3%	-0.3%	2.4%
East South Central	556	-2.2%	-0.4%	2.3%
West North Central	957	-2.3%	-0.5%	2.2%
West South Central	1,413	-2.3%	0.3%	3.1%
Mountain	552	-2.3%	-0.1%	2.5%
Pacific	1,393	-2.4%	1.0%	3.6%
Outlying	6	-2.0%	-1.5%	1.4%
Rural by region				
New England	115	-2.3%	0.3%	3.0%
Middle Atlantic	210	-2.2%	-0.5%	2.2%
South Atlantic	499	-2.2%	-0.2%	2.6%
East North Central	935	-2.2%	-0.9%	1.8%
East South Central	489	-2.2%	-0.3%	2.5%
West North Central	1,038	-2.2%	0.0%	2.7%
West South Central	723	-2.2%	0.6%	3.4%
Mountain	211	-2.3%	-0.3%	2.4%
Pacific	95	-2.4%	-1.0%	1.6%
Outlying	1	-2.3%	0.0%	2.7%
Ownership				
For profit	10,901	-2.3%	0.1%	2.7%
Non-profit	3,638	-2.3%	-0.2%	2.5%
Government	1,002	-2.3%	-0.1%	2.6%

Note: The Total column includes the FY 2023 5.1 percent market basket update factor. The values presented in this table may not sum due to rounding.

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5. Impacts for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) for FY 2023

Estimated impacts for the SNF QRP are based on analysis discussed in section IX.B. of the proposed rule.

In accordance with section 1888(e)(6)(A)(i) of the Act, the Secretary must reduce by 2 percentage points the annual payment update applicable to a SNF for a fiscal year if the SNF does not comply with the requirements of the SNF QRP for that fiscal year. In section VI.A. of the proposed rule, we discussed the method for applying the 2-percentage point reduction to SNFs that fail to meet the SNF QRP requirements.

As discussed in section VI.C.1. of the proposed rule, we proposed the adoption of one new measure to the SNF QRP beginning with the FY 2024 SNF QRP, the Influenza Vaccination Coverage among HCP (NQF #0431) measure. We believe that the burden associated with the SNF QRP is the time and effort associated with complying with the non-claims-based measures requirements of the SNF QRP. Although the burden associated with the Influenza Vaccination Coverage among HCP (NQF #0431) measure is not accounted for under the Centers for Diseases Control and Prevention Paperwork Reduction Act (CDC PRA) package due to the NCVIA waiver discussed in section IX. of this final rule, the cost and burden are discussed here.

Consistent with the CDC's experience of collecting data using the NHSN, we estimated that it would take each SNF an average of 15 minutes per year to collect data for the Influenza Vaccination Coverage among HCP (NQF #0431) measure and enter it into NHSN. We did not estimate that it will take SNFs additional time to input their data into NHSN, once they have logged onto the system for the purpose of submitting their monthly COVID–19 vaccine report. We believe it would take an administrative assistant 15 minutes to enter this data into NHSN. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and

Wage Estimates.[300] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 20.

TABLE 20: U.S. Bureau of Labor and Statistics' May 2020 National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Administrative Assistant	43-6013	$18.75	$18.75	$37.50

Based on this time range, it would cost each SNF an average cost of $9.38 each year. We believe the data submission for the Influenza Vaccination Coverage among HCP (NQF #0431) measure would cause SNFs to incur additional average burden of 15 minutes per year for each SNF and a total annual burden of 3,868 hours across all SNFs. The estimated annual cost across all 15,472 SNFs in the U.S. for the submission of the Influenza Vaccination Coverage among HCP (NQF #0431) measure would be an average of $145,127.36.

As discussed in section VII.C.2. of the proposed rule, we proposed that SNFs would begin collecting data on two quality measures and certain standardized patient assessment data elements beginning with discharges on October 1, 2023. CMS estimated the impacts for collecting the new data elements in the FY 2020 SNF PPS final rule (84 FR 38829). When we delayed the compliance date for certain reporting requirements under the SNF QRP in the May 8th COVID–19 IFC, we did not remove the impacts for the new reporting requirements. However, we are providing updated impact information.

For these two quality measures, we are adding 4 data elements on discharge which would require an additional 1.2 minutes of nursing staff time per discharge. We estimate these data elements for these quality measures would be completed by registered nurses (25 percent of the time or 0.30 minutes) and by licensed practical and vocational nurses (75 percent of the time or 0.90 minutes). For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates.[301] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 21.

TABLE 21: U.S. Bureau of Labor and Statistics' May 2020 National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse	29-1141	$38.47	$38.47	$76.94
Licensed Vocational Nurse (LVN)	29-2061	$24.08	$24.08	$48.16

With 2,406,401 discharges from 15,472 SNFs annually, we estimate an annual burden of 48,128 additional hours (2,406,401 discharges × 1.2 min/60) at a cost of $2,664,127 (2,406,401 × [(0.30/60 × $76.94/hr) + (0.90/60 × $48.16/hr)]). For each SNF we estimate an annual burden of 3.11 hours (48,128 hr/15,472 SNFs) at a cost of $172.19 ($2,664,127/15,472 SNFs).

We also proposed SNFs would begin collecting data on certain standardized patient assessment data elements, beginning with admissions and discharges (except for the preferred language, need for interpreter services, hearing, vision, race, and ethnicity standardized patient assessment data elements, which would be collected at admission only) on October 1, 2023. If finalized as proposed, SNFs would use the MDS 3.0 V1.18.11 to submit SNF QRP data. We are finalizing requirements to collect 55.5 standardized patient assessment data elements consisting of 8 data elements on admission and 47.5 data elements on discharge beginning with the FY 2024 SNF QRP. We estimate that the data elements would take an additional 12.675 minutes of nursing staff time consisting of 1.725 minutes to report on each admission and 10.95 minutes to report on each discharge. We assume the added data elements would be performed by both registered nurses (25 percent of the time or 3.169 minutes) and licensed practical and vocational (75 percent of the time or 9.506 minutes). We estimate the reporting of these assessment items will impose an annual burden of 508,352 total hours (2,406,401 discharges × 12.675 min/60) at a cost of $28,139,825 ((508,352 hr × 0.25 × $76.94/hr) + (508,352 hr × 0.75 × $48.16/hr)). For each SNF the annual burden is 32.86 hours (508,352 hr/15,472 SNFs) at a cost of $1,818.76 ($28,139,825/15,472 SNFs). The overall annual cost of the finalized changes associated with the newly added 59.5 assessment items is estimated at $1,990.95 per SNF annually ($172.19 + $1,818.76), or $30,803,952 ($2,664,127 + $28,139,825) for all 15,472 SNFs annually.

[300] *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed February 1, 2022.

[301] *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed February 1, 2022.

We proposed in section VI.C.3. of the proposed rule to make certain revisions in the regulation text itself at § 413.360 to include new paragraph (f) to reflect all the data completion thresholds required for SNFs to meet the compliance threshold for the annual payment update, as well as certain conforming revisions. As discussed in section IX. of the final rule, this change would not affect the information collection burden for the SNF QRP.

We welcomed comments on the estimated time to collect influenza vaccination data and enter it into NHSN. We received public comments on this issue. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed concern with respect to CMS' 15-minute burden estimate for reporting the measure, noting it may be an underestimation.

Response: The burden associated with the proposed measure is the time it takes to sign into the NHSN, complete the required NHSN forms and submit the data. We estimate that data collection and reporting of the measure into the NHSN should take approximately 15-minutes annually, and can be completed once they have logged onto the system for the purpose of submitting their monthly COVID–19 vaccine report. The commenter did not provide additional information to support why CMS' estimate did not capture the full burden for the reporting requirements. We are confident with this estimation since the measure has been reported in the IRF and LTCH quality reporting programs for several years. Additionally, all SNF providers have been using the NHSN for data submission for approximately 15 months, and therefore, have familiarity with it. Without additional information, we are unable to respond further.

Although we did not seek comment on the proposal to Revise the Compliance Date for the Transition of Health (TOH) information measures and certain standardized patient assessment data elements beginning with the FY 2024 QRP, we did receive one comment.

Comment: A commenter expressed concern with CMS' burden estimate of 3.11 hours annually for reporting of the TOH Information measures and 32.86 hours annually for the collection of the standardized patient assessment data elements, noting that it may not capture the full actual burden of the new reporting requirements.

Response: We interpret the commenter to be referring to CMS' estimated impacts for collecting the new data elements published in the FY 2020 SNF PPS final rule (84 FR 38829). However, the commenter did not provide additional information to support why CMS' estimate did not capture the full burden for the reporting requirements. The estimate is based on CMS' assumption that the data elements would be performed by both Registered Nurses and Licensed Practical Nurses. Without additional information, we are unable to respond further.

After consideration of public comments, we are finalizing our burden estimate for the data submission for the Influenza Vaccination Coverage among HCP (NQF #0431) measure. The burden estimate for the reporting of the TOH Information measures and collection of the standardized patient assessment data elements was finalized in the FY 2020 SNF PPS final rule (84 FR 38829).

6. Impacts for the SNF VBP Program

The estimated impacts of the FY 2023 SNF VBP Program are based on historical data and appear in Table 22. We modeled SNF performance in the Program using SNFRM data from FY 2018 as the baseline period and April 1st through December 1st, 2019 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621).

However, in section VIII.B.1 of this final rule, we discuss the suppression of the SNFRM for the FY 2023 program year. As finalized, we will award each participating SNF 60 percent of their 2 percent withhold. Additionally, we finalized our proposal to apply a case minimum requirement for the SNFRM in section VIII.E.3.b. of this final rule. In section VIII.E.5. of this final rule, we also finalized our proposal to remove the Low-Volume Adjustment policy beginning with the FY 2023 Program year. As a result of these provisions, SNFs that do not meet the case minimum specified for the FY 2023 program year will be excluded from the Program and will receive their full Federal per diem rate for that fiscal year. As finalized, this policy will maintain the overall payback percentage at 60 percent.

Based on the 60 percent payback percentage, we estimated that we will redistribute approximately $278.32 million (of the estimated $463.86 million in withheld funds) in value-based incentive payments to SNFs in FY 2023, which means that the SNF VBP Program is estimated to result in approximately $185.55 million in savings to the Medicare Program in FY 2023.

Our detailed analysis of the impacts of the FY 2023 SNF VBP Program is shown in Table 22.

TABLE 22: Estimated SNF VBP Program Impacts for FY 2023

Characteristic	Number of facilities	Mean Risk-Standardized Readmission Rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total payment
Group					
Total*	10,707	19.74	0.0000	0.99200	100.00
Urban	8,352	19.77	0.0000	0.99200	87.09
Rural	2,355	19.64	0.0000	0.99200	12.91
Hospital-based urban**	208	19.45	0.0000	0.99200	1.79
Freestanding urban**	8,132	19.78	0.0000	0.99200	85.28
Hospital-based rural**	88	19.19	0.0000	0.99200	0.35
Freestanding rural**	2,197	19.65	0.0000	0.99200	12.42
Urban by region					
New England	617	19.83	0.0000	0.99200	5.46
Middle Atlantic	1,246	19.56	0.0000	0.99200	17.97
South Atlantic	1,626	19.86	0.0000	0.99200	17.71
East North Central	1,486	19.95	0.0000	0.99200	12.62
East South Central	446	19.91	0.0000	0.99200	3.52
West North Central	544	19.79	0.0000	0.99200	3.74
West South Central	874	20.05	0.0000	0.99200	6.82
Mountain	379	19.30	0.0000	0.99200	3.84
Pacific	1,131	19.48	0.0000	0.99200	15.42
Outlying	3	21.41	0.0000	0.99200	0.00
Rural by region					
New England	81	18.99	0.0000	0.99200	0.58
Middle Atlantic	161	19.42	0.0000	0.99200	0.92
South Atlantic	342	19.81	0.0000	0.99200	2.09
East North Central	568	19.50	0.0000	0.99200	3.02
East South Central	388	19.86	0.0000	0.99200	2.19
West North Central	298	19.55	0.0000	0.99200	1.19
West South Central	350	20.14	0.0000	0.99200	1.76
Mountain	101	19.11	0.0000	0.99200	0.55
Pacific	66	18.54	0.0000	0.99200	0.63
Outlying	0	-	-	-	-
Ownership					
Government	453	19.50	0.0000	0.99200	2.89
Profit	7,738	19.79	0.0000	0.99200	75.02
Non-Profit	2,516	19.62	0.0000	0.99200	22.08

* The total group category excludes 4,213 SNFs who failed to meet the proposed measure minimum policy.
** The group category which includes hospital-based/freestanding by urban/rural excludes 82 swing bed SNFs which satisfied the proposed case minimum policy.

In section VIII.B.2. of this final rule, we are adopting two additional measures (the SNF HAI and Total Nurse Staffing measures) beginning with the FY 2026 program year. Additionally, we finalized our proposal to apply a case minimum requirement for the SNF HAI and Total Nurse Staffing measures in section VIII.E.3.c. of this final rule. In section VIII.E.3.d. of this final rule, we also finalized our proposal to adopt a measure minimum policy for the FY 2026 program year. Therefore, we are providing estimated impacts of the FY 2026 SNF VBP Program, which are based on historical data and appear in Table 23. We modeled SNF performance in the Program using measure data from FY 2018 as the baseline period and FY 2019 as the performance period for the SNFRM, SNF HAI, and Total Nurse Staffing measures. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621), though we noted that the logistic exchange function and payback percentage policies could be reconsidered in a future rulemaking. Based on the 60 percent payback percentage, we estimated that we will redistribute approximately $296.44 million (of the estimated $494.07 million in withheld funds) in value-based incentive payments to SNFs in FY 2026, which means that the SNF VBP Program is estimated to result in approximately $197.63 million in

savings to the Medicare Program in FY 2026.

Our detailed analysis of the impacts of the FY 2026 SNF VBP Program is shown in Table 23.

TABLE 23: Estimated SNF VBP Program Impacts for FY 2026

Characteristic	Number of facilities	Mean Risk-Standardized Rate of Hospital-Acquired Infections (SNF HAI) (%)	Mean Total Nursing Hours per Resident Day (Total Nurse Staffing)	Mean Risk-Standardized Readmission Rate (SNFRM) (%)	Mean performance score	Mean incentive payment multiplier	Percent of total payment
Group							
Total*	13,188	5.93	3.83	19.97	35.4559	0.99144	100.00
Urban	9,851	5.88	3.85	20.02	35.7219	0.99158	85.97
Rural	3,337	6.09	3.77	19.83	34.6706	0.99102	14.03
Hospital-based urban**	250	4.50	5.25	19.68	57.6328	1.00449	1.85
Freestanding urban**	9,582	5.92	3.81	20.03	35.1215	0.99122	84.09
Hospital-based rural**	126	4.94	4.88	19.30	53.2646	1.00219	0.41
Freestanding rural**	3,106	6.20	3.72	19.85	33.2724	0.99020	13.46
Urban by region							
New England	697	5.48	3.89	20.27	37.2305	0.99201	5.31
Middle Atlantic	1,385	5.77	3.63	19.76	35.5796	0.99174	17.26
South Atlantic	1,795	5.90	3.96	20.11	36.1595	0.99164	17.12
East North Central	1,803	5.85	3.64	20.19	32.7999	0.99002	12.64
East South Central	522	5.98	3.87	20.24	33.6477	0.99035	3.48
West North Central	740	5.79	4.18	20.01	39.3962	0.99374	3.94
West South Central	1,182	6.21	3.61	20.33	29.2867	0.98803	7.32
Mountain	460	5.32	4.00	19.43	44.0399	0.99642	3.85
Pacific	1,262	6.15	4.19	19.63	40.2634	0.99407	15.04
Outlying	5	4.84	4.83	21.00	44.0008	0.99456	0.00
Rural by region							
New England	106	5.30	4.13	19.02	48.9337	0.99981	0.61
Middle Atlantic	191	5.71	3.45	19.27	36.2703	0.99190	0.91
South Atlantic	425	6.06	3.61	19.97	31.9994	0.98959	2.11
East North Central	752	5.94	3.59	19.68	34.0636	0.99061	3.20
East South Central	455	6.34	3.84	20.20	34.1364	0.99085	2.18
West North Central	637	6.15	4.04	19.77	36.7251	0.99187	1.69
West South Central	546	6.57	3.68	20.35	28.4586	0.98762	2.09
Mountain	148	5.60	3.93	19.21	41.2598	0.99468	0.63
Pacific	77	5.50	4.22	18.71	49.2824	0.99987	0.62
Outlying	0	-	-	-	-	-	-
Ownership							
Government	617	5.75	4.07	19.79	40.2540	0.99434	3.05
Profit	9,507	6.13	3.66	20.04	31.9439	0.98935	74.88
Non-Profit	3,064	5.38	4.32	19.81	45.3868	0.99731	22.06

* The total group category excludes 2,144 SNFs who failed to meet the proposed measure minimum policy.
** The group category which includes hospital-based/freestanding by urban/rural excludes 124 swing bed SNFs which satisfied the proposed measure minimum policy.

In section VIII.B.2. of this final rule, we are adopting one additional measure (the DTC PAC SNF measure) beginning with the FY 2027 program year. Additionally, we finalized our proposal to apply a case minimum requirement for the DTC PAC SNF measure in section VIII.E.3.c. of this final rule. In section VIII.E.3.d, of this final rule, we also finalized our proposal to adopt a measure minimum policy for the FY 2027 program year. Therefore, we are providing estimated impacts of the FY 2027 SNF VBP Program, which are based on historical data and appear in

Table 24. We modeled SNF performance in the Program using measure data from FY 2018 (the SNFRM, SNF HAI, and Total Nurse Staffing measures) and FY 2017 through FY 2018 (the DTC PAC SNF measure) as the baseline period and FY 2019 (the SNFRM, SNF HAI, and Total Nurse Staffing measures) and FY 2019 through FY 2020 (the DTC PAC SNF measure) as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621), though we noted that the logistic exchange function and payback percentage policies could be reconsidered in a future rule. Based on the 60 percent payback percentage, we estimated that we will redistribute approximately $294.67 million (of the estimated $491.12 million in withheld funds) in value-based incentive payments to SNFs in FY 2027, which means that the SNF VBP Program is estimated to result in approximately $196.45 million in savings to the Medicare Program in FY 2027.

Our detailed analysis of the impacts of the FY 2027 SNF VBP Program is shown in Table 24.

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TABLE 24: Estimated SNF VBP Program Impacts for FY 2027

Characteristic	Number of facilities	Mean Risk-Standardized Rate of Hospital-Acquired Infections (SNF HAI) (%)	Mean Total Nursing Hours per Resident Day (Total Nurse Staffing)	Mean Risk-Standardized Discharge to Community Rate (DTC PAC) (%)	Mean Risk-Standardized Readmission Rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total payment
Total*	12,929	5.94	3.82	53.39	19.97	36.3098	0.99067	100.00
Urban	9,675	5.89	3.84	54.02	20.02	37.0070	0.99107	86.03
Rural	3,254	6.10	3.76	51.54	19.83	34.2368	0.98950	13.97
Hospital-based urban**	222	4.54	5.13	64.29	19.69	61.4924	1.00497	1.74
Freestanding urban**	9,436	5.92	3.81	53.75	20.03	36.3859	0.99072	84.27
Hospital-based rural**	117	4.98	4.75	57.06	19.30	52.2485	0.99924	0.40
Freestanding rural**	3,035	6.20	3.72	50.71	19.84	32.5035	0.98851	13.41
Urban by region								
New England	690	5.47	3.89	57.59	20.27	40.3491	0.99250	5.34
Middle Atlantic	1,365	5.78	3.61	51.75	19.75	35.1747	0.99015	17.30
South Atlantic	1,781	5.90	3.94	54.31	20.11	37.5012	0.99120	17.19
East North Central	1,776	5.86	3.63	54.87	20.20	35.2015	0.99021	12.64
East South Central	516	5.99	3.86	52.97	20.24	34.6611	0.98973	3.49
West North Central	720	5.79	4.18	53.70	20.01	39.3350	0.99230	3.93
West South Central	1,125	6.23	3.60	51.21	20.35	30.1480	0.98761	7.22
Mountain	450	5.32	3.98	60.00	19.42	47.5690	0.99682	3.85
Pacific	1,247	6.16	4.18	53.90	19.64	40.9666	0.99318	15.07
Outlying	5	4.84	4.83	65.19	21.00	53.3254	1.00110	0.00
Rural by region								
New England	106	5.30	4.13	56.39	19.02	48.3424	0.99732	0.61
Middle Atlantic	188	5.72	3.45	49.69	19.26	34.0341	0.98928	0.91
South Atlantic	416	6.04	3.61	50.48	19.97	31.8067	0.98829	2.11
East North Central	740	5.94	3.59	53.62	19.68	34.9419	0.98974	3.20
East South Central	450	6.36	3.84	50.57	20.21	33.5263	0.98947	2.18
West North Central	615	6.17	4.05	50.05	19.77	34.4533	0.98918	1.67
West South Central	518	6.57	3.67	50.02	20.35	28.6480	0.98679	2.04
Mountain	144	5.62	3.83	54.57	19.21	40.8260	0.99289	0.63
Pacific	77	5.50	4.22	57.20	18.71	49.3633	0.99804	0.62
Outlying	0	-	-	-	-	-	-	-
Ownership								
Government	591	5.77	4.03	53.36	19.78	40.0316	0.99271	3.01
Profit	9,331	6.13	3.66	52.15	20.04	32.7939	0.98874	74.96

Characteristic	Number of facilities	Mean Risk-Standardized Rate of Hospital-Acquired Infections (SNF HAI) (%)	Mean Total Nursing Hours per Resident Day (Total Nurse Staffing)	Mean Risk-Standardized Discharge to Community Rate (DTC PAC) (%)	Mean Risk-Standardized Readmission Rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total payment
Non-Profit	3,007	5.39	4.30	57.25	19.81	46.4886	0.99629	22.03

* The total group category excludes 2,403 SNFs who failed to meet the proposed measure minimum policy.
** The group category which includes hospital-based/freestanding by urban/rural excludes 119 swing bed SNFs which satisfied the proposed measure minimum policy.

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7. Impacts for LTC Physical Environment Changes

As discussed at section IX. of this rule, we are finalizing our proposal at § 483.90(a)(1)(iii) based on public comments. We are allowing those existing LTC facilities (those that were Medicare or Medicaid certified before July 5, 2016) that have previously used the FSES to determine equivalent fire protection levels, to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment and people movement requirements. This will allow existing LTC facilities that previously met the FSES requirements to continue to do so without incurring great expense to change construction type—essentially undertake an effort to completely rebuild.

While we do not have information on the number of facilities that undertake reconstruction in a given year, we can estimate the number of facilities placed at risk of a deficiency citation by these requirements, and thus the risk of being required to rebuild the structure in order to update the building's construction type, by considering the age of the facility and the building methodologies used in given time periods. We consulted with CMS Regional Office survey staff, and based on information received from them, we estimate that 50 facilities are directly impacted by the change in the scoring of the FSES and would no longer achieve a passing score on the FSES. We estimate the average size of the affected nursing homes to be roughly 25,000 sq. ft. The cost of construction per sq. ft. is estimated at $180 in 2013 dollars (*https://www.rsmeans.com/model-pages/nursing-home.aspx*). Assuming a construction cost increase over this period of 10.33 percent using GDP deflator, the 2019 construction cost per square foot would be about $199 a square foot. The total savings from this proposal in 2019 dollars would be approximately $248,750,000 (25,000 sq. ft. × $199 per sq. ft. × 50 facilities).

This estimate assumes that essentially all these facilities would be replaced. Based on our research, we assume that there are two major and offsetting trends affecting the nursing home care market in coming decades: the increasing preference and ability of elderly and disabled adults to finance and obtain long term nursing care in their own homes; and the increasing number of elderly and disabled adults as the baby boom population ages.[302] [303] Assuming, absent specific evidence, that these two trends roughly offset each other, the preceding estimates are a reasonable projection of likely investment costs in new (or totally reconstructed) facilities. For purposes of annual cost estimates, we assume that those costs would be spread over 5 years, and would therefore be approximately $49,750,000 million annually in those years ($248,750,000 million/5 years). There are additional uncertainties in these estimates and we therefore provide estimates that are 25 percent lower and higher in Table 28.

8. Impacts for Changes to the Requirements for the Director of Food and Nutrition Services in LTC Facilities

As discussed in section IX. of this final rule, we are revising our proposal to revise the required qualifications for a director of food and nutrition services to provide that those with several years of experience performing as the director of food and nutrition services in a facility can continue to do so. In addition to the existing credentialing requirements for the director of food and nutrition services to include being a ''certified food service manager,'' or ''certified dietary manager,'' or ''has similar national certification from a national certifying body,'' or ''has an associate's or higher degree in food service or restaurant management'', we have added that an individual with 2 or more years of experience and completion of a course in food safety and management may also meet the required qualifications. Under the October 2016 final rule, a significant fraction of current directors of food and nutrition services would have had to be replaced or, at great expense, have had to attend an institution of higher education to obtain required credentials.

The current annual cost for the director of food and nutrition services is an estimated $122,400 annually (updated to reflect current salary information and including fringe benefits and overhead costs). We previously estimated that 10 percent of facilities would need to pursue additional candidates that meet the new qualifications for a director of food and nutrition services. Assuming that, on average, there is a 10 percent wage differential between those with experience but no further credentials, and those who would have met the standards of the October 2016 final rule for director of food and nutrition services either as specified in that rule, or by meeting the even higher standards for ''qualified dietician,'' this means that removing those standards would reduce costs to facilities by $18,929,840.00 (10 percent of 15,266 facilities × $12,400). In this calculation, the wage differential is assumed to be about 10 percent because there are offsetting costs to the facility for retaining staff who are qualified by experience but who may need expert help, such as the proposed requirement for frequently scheduled consultation with a qualified dietician.

We are requiring that an individual may also be designated as the director of food and nutrition services if they have 2 or more years of experience in the position and has completed a minimum course of study in food safety. These revisions will provide an experience qualifier that will likely eliminate the need for many facilities to hire additional or higher salaried staff.

9. Alternatives Considered

As described in this section, we estimate that the aggregate impact of the provisions in this final rule will result in an estimated net increase in SNF payments of 2.7 percent, or $904 million, for FY 2023. This reflects a 5.1 percent increase from the final update to the payment rates and a 2.3 percent decrease from the reduction to the SNF payment rates to account for the recalibrated parity adjustment, using the formula to multiply the percentage change described in section X.A.4. of this final rule.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating base payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the Federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY; accordingly, we are not pursuing alternatives for this process.

[302] *https://www.cbo.gov/sites/default/files/cbofiles/attachments/44363-LTC.pdf.*

[303] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1464018/.*

With regard to the alternatives considered related to the methodology for calculating the proposed parity adjustment to the rates, we considered numerous alternative approaches to the methodology, including alternative data sets, applying the parity adjustment to targeted components of the payment system, and delaying or phasing-in the parity adjustment. These alternatives were described in full detail in section V.C. of the proposed rule.

With regard to the proposal to add the HCP Influenza Vaccine measure to the SNF QRP Program, the COVID–19 pandemic has exposed the importance of implementing infection prevention strategies, including the promotion of HCP influenza vaccination. We believe this measure will encourage healthcare personnel to receive the influenza vaccine, resulting in fewer cases, less hospitalizations, and lower mortality associated with the virus, but were unable to identify any alternative methods for collecting the data. A compelling public need exists to target quality improvement among SNF providers and this proposed measure has the potential to generate actionable data on HCP vaccination rates.

With regard to the proposal to revise the compliance date for the MDS v1.18.11, section 1888(d)(6)(B)(i)(III) of the Act requires that, for fiscal years 2019 and each subsequent year, SNFs must report standardized patient assessment data required under section 1899B(b)(1) of the Act. Section 1899(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including SNFs, to submit standardized patient assessment data under the Medicare program. Further delay of collecting this data would delay compliance with the current regulations.

As discussed previously the burden for these proposals is minimal, and we believe the importance of the information necessitates these provisions.

With regard to the proposals for the SNF VBP Program, we discussed alternatives considered within those sections. In section VIII.B.2. of this final rule, we considered 4 options to adjust for COVID–19 in a technical update to the SNFRM. None of the alternatives will change the analysis of the impacts of the FY 2023 SNF VBP Program described in section VIII.B.2. of this final rule. In section VIII.C.2. of this final rule, we finalized our proposal to revise the baseline period for the FY 2025 SNF VBP Program to FY 2019. We considered using alternative baseline periods, including FY 2020 and FY 2022, but these options are operationally infeasible.

In section VIII.E.3.c. of this final rule, we finalized our proposal that SNFs must have a minimum of 25 residents, on average, across all available quarters during the applicable 1-year performance period in order to be eligible to receive a score on the Total Nurse Staffing measure. We tested three alternative case minimums for this measure: a 25-resident minimum, a minimum of one quarter of PBJ data, and a minimum of two quarters of PBJ data. After considering these alternatives, we determined that the proposed 25-resident minimum best balances quality measure reliability with our desire to score as many SNFs as possible on this measure.

In section VIII.E.3.d. of this final rule, we finalized our proposed measure minimums for the FY 2026 and FY 2027 SNF VBP Programs. SNFs that do not meet these minimum requirements would be excluded from the Program and would receive their full Federal per diem rate for that fiscal year. We also discussed alternatives, which are detailed below, that would result in more SNFs being excluded from the Program.

We finalized that for FY 2026, SNFs must have the minimum number of cases for two of the three measures during the performance period to receive a performance score and value-based incentive payment. Under these minimum requirements for the FY 2026 program year, we estimated that approximately 14 percent of SNFs would be excluded from the FY 2026 Program. Alternatively, if we required SNFs to have the minimum number of cases for all three measures during the performance period, approximately 21 percent of SNFs would be excluded from the FY 2026 Program. We also assessed the consistency of incentive payment multipliers (IPMs) between time periods as a proxy for performance score reliability under the different measure minimum options. The testing results indicated that the reliability of the SNF performance score would be relatively consistent across the different measure minimum requirements. Specifically, for the FY 2026 program year, we estimated that under the proposed minimum of two measures, 82 percent of SNFs receiving a net-negative IPM in the first testing period also received a net-negative IPM in the second testing period. Alternatively, under a minimum of three measures for the FY 2026 program year, we found that the consistency was 81 percent. Based on these testing results, we believe the minimum of two out of three measures for FY 2026 best balances SNF performance score reliability with our desire to ensure that as many SNFs as possible can receive a performance score and value-based incentive payment.

We finalized that for FY 2027, SNFs must have the minimum number of cases for three of the four measures during a performance period to receive a performance score and value-based incentive payment. Under these minimum requirements, we estimated that approximately 16 percent of SNFs would be excluded from the FY 2027 Program. Alternatively, if we required SNFs to report the minimum number of cases for all four measures, we estimated that approximately 24 percent of SNFs would be excluded from the FY 2027 Program. We also assessed the consistency of incentive payment multipliers (IPMs) between time periods as a proxy for performance score reliability under the different measure minimum options. The testing results indicated that the reliability of the SNF performance score for the FY 2027 program year would be relatively consistent across the different measure minimum requirements. That is, among the different measure minimums for the FY 2027 program year, a strong majority (between 85 and 87 percent) of the SNFs receiving a net-negative IPM for the first testing period also received a net-negative IPM for the second testing period. These findings indicated that increasing the measure minimum requirements did not meaningfully increase the consistency of the performance score. Based on these testing results, we believe the minimum of three out of four measures for FY 2027 best balances SNF performance score reliability with our desire to ensure that as many SNFs as possible can receive a performance score and value-based incentive payment.

10. Accounting Statement

As required by OMB Circular A–4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Tables 25 through 27, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule for FY 2023. Tables 19 and 25 provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,541 SNFs in our database. Table 26 provides our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies for this program. Tables 20 and

27 provide our best estimate of the additional cost to SNFs to submit the data for the SNF QRP as a result of the policies in this final rule. Table 28 provides our best estimate of the costs avoided by Medicare and Medicaid SNFs/NFs. This is our estimate of the aggregate costs of SNFs nationwide to rebuild facility structures for compliance for fire protection or LTC Physical Environment Changes. These costs will be avoided as a result of the policies in this final rule. Table 29 provides our best estimate of the amount saved by Medicare and Medicaid-participating SNFs/NFs to designate a director of Food and Nutrition (F&N) Services as a result of the policies in this final rule.

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TABLE 25: Accounting Statement: Classification of Estimated Expenditures, from the 2022 SNF PPS Fiscal Year to the 2023 SNF PPS Fiscal Year

Category	Transfers
Annualized Monetized Transfers	$904 million*
From Whom To Whom?	Federal Government to SNF Medicare Providers

* The net increase of $904 million in transfer payments reflects a 2.7 percent increase, which is the product of the multiplicative formula described in section XI.A.4 of this rule. It reflects the 5.1 percent increase (approximately $1.7 billion) from the final update to the payment rates as well as a negative 2.3 percent decrease (approximately $780 million) from the final parity adjustment. Due to rounding and the nature of the multiplicative formula, dollar figures are approximations and may not sum.

TABLE 26: Accounting Statement: Classification of Estimated Expenditures for the FY 2023 SNF VBP Program

Category	Transfers
Annualized Monetized Transfers	$278.32 million*
From Whom To Whom?	Federal Government to SNF Medicare Providers

*This estimate does not include the 2 percent reduction to SNFs' Medicare payments (estimated to be $463.86 million) required by statute.

TABLE 27: Accounting Statement: Classification of Estimated Expenditures for the FY 2024 SNF QRP Program

Category	Transfers/Costs
Costs for SNFs to Submit Data for QRP	$30,949,079.36

*Costs associated with the submission of data for the Influenza Vaccination among HCP (NQF #0431) and the collection of the Transfer of Health Information measures and certain standardized patient assessment data elements will occur in FY 2023 and is likely to continue in future years.

TABLE 28: Accounting Statement: FY 2023 Physical Environment Changes for SNFs to rebuild facility structures for compliance for fire protection or LTC Physical Environment Changes as a result of the policies in this final rule

Category	Transfers/Costs
Cost Savings for revised Fire Safety Standards	$50 million*

* The cost of $50 million per year for 5 years does not consider two SNF market trends: (1) the increase in elderly and disabled adults ability and preference to finance and obtain long term nursing care in their own homes; and (2) the increase in number of elderly and disabled adults due to an ageing "baby boomer" population. We anticipate these two trends will offset each other; however, we cannot estimate the degree. Thus, we caveat the cost may be closer to $37.5 million (25% decrease) or $62.5 million (25% increase) for FY 2023.

TABLE 29: Accounting Statement: Designation of F&N Services Director for FY 2023

Category	Transfers/Costs
Costs for SNFs to designate a director of food and nutrition services	-$19 million*

* The cost savings of $19 million is expected to occur in the first year, FY 2023.

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11. Conclusion

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2022 (86 FR 42424). Based on the above, we estimate that the overall payments for SNFs under the SNF PPS in FY 2023 are projected to increase by approximately $904 million, or 2.7 percent, compared with those in FY 2022. We estimate that in FY 2023, SNFs in urban and rural areas would experience, on average, a 2.7 percent increase and 2.5 percent increase, respectively, in estimated payments compared with FY 2022. Providers in the urban Pacific region would experience the largest estimated increase in payments of approximately 3.6 percent. Providers in the urban Outlying region would experience the smallest estimated increase in payments of 1.4 percent.

B. Regulatory Flexibility Act Analysis

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, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $30 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $30 million or less in any 1 year. (For details, see the Small Business Administration's website at *https://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*.) In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2022 (86 FR 42424). Based on the above, we estimate that the aggregate impact for FY 2023 will be an increase of $904 million in payments to SNFs, resulting from the final SNF market basket update to the payment rates, reduced by the parity adjustment discussed in section VI.C. of this final rule, using the formula described in section X.A.4. of this rule. While it is projected in Table 19 that all providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2023 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. In their March 2022 Report to Congress (available at *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch7_SEC.pdf*), MedPAC states that Medicare covers approximately 10 percent of total patient days in freestanding facilities and 17 percent of facility revenue (March 2022 MedPAC Report to Congress, 238). As indicated in Table 19, the effect on facilities is projected to be an aggregate positive impact of 2.7 percent for FY 2023. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities for FY 2023.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis 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 604 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 an MSA and has fewer than 100 beds. This final rule will affect small rural hospitals that: (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2022 (86 FR 42424)), the category of small rural hospitals is included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 19, the effect on facilities for FY 2023 is projected to be an aggregate positive impact of 2.7 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals for FY 2023.

C. Unfunded Mandates Reform Act Analysis

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 final rule will impose no mandates on State, local, or tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This final rule will have no substantial direct effect on State and local governments, preempt State law, or otherwise have federalism implications.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this

final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this year's final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we believe that the number of commenters on this year's proposed rule is a fair estimate of the number of reviewers of this year's final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the national mean hourly wage data from the May 2020 BLS Occupational Employment Statistics (OES) for medical and health service managers (SOC 11–9111), we estimate that the cost of reviewing this rule is $114.24 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of the final rule. For each SNF that reviews the rule, the estimated cost is $456.96 (4 hours × $114.24). Therefore, we estimate that the total cost of reviewing this regulation is $3,185,011.20 ($456.96 × 6,970 reviewers).

In accordance with the provisions of Executive Order 12866, this final 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 July 25, 2022.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Amend § 413.337 by revising paragraph (b)(4) to read as follows:

§ 413.337 Methodology for calculating the prospective payment rates.

* * * * *

(b) * * *

(4) *Standardization of data for variation in area wage levels and case-mix.* The cost data described in paragraph (b)(2) of this section are standardized to remove the effects of geographic variation in wage levels and facility variation in case-mix.

(i) The cost data are standardized for geographic variation in wage levels using the wage index. The application of the wage index is made on the basis of the location of the facility in an urban or rural area as defined in § 413.333.

(ii) Starting on October 1, 2022, CMS applies a cap on decreases to the wage index such that the wage index applied to a SNF is not less than 95 percent of the wage index applied to that SNF in the prior FY.

(iii) The cost data are standardized for facility variation in case-mix using the case-mix indices and other data that indicate facility case-mix.

* * * * *

■ 3. Amend § 413.338 by—

■ a. Revising paragraphs (a)(1) and (4) through (17);

■ b. Revising paragraphs (b) and (c)(2)(i), paragraph (d) paragraph heading, and paragraph (d)(3);

■ c. Adding paragraphs (d)(5) and (6);

■ d. Redesignating paragraphs (e) through (g) as paragraphs (f) through (h);

■ e. Adding a new paragraph (e);

■ f. Revising newly redesignated paragraph (f)(1) and paragraph (f)(3) introductory text; and

■ g. Adding paragraphs (f)(4), (i), and (j).

The revisions and additions read as follows:

§ 413.338 Skilled nursing facility value-based purchasing program.

(a) * * *

(1) *Achievement threshold (or achievement performance standard)* means the 25th percentile of SNF performance on a measure during the baseline period for a fiscal year.

* * * * *

(4) *Baseline period* means the time period used to calculate the achievement threshold, benchmark, and improvement threshold that apply to a measure for a fiscal year.

(5) *Benchmark* means, for a fiscal year, the arithmetic mean of the top decile of SNF performance on a measure during the baseline period for that fiscal year.

(6) *Eligible stay* means, for purposes of the SNF readmission measure, an index SNF admission that would be included in the denominator of that measure.

(7) *Improvement threshold (or improvement performance standard)* means an individual SNF's performance on a measure during the applicable baseline period for that fiscal year.

(8) *Logistic exchange function* means the function used to translate a SNF's performance score into a value-based incentive payment percentage.

(9) *Low-volume SNF* means a SNF with fewer than 25 eligible stays included in the SNF readmission measure denominator during the performance period for each of fiscal years 2019 through 2022.

(10) *Performance period* means the time period during which SNF performance on a measure is calculated for a fiscal year.

(11) *Performance score* means the numeric score ranging from 0 to 100 awarded to each SNF based on its performance under the SNF VBP Program for a fiscal year.

(12) *Performance standards* are the levels of performance that SNFs must meet or exceed to earn points on a measure under the SNF VBP Program for a fiscal year.

(13) *Ranking* means the ordering of SNFs based on each SNF's performance score under the SNF VBP Program for a fiscal year.

(14) *SNF readmission measure* means, prior to October 1, 2019, the all-cause all-condition hospital readmission measure (SNFRM) or the all-condition risk-adjusted potentially preventable hospital readmission rate (SNFPPR) specified by CMS for application in the SNF Value-Based Purchasing Program. Beginning October 1, 2019, the term SNF readmission measure means the all-cause all-condition hospital

readmission measure (SNFRM) or the all-condition risk-adjusted potentially preventable hospital readmission rate (Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure) specified by CMS for application in the SNF VBP Program.

(15) *SNF Value-Based Purchasing (VBP) Program* means the program required under section 1888(h) of the Act.

(16) *Value-based incentive payment adjustment factor* is the number that will be multiplied by the adjusted Federal per diem rate for services furnished by a SNF during a fiscal year, based on its performance score for that fiscal year, and after such rate is reduced by the applicable percent.

(17) *Value-based incentive payment amount* is the portion of a SNF's adjusted Federal per diem rate that is attributable to the SNF VBP Program.

(b) *Applicability of the SNF VBP Program.* The SNF VBP Program applies to SNFs, including facilities described in section 1888(e)(7)(B) of the Act. Beginning with fiscal year 2023, the SNF VBP Program does not include a SNF, with respect to a fiscal year, if:

(1) The SNF does not have the minimum number of cases that applies to each measure for the fiscal year, as specified by CMS; or

(2) The SNF does not have the minimum number of measures for the fiscal year, as specified by CMS.

(c) * * *

(2) * * *

(i) *Total amount available for a fiscal year.* The total amount available for value-based incentive payments for a fiscal year is at least 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS, and will be increased as appropriate for each fiscal year to account for the assignment of a performance score to low-volume SNFs under paragraph (d)(3) of this section. Beginning with the FY 2023 SNF VBP, the total amount for value-based incentive payments for a fiscal year is 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS.

* * * * *

(d) *Performance scoring under the SNF VBP Program (applicable, as described in this paragraph, to fiscal year 2019 through and including fiscal year 2025).*

* * * * *

(3) If, with respect to a fiscal year beginning with fiscal year 2019 through and including fiscal year 2022, CMS determines that a SNF is a low-volume SNF, CMS will assign a performance score to the SNF for the fiscal year that, when used to calculate the value-based incentive payment amount (as defined in paragraph (a)(17) of this section), results in a value-based incentive payment amount that is equal to the adjusted Federal per diem rate (as defined in paragraph (a)(2) of this section) that would apply to the SNF for the fiscal year without application of § 413.337(f).

* * * * *

(5) CMS will specify the measures for application in the SNF VBP Program for a given fiscal year.

(6)(i) Performance standards are announced no later than 60 days prior to the start of the performance period that applies to that measure for that fiscal year.

(ii) Beginning with the performance standards that apply to FY 2021, if CMS discovers an error in the performance standard calculations subsequent to publishing their numerical values for a fiscal year, CMS will update the numerical values to correct the error. If CMS subsequently discovers one or more other errors with respect to the same fiscal year, CMS will not further update the numerical values for that fiscal year.

(e) *Performance scoring under the SNF VBP Program beginning with fiscal year 2026.* (1) *Points awarded based on SNF performance.* CMS will award points to SNFs based on their performance on each measure for which the SNF reports the applicable minimum number of cases during the performance period applicable to that fiscal year as follows:

(i) CMS will award from 1 to 9 points for achievement to each SNF whose performance on a measure during the applicable performance period meets or exceeds the achievement threshold for that measure but is less than the benchmark for that measure.

(ii) CMS will award 10 points for achievement to a SNF whose performance on a measure during the applicable performance period meets or exceeds the benchmark for that measure.

(iii) CMS will award from 0 to 9 points for improvement to each SNF whose performance on a measure during the applicable performance period exceeds the improvement threshold but is less than the benchmark for that measure.

(iv) CMS will not award points for improvement to a SNF that does not meet the case minimum for a measure for the applicable baseline period.

(v) The highest of the SNF's achievement and improvement score for a given measure will be the SNF's score on that measure for the applicable fiscal year.

(2) *Calculation of the SNF performance score.* The SNF performance score for a fiscal year is calculated as follows:

(i) CMS will sum all points awarded to a SNF as described in paragraph (e)(1) of this section for each measure applicable to a fiscal year to calculate the SNF's point total.

(ii) CMS will normalize the point total such that the resulting SNF performance score is expressed as a number of points earned out of a total of 100.

(f) * * *

(1) CMS will provide quarterly confidential feedback reports to SNFs on their performance on each measure specified for the fiscal year. Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, which contain the baseline period and performance period measure rates, respectively, SNFs will have 30 days following the date CMS provides each of these reports to review and submit corrections to the measure rates contained in that report. The administrative claims data used to calculate measure rates are not subject to review and correction under paragraph (f)(1) of this section. All correction requests must be accompanied by appropriate evidence showing the basis for the correction to each of the applicable measure rates.

* * * * *

(3) CMS will publicly report the information described in paragraphs (f)(1) and (2) of this section on the Nursing Home Compare website or a successor website. Beginning with information publicly reported on or after October 1, 2019, and ending with information publicly reported on September 30, 2022 the following exceptions apply:

* * * * *

(4) Beginning with the information publicly reported on or after October 1, 2022, the following exceptions apply:

(i) If a SNF does not have the minimum number of cases during the baseline period that applies to a measure for a fiscal year, CMS will not publicly report the SNF's baseline period measure rate for that particular measure, although CMS will publicly report the SNF's performance period measure rate and achievement score if the SNF had the minimum number of cases for the measure during the performance period of the same program year;

(ii) If a SNF does not have the minimum number of cases during the

performance period that applies to a measure for a fiscal year, CMS will not publicly report any information with respect to the SNF's performance on that measure for the fiscal year;

(iii) If a SNF does not have the minimum number of measures during the performance period for a fiscal year, CMS will not publicly report any data for that SNF for the fiscal year.

* * * * *

(i) *Special rules for the FY 2023 SNF VBP Program.* (1) CMS will calculate a SNF readmission measure rate for each SNF based on its performance on the SNF readmission measure during the performance period specified by CMS for fiscal year 2023, but CMS will not calculate a performance score for any SNF using the methodology described in paragraphs (d)(1) and (2) of this section. CMS will instead assign a performance score of zero to each SNF.

(2) CMS will calculate the value-based incentive payment adjustment factor for each SNF using a performance score of zero and will then calculate the value-based incentive payment amount for each SNF using the methodology described in paragraph (c)(2)(ii) of this section.

(3) CMS will provide confidential feedback reports to SNFs on their performance on the SNF readmission measure in accordance with paragraphs (f)(1) and (2) of this section.

(4) CMS will publicly report SNF performance on the SNF readmission measure in accordance with paragraph (f)(3) of this section.

(j) *Validation.* (1) Beginning with the FY 2023 Program year, for the SNFRM measure, information reported through claims for the SNFRM measure are validated for accuracy by Medicare Administrative Contractors (MACs) to ensure accurate Medicare payments.

(2) [Reserved]

■ 4. Amend § 413.360 by—

■ a. Removing paragraph (b)(2);

■ b. Redesignating paragraph (b)(3) as paragraph (b)(2); and

■ c. Adding paragraph (f).

The addition reads as follows:

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

* * * * *

(f) *Data completion threshold.* (1) SNFs must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of required quality measures data and standardized patient assessment data collected using the MDS submitted through the CMS designated data submission system; beginning with FY 2018 and for all subsequent payment updates; and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN, beginning with FY 2023 and for all subsequent payment updates.

(2) These thresholds (80 percent for completion of required quality measures data and standardized patient assessment data on the MDS; 100 percent for CDC NHSN data) will apply to all measures and standardized patient assessment data requirements adopted into the SNF QRP.

(3) A SNF must meet or exceed both thresholds to avoid receiving a 2-percentage point reduction to their annual payment update for a given fiscal year.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 5. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 6. Amend § 483.60 by—

■ a. Revising paragraphs (a)(2) introductory text, and (a)(2)(i) introductory text;

■ b. Removing the word ''or'' at the end of paragraphs (a)(2)(i)(C);

■ c. Revising paragraph (a)(2)(i)(D); and

■ d. Adding paragraph (a)(2)(i)(E).

The revisions and addition read as follows:

§ 483.60 Food and nutrition services.

* * * * *

(a) * * *

(2) If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services.

(i) The director of food and nutrition services must at a minimum meet one of the following qualifications—

* * * * *

(D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning; or

(E) Has 2 or more years of experience in the position of director of food and nutrition services in a nursing facility setting and has completed a course of study in food safety and management, by no later than October 1, 2023, that includes topics integral to managing dietary operations including, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving; and

* * * * *

■ 7. Amend § 483.90 by adding paragraph (a)(1)(iii) to read as follows:

§ 483.90 Physical environment.

(a) * * *

(1) * * *

(iii) If a facility is Medicare- or Medicaid-certified before July 5, 2016 and the facility has previously used the Fire Safety Evaluation System for compliance, the facility may use the scoring values in the following Mandatory Values Chart:

Table 1 to paragraph (a)(1)(iii) -- Mandatory Values—Nursing Homes

	Containment (Sa)		Extinguishment (Sb)		People Movement (Sc)	
Zone Location	New	Exist.	New	Exist.	New	Exist.
1st story	11	5	**15(12)***	4	**8(5)***	1
2nd or 3rd story	15	9	**17(14)***	6	**10(7)***	3
4th story or higher	18	9	**19(16)***	6	**11(8)***	3

* Use ( ) in zones that do not contain patient sleeping rooms.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Vol. 87, No. 148

Wednesday, August 3, 2022

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FEDERAL REGISTER PAGES AND DATE, AUGUST

46883–47092 1
47093–47330 2
47331–47620 3

CFR PARTS AFFECTED DURING AUGUST

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

7 CFR

210 47331
215 47331
220 47331
226 47331

13 CFR

120 46883

14 CFR

25 47332
39 ..... 47093, 47334, 47337
71 ..... 47097, 47098, 47342
Proposed Rules:
25 46892
39 ..... 46903, 46906, 47141, 47144
71 ..... 47146, 47149, 47150
121 46892
1212 46908

21 CFR

573 47343

31 CFR

587 ..... 47344, 47347, 47348

32 CFR

199 46884

33 CFR

100 47348
165 ..... 46887, 47350, 47352
334 46888
Proposed Rules:
165 47381

34 CFR

Proposed Rules:
Ch. II 47152, 47159

36 CFR

2 47296

38 CFR

17 47099
Proposed Rules:
61 46909

40 CFR

52 ..... 46890, 47101, 47354
372 47102
721 47103
723 47103
Proposed Rules:
52 46916
180 47167

42 CFR

412 47038
413 47502
483 47502
Proposed Rules:
Ch. IV 46918

43 CFR

49 47296
8360 47296

44 CFR

206 47359

47 CFR

64 47103

48 CFR

Ch. 28 47116

50 CFR

27 47296
Proposed Rules:
224 46921
648 ..... 47177, 47181

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Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List August 2, 2022

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