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Contents

Federal Register

Vol. 89, No. 118

Tuesday, June 18, 2024

Agency for International Development

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Science Champion Award for International Science and Engineering Fair-Affiliated Fairs, 51492

Agricultural Research Service

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 51492–51493

Agriculture Department

See Agricultural Research Service
See Natural Resources Conservation Service
See Rural Business-Cooperative Service

Bureau of Consumer Financial Protection

PROPOSED RULES

Prohibition on Creditors and Consumer Reporting Agencies Concerning Medical Information (Regulation V), 51682–51736

Children and Families Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Legal and Advocacy Services for Unaccompanied Children, 51528–51530

Coast Guard

RULES

Safety Zone:
Fourth of July Events for the Los Angeles Long Beach Captain of the Port Zone, 51440–51442

Commerce Department

See Foreign-Trade Zones Board
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Consumer Product Safety Commission

PROPOSED RULES

Safety Standard:
Bassinets and Cradles, 51475–51476

Energy Department

See Federal Energy Regulatory Commission

PROPOSED RULES

Financial Assistance Regulations:
Conflict of Interest and Conflict of Commitment Policy Requirements, 51460–51468

Environmental Protection Agency

NOTICES

Exemption:
Helicoverpa zea nudiviruses 2 strain 90DR71, 51523–51524
Pesticide Emergency, 51520–51521
Existing Stocks Provisions in Winfield and Liberty Product Cancellation Orders; Amendments:
Chlorpyrifos, 51521–51522

Requests for Nominations:

Great Lakes Advisory Board, 51522–51523

Federal Aviation Administration

RULES

Airspace Designations and Reporting Points:

Alaska, 51408–51409
Lincoln Airport, Lincoln MT, 51406–51407
Northcentral United States, 51403–51406, 51410–51413
Yerington, NV, 51407–51408

Airworthiness Directives:

Airbus Helicopters, 51401–51403

Instrument Flight Rules Altitudes; Miscellaneous

Amendments, 51432–51440

Removal of Check Pilot Medical Certificate Requirement, 51415–51432

Restricted Area:

Camp Grayling, MI, 51414–51415

Special Conditions:

H4 Aerospace (UK) Ltd., Boeing Model 757–200
Airplane, Non-Rechargeable Lithium Battery and
Battery System Installations; Correction, 51401

PROPOSED RULES

Airworthiness Directives:

Airbus Helicopters, 51468–51471
Airbus SAS Airplanes, 51471–51475

Federal Emergency Management Agency

NOTICES

Public Assistance Program and Policy Guide, 51545

Federal Energy Regulatory Commission

NOTICES

Application:

Green Mountain Power Corp., 51513–51514
Combined Filings, 51517–51518

Environmental Assessments; Availability, etc.:

Southern California Edison Co., 51512–51513
Totem Enhanced Deliverability Project; Colorado
Interstate Gas Co., LLC, 51512

Hearings, Meetings, Proceedings, etc.:

Stingray Pipeline Co., LLC; Technical Conference, 51513

Initial Market-Based Rate Filings Including Requests for

Blanket Section 204 Authorizations:

Aron Energy Prepay 41 LLC, 51519
Aron Energy Prepay 42, LLC, 51519–51520
Aron Energy Prepay 43, LLC, 51518

Licenses; Exemptions, Applications, Amendments, etc.:

Lyonsdale Associates, LLC, 51515–51517

Permits; Applications, Issuances, etc.:

Gravity Storage, LLC, 51514–51515

Federal Motor Carrier Safety Administration

NOTICES

Exemption Application:

Commercial Driver's License; U.S. Custom Harvesters,
Inc., 51589–51592

Entry-Level Driver Training; State of Alaska, 51592–
51594

Parts and Accessories Necessary for Safe Operation;
Agricultural and Food Transporters Conference of
American Trucking Associations, 51586–51589

Federal Procurement Policy Office**PROPOSED RULES**

Application of Cost Accounting Standards to Indefinite Delivery Vehicles, 51491

Food and Drug Administration**RULES**

Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases, 51738–51783

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications, 51534–51536

State Enforcement Notifications, 51533–51534

Guidance:

Goal Date Decisions Under Generic Drug User Fee Amendments, 51530–51531

Hearings, Meetings, Proceedings, etc.:

First Annual Animal Drug User Fee Educational Conference, 51531–51533

Foreign-Trade Zones Board**NOTICES**

Approval of Subzone Status:

Sediver USA, Inc., West Memphis, AR, 51495

Proposed Production Activity:

AbbVie, Inc., Foreign-Trade Zone 22, North Chicago, IL, 51495

General Services Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements, 51527–51528

Privacy Act; Systems of Records, 51524–51527

Government Accountability Office**RULES**

Personnel Appeals Board:

Procedural Rules, 51395–51400

Health and Human Services Department

See Children and Families Administration

See Food and Drug Administration

See National Institutes of Health

Homeland Security Department

See Coast Guard

See Federal Emergency Management Agency

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

DHS Civil Rights Evaluation Tool, Collection Instrument DHS Form 3095, 51545–51546

Indian Affairs Bureau**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Use of Bureau-Operated Schools by Third Parties, 51547–51548

Industry and Security Bureau**RULES**

Additional Sanctions against Russia and Belarus under the Export Administration Regulations and Refinements to Existing Controls, 51644–51680

Inter-American Foundation**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 51546–51547

Interior Department

See Indian Affairs Bureau

Internal Revenue Service**PROPOSED RULES**

Certain Partnership Related-Party Basis Adjustment Transactions as Transactions of Interest, 51476–51491

International Trade Administration**NOTICES**

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China, 51497–51499

Fresh Garlic from the People's Republic of China, 51495–51497

Lightweight Thermal Paper from the People's Republic of China, 51499–51501

International Trade Commission**NOTICES**

Investigations; Determinations, Modifications, and Rulings, etc.:

Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same, 51548–51549

Certain Products Containing Tirzepatide and Products Purporting to Contain Tirzepatide, 51549–51550

Justice Department**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

School Crime Supplement to the National Crime Victimization Survey, 51550–51551

Labor Department

See Occupational Safety and Health Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Work Schedules Supplement to the Current Population Survey, 51551

Management and Budget Office

See Federal Procurement Policy Office

Millennium Challenge Corporation**NOTICES**

Charter Amendments, Establishments, Renewals and Terminations:

Advisory Council; Requests for Nominations, 51553–51554

National Highway Traffic Safety Administration**NOTICES**

Petition for Decision of Inconsequential Noncompliance: FCA US LLC, 51594–51596

National Institutes of Health**NOTICES**

Hearings, Meetings, Proceedings, etc.:

Center for Scientific Review, 51536, 51544

Eunice Kennedy Shriver National Institute of Child Health and Human Development, 51537

National Eye Institute, 51537

National Institute of Allergy and Infectious Diseases, 51544–51545

Request for Information:

Draft Public Access Policy, 51537–51543

National Oceanic and Atmospheric Administration**RULES**

Fisheries of the Exclusive Economic Zone off Alaska:

Cook Inlet; Final 2024 Harvest Specifications for Salmon, 51448–51459

Regulations Governing the Taking of Marine Mammals, 51600–51642

NOTICES

Endangered and Threatened Species:

5-Year Review for Maui's Dolphin and the South Island Hector's Dolphin, 51511

Hearings, Meetings, Proceedings, etc.:

Pacific Island Fisheries; Western Pacific Stock Assessment Review, 51501

Matching Fund Opportunity:

Ocean and Coastal Mapping and Request for Partnership Proposals, 51508–51511

Taking or Importing of Marine Mammals:

Site Characterization Surveys Offshore from Massachusetts to New Jersey for Vineyard Northeast, LLC, 51501–51508

National Science Foundation**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Digital Twins Research and Development, 51554–51555

NSF Small Business Innovation Research Program Phase I, NSF Small Business Technology Transfer Program Phase I, and NSF SBIR/STTR Fast-Track Pilot Pre-submission Project Pitch Form, 51555–51556

Permits; Applications, Issuances, etc.:

Antarctic Conservation Act, 51556

Natural Resources Conservation Service**NOTICES**

Hearings, Meetings, Proceedings, etc.:

Urban Agriculture and Innovative Production Advisory Committee, 51493–51494

Nuclear Regulatory Commission**RULES**

List of Approved Spent Fuel Storage Casks:

NAC International, Inc., NAC–UMS Universal Storage System, Certificate of Compliance No. 1015, Renewal of Initial Certificate and Amendment Nos. 1 through 9, 51400–51401

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Authorization for Use or Disclosure of Protected Health Information, 51558–51559

Financial Protection Requirements and Indemnity Agreements, 51556–51558

Occupational Safety and Health Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Shipyard Employment Standards, 51551–51553

Peace Corps**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 51559–51562

Postal Service**RULES**

Known Mailer and Exceptions, 51446–51448

Rural Business-Cooperative Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 51494–51495

Securities and Exchange Commission**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 51576

Privacy Act; Systems of Records, 51582–51584

Self-Regulatory Organizations; Proposed Rule Changes:

MEMX LLC, 51576–51580

MIAX PEARL, LLC, 51562–51576

Nasdaq PHLX LLC, 51580–51582

Small Business Administration**NOTICES**

Disaster Declaration:

Mississippi, 51584–51585

Surface Transportation Board**NOTICES**

Exemption:

Abandonment and Discontinuance; State of Oklahoma by and through the Oklahoma Department of Transportation, Stillwater Central Railroad, LLC; Payne County, Ok, 51585–51586

Trade Representative, Office of United States**NOTICES**

Fiscal Year 2022 Service Contract Inventory, 51586

Transportation Department

See Federal Aviation Administration

See Federal Motor Carrier Safety Administration

See National Highway Traffic Safety Administration

Treasury Department

See Internal Revenue Service

Veterans Affairs Department**RULES**

Exemption of Diversity and Equal Employment Opportunity Program Records, 51442–51444

Health Professional Scholarship Program, 51444–51446

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Application for Reimbursement of Headstone or Marker Expense, 51596

Trainee Request For Leave (Chapter 31, Veteran Readiness and Employment), 51596–51597

Separate Parts In This Issue**Part II**

Commerce Department, National Oceanic and Atmospheric Administration, 51600–51642

Part III

Commerce Department, Industry and Security Bureau, 51644–51680

Part IV

Bureau of Consumer Financial Protection, 51682–51736

Part V

Health and Human Services Department, Food and Drug Administration, 51738–51783

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.

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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.

2 CFR**Proposed Rules:**

910.....51460

4 CFR

28.....51395

10 CFR

72.....51400

12 CFR**Proposed Rules:**

1022.....51682

14 CFR

25.....51401

39.....51401

71 (6 documents) 51403,

51405, 51406, 51407, 51408,

51410

73.....51414

91.....51415

95.....51432

121.....51415

135.....51415

Proposed Rules:

39 (2 documents) 51468,

51471

15 CFR

734.....51644

740.....51644

744.....51644

746.....51644

774.....51644

16 CFR**Proposed Rules:**

1218.....51475

21 CFR

4.....51738

16.....51738

201.....51738

210.....51738

211.....51738

213.....51738

230.....51738

314.....51738

514.....51738

26 CFR**Proposed Rules:**

1.....51476

33 CFR

165.....51440

38 CFR

1.....51442

17.....51444

39 CFR

20.....51446

48 CFR**Proposed Rules:**

Ch. 99.....51401

50 CFR

216.....51600

679.....51448

Rules and Regulations

Federal Register

Vol. 89, No. 118

Tuesday, June 18, 2024

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

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GOVERNMENT ACCOUNTABILITY OFFICE

4 CFR Part 28

Personnel Appeals Board; Procedural Rules

AGENCY: Government Accountability Office Personnel Appeals Board.

ACTION: Final rule.

SUMMARY: The Government Accountability Office Personnel Appeals Board (PAB or Board) is finalizing amendments to its regulations. The PAB published a proposed rule on November 24, 2023, which contained several significant refinements to the Board's procedures. The General Accounting Office Personnel Act of 1980 provides authority to make these changes.

DATES: This rule is effective as of July 18, 2024.

FOR FURTHER INFORMATION CONTACT: Stuart Melnick, Executive Director, 202-512-3836 or Kevin Wilson, Solicitor, 202-512-7517, pab@gao.gov.

SUPPLEMENTARY INFORMATION: The Board is authorized by Congress, pursuant to 31 U.S.C. 751-755, to hear and decide cases brought by Government Accountability Office (GAO) employees concerning various personnel matters, including adverse or performance-based actions, claims of discrimination, alleged prohibited personnel practices, and labor-management relations. The Board also exercises authority over GAO's EEO process at the agency. The Board's procedural regulations applicable to GAO appear at 4 CFR parts 27 and 28. The Board is revising two sections of these regulations to ensure consistency with current law and to address a process ambiguity in the current language. The Board is also replacing gendered pronouns with gender-neutral pronouns.

4 CFR 28.95

The Board is amending section 28.95 by specifically referencing the Equal Pay Act of 1963 (29 U.S.C. 206(d)), the Genetic Information Nondiscrimination Act of 2008 (42 U.S.C. 2000ff-1), and the Pregnancy Workers Fairness Act (42 U.S.C. 2000gg-1) in its definition of prohibited EEO discrimination. The addition of the reference to the Equal Pay Act of 1963 is to clarify that the prohibition on discrimination in wages on the basis of sex derives from the Equal Pay Act of 1963's amendment of the Fair Labor Standards Act of 1938 (29 U.S.C. 206(d)).

The additions of the references to the Genetic Information Nondiscrimination Act of 2008 and the Pregnancy Workers Fairness Act in paragraph (e) and new paragraph (f) of 4 CFR 28.95 reflect types of discrimination that became prohibited on the effective dates of the respective statutes but had not yet been codified into the Board's regulations.

Similarly, the revision of the definition of prohibited discrimination in new paragraph (h) of 4 CFR 28.95 includes a list of activities that may not form the basis for employment actions. Discrimination in retaliation for protected EEO activity became prohibited on the effective dates of the respective EEO statutes. This revision codifies existing prohibitions and does not create a new cause of action.

Five sets of comments responded to the proposed changes to this section. The Women and Gender Liaison Group and the GAO Employees Organization, IFPTE Local 1921, supported the Board's codification of employee protections in the Equal Pay Act of 1963, the Genetic Information Nondiscrimination Act of 2008, and the Pregnant Workers Fairness Act.

28.95(c)

The National Employment Lawyers Association commented that "[t]he edit in proposed 4 CFR § 28.95(c) is legally incorrect, since sex-basis pay discrimination claims do not sound solely in the Equal Pay Act (EPA). Instead, sex-basis pay discrimination claims concurrently sound in both the EPA and in Title VII. . . ." The Board thanks the National Employment Lawyers Association for this comment. The proposed amendment was not intended to give the impression that § 28.95(c) is the only section under

which a claim of sex-basis pay discrimination may be brought. Section 28.95(a), among other things, already includes in its definition of prohibited discrimination claims under Title VII on the basis of sex.

28.95(d)

The National Employment Lawyers Association commented, "GAO should consider modifying proposed 4 CFR § 28.95(d) to also include claims for improper collection, archival and/or dissemination of employees' confidential medical information." The Board thanks the National Employment Lawyers Association for this suggestion. The Board will not consider this suggestion at this time because the Board has not proposed any amendments to § 28.95(d) in its proposed rule, and the Board's stakeholders have not had an opportunity to comment on it.

28.95(h)

Both GAO's Office of General Counsel and the PAB's Office of General Counsel (PAB/OGC) suggested the Board replace the term "employment action" in § 28.95(h). GAO's Office of General Counsel indicated that "employment action" is not a commonly used term in the context of retaliation and suggested that "adverse" or "materially adverse" employment action should be used instead. The PAB/OGC suggested that "employment action" be replaced with a broader term, such as "retaliatory action," "retaliation," or "employer action."

Based on these comments, the Board has accepted these suggestions and replaced "employment action" with "materially adverse action" in the final rule. Materially adverse action is a broader term used by the Supreme Court in the EEO context, and it covers actions that go beyond the terms and conditions of employment. *See Burlington Northern Santa Fe Ry. v. White*, 548 U.S. 53 (2006).

The National Employment Lawyers Association commented that "GAO should also consider modifying proposed 4 CFR § 28.95(h) to include other activity likely to have a chilling effect as giving rise to a possible retaliation claim. In particular, GAO should consider adopting the EEOC's *per se* reprisal line of cases, under *Binseel* and its progeny, which recognize a freestanding *per se* violation

claim for comments or conduct [that] are likely to have a chilling effect on employees' protected EEO activity. . . ."

The Board considered this comment in deciding to replace the phrase "employment action" with "materially adverse action." The Supreme Court described materially adverse action in *Burlington Northern Santa Fe Ry. v. White*, 548 U.S. 53, 57 (2006) to include an action that "could well dissuade a reasonable worker from making or supporting a charge of discrimination." This language is intended to include activities, including nonemployment actions likely to have a chilling effect on making or supporting a claim of discrimination.

GAO's Office of General Counsel also suggested replacing the term "unlawful employment practice" in § 28.95(h) because it is not a commonly used term in the context of retaliation. The term "unlawful employment practice" is based on guidance contained in the EEOC's Enforcement Guidance on Retaliation and Related Issues. The guidance states, "[i]n addition to participation, an individual is protected from retaliation for opposing any practice made unlawful under the EEO laws." Therefore, the Board considered this suggestion, but elected to keep the language in the proposed rule.

GAO's Office of General Counsel commented that "the reference to a 'claim of retaliation that could be raised under § 28.95(h)' in § 28.98(e)(1) also is not clear." The Board intends "a claim of retaliation that could be raised under § 28.95(h)" to mean an EEO-related retaliation claim. The use of "retaliation" here is admittedly redundant because all claims that could be raised under § 28.95(h) are necessarily retaliation claims. The inclusion of it here is designed to help individuals better recognize that § 28.95(h) claims are retaliation claims because the term "retaliation" is not used in § 28.95(h).

4 CFR 28.98

The final rule also resolves ambiguity over when retaliation claims related to discrimination on one of the EEO-protected bases, including claims of retaliation under prohibited personnel practices laws like 5 U.S.C. 2302(b)(9), must go through GAO's EEO process pursuant to GAO Order 2713.2 before a charge containing these claims can be filed with the PAB/OGC and a petition containing them can be filed with the Board. Retaliation claims related to discrimination on one of the EEO-protected bases involving a removal, a suspension of more than 14 days, or a

furlough of not more than 30 days continue to have the option, pursuant to 4 CFR 28.98(c), of filing a discrimination complaint with GAO pursuant to GAO Order 2713.2 or bypassing the EEO process and filing a charge directly with the PAB/OGC. The final rule revisions clarify that other retaliation claims related to discrimination on one of the EEO-protected bases may also bypass GAO's EEO process if they are not reasonably related to the filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2. The PAB/GC will be empowered to decide whether retaliation claims related to discrimination on one of the EEO-protected bases are reasonably related to filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2. If the claims are reasonably related to the filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2, the PAB/OGC would inform the individual that they need to file their complaint with GAO pursuant to GAO Order 2713.2 before the PAB/OGC is permitted to process their charge on these allegations. If the PAB/GC determines the claims are not reasonably related to filing or assisting with a discrimination complaint pursuant to GAO Order 2713.2, the PAB/OGC would advise the individual that the charge containing these claims can be processed by the PAB/OGC without delay. The purpose of giving this unreviewable discretion to the PAB/GC is to give certainty to individuals that their claims may be processed immediately by the PAB/OGC without fear of having the claims subsequently dismissed for failure to exhaust the administrative remedies contained in GAO Order 2713.2.

Finally, the final rule amendments allow the PAB/OGC to hold in abeyance nondiscrimination allegations while related discrimination allegations are being pursued through GAO's EEO process. Once the discrimination complaint resolution process concludes, or the individual opts out, both types of claims could be investigated together. The PAB/GC is to utilize this provision when the claims are so related that the PAB/GC determines it would be most appropriate to conduct a single investigation into them. The PAB/GC will have discretion to revisit this decision at any time and no longer hold a claim in abeyance. For purposes of 4 CFR 28.12(g), the length of time a claim is held in abeyance will count toward the 180-day period, after which a charging party may opt out of the PAB/

OGC's investigation and file a petition with the Board.

All seven commenters to the proposed rule addressed section 28.98. The Board has made several changes based on these comments. These changes are discussed in greater detail in this section.

28.98(b)

The GAO Office of General Counsel requested clarification on "what is meant by 'processes a complaint' (*i.e.*, accepts the complaint for investigation, completes the investigation, issues a FAD, etc.)." The language in § 28.98(b) is intended to have the same meaning as the previous version of this section, which stated, "A charge relating to GAO's disposition of any individual EEO complaint may be filed with the Board's General Counsel at the following times . . ." The final rule changes the language to the active voice and describes the EEO process. It should be interpreted in the same way as the previous § 28.98(b).

28.98(c)

The PAB/OGC suggested adding "certain" to the title of 4 CFR 28.98(c) so that it reads "Special rules for certain adverse and performance-based actions." The PAB/OGC was concerned that there could be confusion over whether "materially adverse action" in 4 CFR 28.98(h) is limited to the commonly known Chapter 75 adverse actions listed in 4 CFR 28.98(c)—namely a removal, suspension for more than 14 days, reduction in grade or pay, or furlough of not more than 30 days. The Board's addition of the word "certain" to the title of 4 CFR 28.98(c) is intended to connote that adverse actions listed in 4 CFR 28.98(c) are only a subset of the "materially adverse actions" covered by 4 CFR 28.98(h).

28.98(e)

All seven commenters submitted comments on § 28.98(e). The Office of Opportunity and Inclusiveness (O&I), which is responsible for GAO's discrimination complaint resolution process under GAO Order 2713.2, appeared to oversimplify the proposed § 28.98(e) process when it wrote that "the forum for processing certain retaliation claims would depend on whether the Board's General Counsel determines that the claim relates to retaliation 'for filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2'" The § 28.98(e) process was designed to give individuals the ability to choose the forum where they want to bring their EEO-based retaliation claims. The key is

that individuals choose their desired forum. The PAB/GC does not make this determination for them. The PAB/GC's role is to determine whether an individual's requested forum can be accommodated.

The most commonly raised issue was a request to clarify what claims relate to retaliation for filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2. Two commenters specifically asked whether informal contact with an EEO counselor would be related to filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2.

The phrase "relates to retaliation for filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2" is intended to include retaliation for any task reasonably related to the discrimination complaint process listed in GAO Order 2713.2. Such task need not be limited to participating in the formal complaint process. As such, it should be interpreted to include retaliation for engaging in pre-complaint EEO counseling with O&I. To make clear that the "relates to retaliation" language is not to be strictly interpreted, the Board has added "reasonably" to this phrase so that it reads "reasonably relates to retaliation" in §§ 28.98(e), (e)(1)(i), and (e)(1)(ii).

Several commenters requested examples of actions that relate to retaliation for filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2 and examples of ones that would not. Examples of actions that would reasonably be related to filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2 include: (1) having previously filed a discrimination complaint with O&I pursuant to GAO Order 2713.2, (2) having previously filed a disability complaint with O&I pursuant to GAO Order 2713.2, (3) having provided testimony in another employee's discrimination claim filed with O&I pursuant to GAO Order 2713.2, and (4) having engaged in pre-complaint counseling with O&I pursuant to GAO Order 2713.2. Examples of actions that would not reasonably be related to filing a discrimination complaint filed pursuant to GAO Order 2713.2 include: (1) filing a complaint against an individual with O&I in the anti-harassment portal, (2) filing a reasonable accommodation request with GAO's Reasonable Accommodation Team, (3) providing testimony resulting from another employee's filing a complaint in the anti-harassment portal with O&I, (4) being associated with, such as a family

member or friend, an individual who filed a discrimination complaint with O&I pursuant to GAO Order 2713.2, (5) refusing to follow a discriminatory directive, and (6) opposing discrimination by speaking up at a meeting against a comment that denigrated an ethnic group.

O&I questioned whether the Board considered replacing "relates to retaliation for filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2" with "participating in an O&I process," which would include both the discrimination complaint resolution process under GAO Order 2713.2 as well as GAO's Anti-Harassment Policy. Yes, the Board did consider this option but decided against requiring retaliation claims related to all O&I activities to be processed first by O&I. The Board did not want individuals with EEO-related retaliation claims to be forced to go through the discrimination complaint resolution process when their claims were insufficiently related to the discrimination complaint resolution process. A former GAO employee commented that having the choice to bypass O&I in such situations was "extraordinarily important and should have been made sooner." The former employee detailed the frustrations they experienced when their claim was required to be reviewed by O&I before it could be filed with the Board. The GAO Employees Organization, IFPTE Local 1921, also supported this change.

O&I requested how a hypothetical would be handled where an individual has an EEO-based retaliation claim that does not relate to filing or assisting with a discrimination complaint pursuant to GAO Order 2713.2 but also contains other bases of discrimination (e.g., sex and race) that involve the same personnel action. Assuming the individual wanted the EEO-related retaliation claim reviewed by the PAB/OGC and not O&I, the employee would still be required to file the other discrimination claims with O&I pursuant to the discrimination complaint resolution process.

After the individual filed the discrimination claims with O&I pursuant to Order 2713.2, the sex and race discrimination claims could later be included in a charge filed with the PAB/OGC at any of the times listed in 4 CFR 28.98(b). While the sex and race discrimination claims were going through O&I's discrimination complaint resolution process, the PAB/GC would have the choice of when to begin the investigation into the EEO-based retaliation claim. Because that claim shares a common personnel action with

the sex and race discrimination claims being reviewed by O&I, the PAB/GC could hold the retaliation claim in abeyance pursuant to 4 CFR 28.98(f) if the PAB/GC determines it would be more appropriate to wait for the sex and race discrimination claims to have completed the discrimination complaint resolution process and investigate all three claims together.

In the context of this same hypothetical, O&I asked, "[h]ow should the General Counsel respond if the individual also raises other discrimination claims, such as harassment based on disability?" If the PAB/GC were to receive a harassment based on a disability claim, the Board would first expect the PAB/GC to determine if the individual were attempting to allege discrimination on the basis of disability. If so, the PAB/OGC could investigate the claim immediately if it involved a removal, suspension for more than 14 days, reduction in grade or pay, or furlough of not more than 30 days. 4 CFR 28.98(c). If it involved a different personnel action, the PAB/OGC would instruct the individual to file a claim with O&I. 4 CFR 28.98(a). If the individual was not attempting to allege discrimination based on disability, the Board expects the PAB/OGC to analyze the claim under all statutes within its jurisdiction and make the individual aware of the anti-harassment protections offered by O&I.

Two commenters made suggestions regarding the length of time the PAB/GC has to make a § 28.98(e) determination. The GAO Employees Organization, IFPTE Local 1921, suggested adding a timeline during which the PAB/GC must make this determination. The National Employment Lawyers Association suggested that the date on which a § 28.98(e)(1) claim is filed with the PAB/OGC should be treated as the filing date with O&I for the subsequent filing under the discrimination complaint resolution process. Both commenters appear concerned that a delay by the PAB/GC in making a § 28.98(e) determination may prevent a timely filing with O&I. The Board's Executive Director plans to contact the Managing Director of O&I to find a mutually acceptable resolution to this potential problem. The Board expects these discussions to fully resolve this issue. However, if O&I does not accept a § 28.98(e)(1) complaint on timeliness grounds where an individual acted reasonably yet could not meet O&I's filing deadline, the individual should refile the complaint with the PAB/OGC. The Board expects that in such a situation, it would find "good cause"

under § 28.16(b) to waive its requirement that O&I review the claim. The Board has no intention of allowing an individual to forfeit their claim by undertaking a process the Board created when they experience delays outside of their control.

28.98(e)(1)

The GAO Office of General Counsel indicated that “the reference to a ‘claim of retaliation that could be raised under § 28.95(h)’ in § 28.98(e)(1) also is not clear.” “A claim of retaliation that could be raised under § 28.95(h)” means an EEO-related retaliation claim. The use of “retaliation” here is admittedly redundant because all claims that could be raised under § 28.95(h) are necessarily retaliation claims. The inclusion of it here is designed to help individuals better recognize that § 28.95(h) claims are retaliation claims because the term “retaliation” is not used in § 28.95(h).

The GAO Office of General Counsel commented on the reference to 5 U.S.C. 2302(b)(9) in § 28.98(e)(1). “This paragraph concerns ‘a claim of retaliation that could be raised under § 28.95(h), including the prohibited personnel practices listed in 5 U.S.C. 2302(b)(9).’ The reference to 5 U.S.C. § 2302(b)(9) appears to be overbroad. Section 2302(b)(9) lists several different prohibited personnel practices, including retaliation for filing whistleblower retaliation claims and disclosing information to an Inspector General. A ‘claim of retaliation that could be raised under § 28.95(h),’ however, is limited to EEO-related protected activity. The reference to section 2302(b)(9) therefore should be narrowed given the context.”

The Board recognizes that 5 U.S.C. 2302(b)(9) broadly covers reprisal for engaging in protected activities. Some of these protected activities cannot relate to the EEO laws, including disclosing information to the Inspector General or refusing to obey an order that would require a law, rule, or regulation violation. The reference to 5 U.S.C. 2302(b)(9) is intended to include only those claims that can be brought under sec. 2302(b)(9) that are related to the EEO process. It has no applicability to non-EEO sec. 2302(b)(9) claims. For example, if an employee brought a claim to the PAB/OGC that they were being retaliated against for disclosing information about a non-EEO topic to GAO’s Office of Inspector General, § 28.98(e) would not apply, and no analysis under § 28.98(e) would be performed. Section 28.98(e)(1) only applies to “claim[s] of retaliation that could be raised under § 28.95(h).” In

this example, § 28.95(h) does not apply because the claim is not related to “opposing any unlawful employment practice, or for participating in any manner in an investigation, hearing, or in any stage of an administrative or judicial proceeding, under any of the [EEO laws].”

The GAO Office of General Counsel commented that it was unclear what information the PAB/GC could use in making a § 28.98(e)(1) determination. “[The GAO Office of General Counsel] suggest[s] that this section should delineate the basis on which the determination is made: the employee’s submission(s), an investigation, or something else. It is also unclear how the PAB General Counsel’s decision is communicated to the employee.”

The Board expects the PAB/GC will primarily rely on the information submitted by the charging party’s description of their allegation. The Board does not anticipate any investigation will need to be performed for the PAB/GC to make this determination, but if some investigation is necessary, the final rule’s amendments would not prohibit it. The final rule’s amendments do not address the method of communication of a § 28.98(e) decision to an employee and defer to the PAB/GC on the best manner to perform this task.

The GAO Office of General Counsel comments that “[t]he determination of the General Counsel should be reviewable as it can have significant implications for employees and the exercise of their rights. The General Counsel’s decision also affects GAO with respect to investigating and resolving employee claims. Accordingly, we believe there should be a mechanism for the Board to review this determination.”

The Board agrees that § 28.98(e) determinations will have significant implications for employees and the exercise of their rights. Notably, § 28.98(e) will take away no employee rights. Individuals retain the same right to bring EEO claims directly to O&I pursuant to the discrimination complaint resolution process. The final rule attempts to clarify that certain EEO-related retaliation claims must be brought to O&I first. The discrimination complaint resolution process must proceed before the PAB/OGC can investigate them. Other EEO-related retaliation claims may be brought directly to the PAB/OGC and investigated without going through the discrimination complaint resolution process. The PAB/GC is tasked with applying the Board’s standard to

determine which EEO-related retaliation claims fall into each category.

The Board acknowledges that if the PAB/GC were to determine that a claim falls under § 28.98(e)(1)(ii), GAO would be directly affected as these claims would no longer go through O&I’s discrimination complaint review process where they could potentially be resolved. Specifically, GAO would be required to investigate the claims much earlier than if the claims were processed pursuant to the discrimination complaint review process. The Board considered various options on reviewability but elected to give the PAB/GC the sole authority to make § 28.98(e)(1) determinations for three reasons. First, other than stay requests the PAB has historically not been involved in the PAB/OGC’s processes before a petition is filed with the Board. Second, § 28.98(e)(1) was designed to give individuals certainty and allow § 28.98(e)(1)(ii) claims to be investigated more expediently without having to go through the O&I process, which can be quite lengthy. A review mechanism would defeat this purpose. Third, the Board Members do not want to be prejudiced by the parties’ descriptions of legal claims and evidence before a petition is even filed, because they may subsequently be assigned the case as an Administrative Judge or review it in an *en banc* appeal.

The PAB/OGC requested that the word “instruct” in § 28.98(e)(1)(i) be replaced with “advise” so the relevant portion would read, “the Board’s Office of General Counsel shall advise the charging party to file the claim as a complaint of discrimination pursuant to GAO Order 2713.2.” The PAB/OGC believes the word “instruct” was too strong, and by replacing it with “advise,” the PAB/OGC would be able to address § 28.98(e)(1)(i) claims similarly to how it already addresses EEO discrimination claims where the charging party has not exhausted the O&I process. The Board considered and agreed with this suggestion.

28.98(e)(2)

GAO’s Office of General Counsel and the PAB/OGC commented that the reference to § 28.95(g) in § 28.98(e)(2) should be a reference to § 28.95(h). The Board thanks the commenters for identifying the error and has made this change.

28.98(f)

The PAB/OGC commented that “Section 28.98(f) contains the sub-title, ‘Claims related to EEO matters pending with EEO.’ Instead of referencing ‘matters pending with EEO,’ the PAB/

OGC suggests that ‘EEO’ be replaced with ‘GAO’s Office of Opportunity and Inclusiveness’ or ‘GAO’s EEO Office.’” The Board considered and agreed with the suggestion, finding that it more accurately described the section than the previous title. The Board opted for the second of the two suggestions, replacing “EEO” with “GAO’s EEO Office.” The Board concluded that more individuals would understand a reference to “EEO Office” than O&I, which is a name and office unique to GAO. Additionally, O&I’s jurisdiction concerns more than EEO matters and the use of “GAO’s EEO Office” instead of “GAO’s Office of Opportunity and Inclusiveness” more accurately describes the type of claims addressed in § 28.98(f)(3).

28.98(f)(3)

The GAO Office of General Counsel commented, “Similar to our comment on § 28.98(e)(1) above, it is unclear what information the PAB General Counsel would use to determine whether a claim is ‘sufficiently related to a discrimination complaint.’” The Board anticipates that the PAB General Counsel would primarily rely upon information submitted by the charging party but could request and consider information from O&I about the potentially related claims.

The GAO Office of General Counsel had several questions related to holding a claim in abeyance. “What happens if the employee decides not to file a charge under § 28.98(b) for the related claim?” If no charge is filed regarding a claim, the PAB/OGC will not investigate that claim. “Is there a timeframe for the abeyance, or may the claim be held in abeyance indefinitely?” The PAB/GC should not hold a claim in abeyance longer than the time it takes O&I (GAO’s EEO Office) to process the sufficiently related claim(s) pursuant to the discrimination complaint review process, which culminates with either O&I’s dismissal of the claim or a Final Agency Decision. “Must the charging party/GAO be notified of the General Counsel’s determination to hold a claim in abeyance and/or to resume an investigation?” The PAB/OGC is expected to notify the charging party and GAO of both the GC’s determination to hold a claim in abeyance as well as to resume an investigation. The final rule’s amendments are silent on the method by which this information is to be transmitted, which is intended to give the PAB/OGC discretion on how to communicate these notifications.

Gender Neutral Pronouns

In addition to the amendments to § 28.95 and § 28.98, the final rule replaces the gendered pronouns in all the Board’s regulations with gender-neutral ones. The Women and Gender Liaison Group and the GAO Employees Organization, IFPTE Local 1921, supported these changes.

List of Subjects in 4 CFR Part 28

Administrative practice and procedure, Claims, Equal employment opportunity, Government employees.

For the reasons stated in the preamble, the Government Accountability Office amends title 4, chapter I, subchapter B, part 28 of the Code of Federal Regulations as follows:

PART 28—GOVERNMENT ACCOUNTABILITY OFFICE PERSONNEL APPEALS BOARD; PROCEDURES APPLICABLE TO CLAIMS CONCERNING EMPLOYMENT PRACTICES AT THE GOVERNMENT ACCOUNTABILITY OFFICE

■ 1. The authority citation for part 28 continues to read as follows:

Authority: 31 U.S.C. 753.

PART 28 [Amended]

■ 2. Amend part 28 by removing the word or phrase indicated in the left column of the table from wherever it appears in the part and adding the word or phrase indicated in the right column in its place:

Remove	Add
“him or her”	“them”.
“him- or herself”	“themselves”.
“himself or herself” ...	“themselves”.
“his or her”	“their”.
“his/her”	“their”.
“he or she has”	“they have”.
“he or she is”	“they are”.

§ 28.80 [Amended]

■ 3. Amend § 28.80 by removing the words “he or she determines” in the second sentence and adding in their place the words “they determine”.

■ 4. Amend § 28.95 by:

- a. Revising paragraph (c);
- b. In paragraph (d) removing the word “or” at the end of the paragraph; and
- c. Redesignate paragraph (e) as paragraph (g); and adding a new paragraph (e) and paragraphs (f) and (h).

The revision and additions read as follows:

§ 28.95 Purpose and scope.

* * * * *

(c) Section 6(d) of the Fair Labor Standard Act of 1938 as amended by the

Equal Pay Act of 1963 (29 U.S.C. 206(d)), prohibiting discrimination in wages on the basis of sex;

* * * * *

(e) Section 202 of the Genetic Information Nondiscrimination Act of 2008 (42 U.S.C. 2000ff–1), prohibiting discrimination on the basis of genetic information;

(f) Section 103 of the Pregnant Workers Fairness Act (42 U.S.C. 2000gg–1), prohibiting discrimination on the basis of pregnancy, childbirth or related medical conditions; or

* * * * *

(h) Prohibited discrimination also includes any materially adverse action taken against an employee or applicant for employment for opposing any unlawful employment practice, or for participating in any manner in an investigation, hearing, or in any stage of an administrative or judicial proceeding, under any of the statutes or laws identified in paragraphs (a) through (g) of this section.

■ 5. Amend § 28.98 by:

- a. Revising paragraphs (a), (b) introductory text, (b)(1) and (2);
- b. Revising the paragraph (c) heading;
- c. Adding the words “Office of” between the words “Board’s” and “General” in paragraph (c)(1);
- d. Revising the second, third, and fourth sentences of paragraph (c)(2) and revising paragraph (d);
- e. Redesignating paragraph (e) as paragraph (f) and adding a new paragraph (e); and
- f. Adding a heading to newly redesignated paragraph (f) and adding paragraph (f)(3).

The revisions and additions read as follows:

§ 28.98 Individual charges in EEO cases.

(a) *General rule for filing EEO claims.* Except as provided in paragraphs (c) and (e) of this section, an employee or applicant alleging prohibited discrimination (as defined in § 28.95) must first file a complaint with GAO in accordance with GAO Order 2713.2 and may not file directly with the Board’s General Counsel.

(b) *Time limits to file EEO claims with PAB/OGC.* After GAO processes a complaint in accordance with GAO Order 2713.2, an employee or applicant for employment may file an individual EEO charge with the Board’s General Counsel as follows:

(1) Within 30 days from the receipt by the charging party of a GAO decision rejecting the complaint in whole or part; or

(2) Whenever a period of more than 120 days has elapsed since the

complaint was filed, and a final GAO decision has not been issued; or

* * * * *

(c) *Special rules for certain adverse and performance-based actions.* * * *

(2) * * * If the employee elects to file a complaint of discrimination with GAO, they may still seek Board review of the matter by filing a charge with the Board's Office of General Counsel at the times authorized in paragraph (b) of this section. Where a discrimination complaint filed with GAO relates to one or more non-EEO issues that are within the Board's jurisdiction in addition to an EEO-related allegation, the subsequent charge filed with the Board's Office of General Counsel under paragraph (b) of this section shall be considered a timely appeal of the non-EEO issue(s). An employee will be deemed to have elected the EEO complaint process if they file a timely written complaint of discrimination with GAO before filing a charge with the Board's Office of General Counsel.

* * *

(d) *Special rules for RIF-based actions.* An individual alleging discrimination issues in connection with a RIF-based separation may follow the procedures outlined above in paragraph (c) of this section for adverse and performance-based actions, or may choose instead a third option. In accordance with the provisions of § 28.13, such an individual may challenge that action by filing directly with the PAB, thus bypassing both the Office of Opportunity and Inclusiveness and the Board's Office of General Counsel.

(e) *Special rules in certain retaliation actions.* (1) Except as outlined in paragraph (c) of this section, whenever a charging party raises a claim of retaliation that could be raised under § 28.95(h), including the prohibited personnel practices listed in 5 U.S.C. 2302(b)(9), and that claim has not already been filed pursuant to GAO Order 2713.2, the Board's General Counsel has authority to, and shall determine whether the claim reasonably relates to retaliation for filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2. The General Counsel's determination shall not be reviewable.

(i) If the Board's General Counsel determines the claim as described in this paragraph (e)(1) reasonably relates to retaliation for filing or assisting with a discrimination complaint filed pursuant to GAO Order 2713.2, the Board's Office of General Counsel shall advise the charging party to file the claim as a complaint of discrimination pursuant to GAO Order 2713.2.

(ii) If the Board's General Counsel determines the claim as described in this paragraph (e)(1) does not reasonably relate to retaliation for filing or assisting with a discrimination complaint pursuant to GAO Order 2713.2, the Board's Office of General Counsel shall investigate the claim in accordance with § 28.12.

(2) A charging party who files a claim that could be raised under § 28.95(h) may bring the retaliation claim both as a complaint of discrimination under § 28.95 and as a prohibited personnel practice under 5 U.S.C. 2302(b)(9).

(f) *Claims related to EEO matters pending with GAO's EEO Office.* * * *

(3) Where the Board's General Counsel concludes that one or more claims are sufficiently related to a discrimination complaint filed by the same claimant pursuant to GAO Order 2713.2 and that it would be appropriate to investigate all claims together, the Board's Office of General Counsel may hold the related claim(s) in abeyance until the Board's General Counsel receives a charge pursuant to paragraph (b) of this section with respect to the formal discrimination complaint or decides that the investigation should resume.

§ 28.112 [Amended]

■ 6. Amend § 28.112 in paragraph (a)(2) by removing the words "his, her or".

Carole W. Wilson,

Chair, Personnel Appeals Board, U.S. Government Accountability Office.

[FR Doc. 2024-13064 Filed 6-17-24; 8:45 am]

BILLING CODE 1610-02-P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC-2024-0034]

RIN 3150-AL07

List of Approved Spent Fuel Storage Casks: NAC International, Inc., NAC-UMS Universal Storage System, Certificate of Compliance No. 1015, Renewal of Initial Certificate and Amendment Nos. 1 Through 9

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of July 15, 2024, for the direct final rule that was published in the **Federal Register** on April 29, 2024.

This direct final rule amended the initial certificate and Amendment Nos. 1 through 9 of Certificate of Compliance No. 1015 for the NAC International, Inc., NAC-UMS Universal Storage System.

DATES: *Effective date:* The effective date of July 15, 2024, for the direct final rule published April 29, 2024 (89 FR 33184), is confirmed.

ADDRESSES: Please refer to Docket ID NRC-2024-0034 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2024-0034. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; email: Dawn.Forder@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The renewal of Certificate of Compliance No. 1015 and associated changes to the technical specifications, and final safety evaluation report are available in ADAMS under Accession ML24151A008.

- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Christopher Markley, Office of Nuclear Material Safety and Safeguards; telephone: 301-415-6293, email: Christopher.Markley@nrc.gov and Greg Trussell, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-6244, email: Gregory.Trussell@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION: On April 29, 2024 (89 FR 33184), the NRC published a direct final rule amending its regulations in part 72 of title 10 of the *Code of Federal Regulations* to the NAC International, Inc., NAC-UMS Universal Storage System listing within the “List of approved spent fuel storage casks” to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1 through 9 of Certificate of Compliance No. 1015. In the direct final rule, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on July 15, 2024. The NRC did not receive any comments on the direct final rule. Therefore, this direct final rule will become effective as scheduled.

Dated: June 13, 2024.

For the Nuclear Regulatory Commission.

Cindy K. Bladey,

Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2024–13356 Filed 6–17–24; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2023–2134; Special Conditions No. 25–845–SC]

Special Conditions: H4 Aerospace (UK) Ltd., Boeing Model 757–200 Airplane, Non-Rechargeable Lithium Battery and Battery System Installations; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments; correction.

SUMMARY: The FAA published a document in the **Federal Register** on May 15, 2024, issuing special conditions for non-rechargeable lithium batteries and battery systems on Boeing Model 757–200 airplanes, as modified by H4 Aerospace (UK) Ltd (H4). The document contained an incorrect reference to the Model 757–200’s type certificate number in the Applicability section of the special conditions.

DATES: This correction is effective on June 18, 2024.

FOR FURTHER INFORMATION CONTACT: Nazih Khaouly, Electrical Systems Unit, AIR–626A, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service, Federal Aviation

Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone (206) 231–3160; email Nazih.Khaouly@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

On May 7, 2024, the FAA issued final special conditions for the Boeing Model 757–200 airplanes, as modified by H4, which published in the **Federal Register** on May 15, 2024 (89 FR 42341). The FAA inevertantly published these special conditions referencing an incorrect type certificate number in the applicability section.

Correction

In the **Federal Register** of May 15, 2024 (89 FR 42341), make the following correction:

On page 42343, in the first column, in the Applicability section, line 7, correct “FAA STC ST00102IB” to read “A2NM”.

Issued in in Kansas City, Missouri, on June 13, 2024.

Patrick R. Mullen,

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

[FR Doc. 2024–13382 Filed 6–17–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0038; Project Identifier MCAI–2023–00645–R; Amendment 39–22756; AD 2024–10–10]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters. This AD was prompted by a report of an obstructed tail rotor (TR) pedal control that was blocked during flight. This AD requires a one-time inspection for proper positioning of the TR actuator harness and cable ties installation and, depending on the results, accomplishing corrective action, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 23, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 23, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2024–0038; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the EASA AD, 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.

Material Incorporated by Reference:

- For EASA material that is incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2024–0038.

FOR FURTHER INFORMATION CONTACT: Dan McCully, Aviation Safety Engineer, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (404) 474–5548; email william.mccully@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 Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters. The NPRM published in the **Federal Register** on February 2, 2024 (89 FR 7305). The NPRM was prompted by EASA AD 2023–0090, dated May 4, 2023 (EASA AD 2023–0090), issued by EASA, which is the Technical Agent for the Member States of the European Union. The EASA AD advises of a report where a TR pedal control was blocked during flight. Subsequent investigation found interference between the cable tie head of the TR actuator harness and the pin fastener of the tail gearbox cowling. To address this unsafe condition, the

manufacturer issued service information to provide instructions for inspecting the positioning of the cable ties on the yaw harness.

In the NPRM, the FAA proposed to require a one-time inspection for proper positioning of the TR actuator harness and cable ties installation and, depending on the results, accomplishing corrective action, as specified in EASA AD 2023–0090. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the EASA AD in the AD docket at *regulations.gov* under Docket No. FAA–2024–0038.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Related Service Information Under 14 CFR Part 51

The FAA reviewed EASA AD 2023–0090 which requires visually inspecting the position of the cable tie heads of the harness and corrective actions (replacing the cable ties) if necessary.

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

Other Related Service Information

The FAA also reviewed Airbus Helicopters Alert Service Bulletin No. AS365–22.00.17, Revision 1, dated June 27, 2023. This service information specifies procedures for accomplishing a one-time check of the position of the two cable tie heads in relation to the dzus prisoner of the right fairing of the tail gearbox and replacing the cable ties if necessary.

Differences Between This AD and the EASA AD

EASA AD 2023–0090 requires accomplishing the inspection within 165 flight hours, whereas this AD requires accomplishing the inspection within 100 hours time-in-service.

Costs of Compliance

The FAA estimates that this AD affects 29 helicopters of U.S. registry. Labor costs are estimated at \$85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Visually inspecting the position of the cable ties on the yaw harness and interpreting the results takes about 1 work-hour for an estimated cost of \$85 per helicopter and \$2,465 for the U.S. fleet.

The FAA estimates the following costs to do any necessary repairs that would be required based on the results of the required inspection. The agency has no way of determining the number of helicopters that might need this repair.

If required, removing and replacing a cable tie takes about 0.5 work-hour and parts cost up to about \$10 for an estimated cost of \$53 per cable tie replacement.

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:

2024–10–10 Airbus Helicopters:

Amendment 39–22756; Docket No. FAA–2024–0038; Project Identifier MCAI–2023–00645–R.

(a) Effective Date

This airworthiness directive (AD) is effective July 23, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code: 6720, Tail Rotor Control System.

(e) Unsafe Condition

This AD was prompted by a report of an obstructed tail rotor (TR) pedal control that was blocked during flight. The FAA is issuing this AD to detect and address interference of the tail rotor pedal control. The unsafe condition, if not addressed, could result in loss of yaw control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required

actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0090, dated May 4, 2023 (EASA AD 2023–0090).

(h) Exceptions to EASA AD 2023–0090

(1) Where paragraph (1) of EASA AD 2023–0090 requires compliance within 165 flight hours, this AD requires accomplishing paragraph (1) of EASA AD 2023–0090 within 100 hours time-in-service.

(2) Where EASA AD 2023–0090 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where the service information referenced in EASA AD 2023–0090 specifies discarding parts, this AD requires removing those parts from service.

(4) This AD does not adopt the “Remarks” section of EASA AD 2023–0090.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2023–0090 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

For more information about this AD, contact Dan McCully, Program Manager, International Validation Branch, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (404) 474–5548; email: william.mccully@faa.gov.

(l) 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) European Union Aviation Safety Agency (EASA) AD 2023–0090, dated May 4, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0090, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADS@easa.europa.eu; internet easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

(4) You may view this service information at the FAA Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on May 15, 2024.

Victor Wicklund,

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

[FR Doc. 2024–13348 Filed 6–17–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2493; Airspace Docket No. 23–AGL–25]

RIN 2120–AA66

Amendment of Jet Route J–89 and VOR Federal Airway V–161, and Establishment of Canadian RNAV Route Q–834; Northcentral United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Jet Route J–89 and Very High Frequency Omnidirectional Range (VOR) Federal Airway V–161 and establishes Canadian Area Navigation (RNAV) Route Q–834 in United States (U.S.) airspace. The FAA is taking this action due to the planned decommissioning of the Winnipeg, Manitoba (MB), Canada, VOR/Tactical Air Navigation (VORTAC) navigational aid (NAVAID). This action is in support of NAV CANADA’s NAVAID Modernization Program.

DATES: Effective date 0901 UTC, September 5, 2024. 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: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT:

Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modifies the Air Traffic Service (ATS) route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2023–2493 in the **Federal Register** (89 FR 1851; January 11, 2024), proposing to amend Jet Route J–89 and VOR Federal Airway V–161, and establish Canadian RNAV Routes Q–834 and T–765 in U.S. airspace due to the planned decommissioning of the Winnipeg, MB, Canada, VORTAC NAVAID in support of NAV CANADA’s NAVAID Modernization Program. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal.

One non-substantive comment, outside the scope of this action, was received.

Difference From the NPRM

Prior to publishing the NPRM for this action, the FAA published a NPRM for Docket No. FAA–2023–2326 in the **Federal Register** (88 FR 85519; December 8, 2023) which also proposed to establish two Canadian RNAV Route

T-765 segments in U.S. airspace. That proposed action was being taken due to NAV CANADA's planned decommissioning of the Thunder Bay, Ontario, Canada, VOR. The proposed new T-765 route segments in that action were to mitigate the removal of the affected VOR Federal Airway V-133 segments; whereas the proposed T-765 routes segments in this action were proposed to mitigate the removal of the VOR Federal Airway V-161 segments affected by the planned decommissioning of the Winnipeg, MB, Canada, VORTAC. Both actions would provide route continuity and cross border connectivity with the T-765 route segments being established by NAV CANADA within Canadian airspace.

The FAA has decided to establish all Canadian RNAV Route T-765 route segments in a single docket action and selected Docket No. FAA-2023-2326 to accomplish that. Therefore, the proposed T-765 route segments being established by this action are removed and will be incorporated in the final rule for Docket No. FAA-2023-2326 accordingly. This rule only amends Jet Route J-89 and VOR Federal Airway V-161, and establishes Canadian RNAV Route Q-834 in U.S. airspace.

Incorporation by Reference

Jet Routes are published in paragraph 2004, Canadian Area Navigation Routes (Q-routes) are published in paragraph 2007, and VOR Federal Airways are published in paragraph 6010(a) of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the ADDRESSES section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by amending Jet Route J-89 and VOR Federal Airway V-161, and by establishing Canadian RNAV Route Q-834 in U.S. airspace. This action is necessary due to the planned decommissioning of the Winnipeg, MB, Canada, VORTAC in support of NAV CANADA's NAVAID Modernization Program. The ATS route actions are described below.

J-89: Prior to this final rule, J-89 extended between the Louisville, KY, VORTAC and the Winnipeg, MB, Canada, VORTAC, excluding the airspace within Canada. The route segment between the Duluth, MN, VORTAC and the Winnipeg VORTAC is removed. As amended, the route is changed to now extend between the Louisville VORTAC and the Duluth VORTAC.

Q-834: Q-834 is a new Canadian RNAV route established within U.S. airspace extending between the Duluth, MN, VORTAC and the ALBNG, MN, waypoint (WP) that replaces the "CFHBZ" Computer Navigation Fix (CNF) on the U.S./Canada border. The new RNAV route mitigates the J-89 route segment removal and provides route continuity and cross-border connectivity with the Q-834 route being established by NAV CANADA within Canadian airspace between the ALBNG WP and the Winnipeg, MB, Canada, area.

V-161: Prior to this final rule, V-161 extended between the Three Rivers, TX, VORTAC and the Tulsa, OK, VORTAC; between the Butler, MO, VORTAC and the Gopher, MN, VORTAC; and between the International Falls, MN, VOR/Distance Measuring Equipment (VOR/DME) and the Winnipeg, MB, Canada, VORTAC, excluding the airspace within Canada. The airway segment between the International Falls VOR/DME and the Winnipeg VORTAC is removed. As amended, the airway is changed to now extend between the Three Rivers VORTAC and the Tulsa VORTAC, and between the Butler VORTAC and the Gopher VORTAC.

The NAVAID radials listed in the VOR Federal Airway V-161 description in the regulatory text of this final rule are unchanged and stated in degrees True north.

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 so 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 (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5-6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5-2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 14 CFR 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 JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J-89 [Amended]

From Louisville, KY; Boiler, IN;
Northbrook, IL; Badger, WI; to Duluth, MN.

* * * * *

*Paragraph 2007 Canadian Area Navigation
Routes.*

* * * * *

Q-834 Duluth, MN (DLH) to ALBNG, MN [New]

Duluth, MN (DLH)	VORTAC	(Lat. 46°48'07.79" N, long. 092°12'10.33" W)
ALBNG, MN	WP	(Lat. 48°59'58.05" N, long. 095°38'10.41" W)

* * * * *

Paragraph 6010(a) VOR Federal Airways.

* * * * *

V-161 [Amended]

From Three Rivers, TX; Center Point, TX;
Llano, TX; INT Llano 026° and Millsap, TX,
193° radials; Millsap; Bowie, TX; Ardmore,
OK; Okmulgee, OK; to Tulsa, OK. From
Butler, MO; Napoleon, MO; Lamoni, IA; Des
Moines, IA; Mason City, IA; Rochester, MN;
Farmington, MN; to Gopher, MN.

* * * * *

Issued in Washington, DC, on June 11,
2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024-13209 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2024-1226; **Airspace**
Docket No. 23-AGL-40]

RIN 2120-AA66

Revocation of VOR Federal Airway V-360; Northcentral United States

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Very High Frequency Omnidirectional Range (VOR) Federal Airway V-360. The FAA is taking this action due to the Midland, Ontario (ON), Canada, VOR/Distance Measuring Equipment (VOR/DME) navigational aid (NAVAID) having been decommissioned in 2022. This action supports NAV CANADA's NAVAID Modernization Program efforts by removing unusable airway segments within United States airspace affected by NAV CANADA's programmatic actions.

DATES: Effective date 0901 UTC, September 5, 2024. 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: A copy of this final rule and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

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 the 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 modifies the Air Traffic Service (ATS) route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

NAV CANADA, which operates Canada's civil air navigation service, has been implementing changes to Canada's instrument flight rules navigational infrastructure as part of their NAVAID Modernization Program. This

modernization program is designed to enhance the efficiency of Canada's flying operations by taking advantage of performance-based navigation and area navigation avionics capabilities. As part of that modernization program, NAV CANADA decommissioned the Midland, ON, VOR/DME, which provided course guidance for V-360 cross-border connectivity between the United States and Canada, effective December 29, 2022.

After the Midland, ON, VOR/DME was decommissioned by NAV CANADA in 2022, the affected V-360 airway segment within Canadian airspace was removed from the aeronautical charts; however, the rulemaking action to remove the remaining portion of V-360 within United States airspace was not accomplished concurrently. The portion of V-360 that remains within United States airspace is an eight nautical mile segment that extends between the Sault Ste Marie, MI, VOR/DME and the "CFHMH" Computer Navigation Fix (CNF) which is located on the United States/Canada border. The remaining V-360 airway segment is no longer usable for cross-border connectivity between the United States and Canada since there is no Canadian airway for the airway segment to connect to. Additionally, CNFs are not used for any air traffic control purpose and are not available for pilots to use for point-to-point navigation (proceed direct), filing a flight plan, or in communications between aircraft and air traffic control (ATC).

As such, the remaining portion of V-360 within United States airspace between the Sault Ste Marie, MI, VOR/DME and the "CFHMH" CNF located on the United States/Canada border serves no useful purpose for ATC or pilots.

Incorporation by Reference

VOR Federal airways are published in paragraph 6010(a) of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly

available as listed in the **ADDRESSES** section of this document. This amendment will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking VOR Federal Airway V-360 due to NAV CANADA having decommissioned the Midland, ON, Canada, VOR/DME NAVAID in 2022. The V-360 airway segment within United States airspace no longer provides cross-border connectivity with any airways or routes within Canada and is unusable by ATC and pilots alike. The airway action is described below.

V-360: Prior to this final rule, V-360 extended between the Sault Ste Marie, MI, VOR/DME and the Midland, ON, Canada, VOR/DME, excluding the airspace within Canada. The airway is removed in its entirety due to the decommissioning of the Midland, ON, VOR/DME.

This action revoking V-360 does not affect any ATC cross-border operating requirements as the airway segment within United States airspace is unusable due to NAV CANADA having decommissioned the Midland, ON, VOR/DME in 2022; therefore, notice and public procedure under 5 U.S.C. 553(b) is unnecessary.

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 so 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 of revoking VOR Federal Airway V-360 qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA

Order 1050.1F, “Environmental Impacts: Policies and Procedures,” paragraph 5–6.5.a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 14 CFR 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 JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V-360 [Removed]

* * * * *

Issued in Washington, DC, on June 11, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–13200 Filed 6–17–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–0562; Airspace Docket No. 23–ANM–24]

RIN 2120–AA66

Establishment of Class E Airspace; Lincoln Airport, Lincoln MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet or more above the surface of the earth at Lincoln Airport, Lincoln, MT. This action supports the airport’s transition from visual flight rules (VFR) to instrument flight rules (IFR) operations.

DATES: Effective date 0901 UTC, September 5, 2024. 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: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Keith T. Adams, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S. 216th Street, Des Moines, WA 98198; telephone (206) 231–2428.

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 the 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 establishes Class E airspace to support IFR operations at Lincoln Airport, Lincoln, MT.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2024–0562 in the **Federal Register** (89 FR 19514; March 19, 2024), proposing to establish Class E airspace at Lincoln Airport, MT. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. Two comments were received in favor of the proposal.

Incorporation by Reference

Class E5 airspace area is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71, to establish Class E airspace extending upward from 700 feet above the surface of the earth at Lincoln Airport, MT.

The airport is transitioning from VFR to IFR operations. Class E airspace is established within a 2.6-mile radius of the airport, within 1.1 miles on either side of the airport's 056° bearing extending 9.2 miles northeast of the airport, and within 2.6 miles on either side of the airport's 251° bearing extending 9 miles southwest of the airport. This airspace contains arriving IFR aircraft descending below 1,500 feet above the surface and departing aircraft until it reaches 1,200 feet above the surface.

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 so 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 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 14 CFR 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 JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

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

* * * * *

ANM MT E5 Lincoln, MT [New]

Lincoln Airport, MT

(Lat. 46°57'17" N., long. 112°39'01" W)

That airspace extending upward from 700 feet above the surface within a 2.6-mile radius of the airport, within 1.1 miles on either side of the airport's 056° bearing extending 9.2 miles northeast of the airport, and within 2.6 miles on either side of the airport's 251° bearing extending 9 miles southwest of the airport.

* * * * *

Issued in Des Moines, Washington, on June 7, 2024.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2024–13177 Filed 6–17–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–0635; Airspace Docket No. 23–AWP–20]

RIN 2120–AA66

Modification of Class E Airspace; Yerington Municipal Airport, Yerington, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the Class E airspace extending upward from 700 feet or more above the surface of the earth at Yerington Municipal Airport, Yerington, NV. This action supports the airport's transition from visual flight rules (VFR) to instrument flight rules (IFR) operations.

DATES: Effective date 0901 UTC, September 5, 2024. 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: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT:

Keith T. Adams, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231-2428.

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 the 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 modifies Class E airspace to support IFR operations at Yerington Municipal Airport, Yerington, NV.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA-2024-0635 in the **Federal Register** (89 FR 20879; March 26, 2024), proposing to modify Class E airspace at Yerington Municipal Airport, NV. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Class E5 airspace area is published in paragraph 6005, respectively, of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 to modify Class E airspace extending upward from 700 feet above the surface of the earth at Yerington Municipal Airport, NV.

The Class E airspace area extending upward from 700 feet above the surface of the earth is modified to a 5.2-mile radius of the airport, within 5.2 miles each side of the airport's 065° bearing extending from the 5.2-mile radius to 8.9 miles northeast of the airport, and within 3 miles each side of the airport's 184° bearing, extending from the 5.2-mile radius to 12.7 miles south of the airport. The modified airspace accommodates IFR arrival operations descending through 1,500 feet above the surface and departing IFR operations until reaching 1,200 feet above the surface.

Additionally, the airport's legal description included references to the Mustang and Lovelock very high frequency omnidirectional range and tactical air navigations (VORTAC). These are no longer needed to describe the airspace and have been removed and replaced by the Yerington Airport Reference Point geographical coordinates.

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 so 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 5-6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 14 CFR 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 JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

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

* * * * *

AWP NV E5 Yerington, NV [Amended]

Yerington Municipal Airport, NV
(Lat. 39°00'19" N, long. 111°09'24" W)

That airspace extending upward from 700 feet above the surface within a 5.2-mile radius of the airport, within 5.2 miles each side of the 065° bearing extending from the 5.2-mile radius to 8.9 miles northeast of the airport, and within 3 miles each side of the 184° bearing, extending from the 5.2-mile radius to 12.7 miles south of the airport.

* * * * *

Issued in Des Moines, Washington, on June 5, 2024.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2024-13179 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2023-2346; Airspace Docket No. 22-AAL-31]

RIN 2120-AA66

Revocation of Colored Federal Airway Amber 1 (A-1) in Alaska

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Amber 1 (A-1) in Alaska due to the pending decommissioning of

the navigational aids (NAVAID) that support the airway.

DATES: Effective date 0901 UTC, September 5, 2024. 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: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modifies the Air Traffic Service (ATS) route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published a NPRM for Docket No. FAA 2023–2346 in the **Federal Register** (88 FR 88283; December 21, 2023), proposing to revoke A–1 in Alaska. Interested parties were invited to participate in this rulemaking effort by submitting written

comments on the proposal to the FAA. No comments were received.

Incorporation by Reference

Colored Federal Airways are published in paragraph 6009 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal Airway A–1, in its entirety in Alaska. The FAA is taking this action due to the pending decommissioning of its supporting NAVAIDs.

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 so 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 airspace action of revoking Colored Federal Airway A–1 in Alaska qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas,

airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 14 CFR 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 JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6009(c) Amber Federal Airways.

A–1 [Removed]

* * * * *

Issued in Washington, DC, on June 11, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–13207 Filed 6–17–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2023–2326; Airspace
Docket No. 23–AGL–21]

RIN 2120–AA66

**Amendment of VOR Federal Airways
V–13, V–133, and V–300, and United
States RNAV Route T–331;
Establishment of Canadian RNAV
Routes Q–924, T–765, T–776, and T–
810; and Revocation of Jet Route J–
533 and VOR Federal Airway V–348;
Northcentral United States**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Very High Frequency Omnidirectional Range (VOR) Federal Airways V–13, V–133, and V–300, and United States (U.S.) Area Navigation (RNAV) Route T–331; establishes Canadian RNAV Routes Q–924, T–765, T–776, and T–810 in U.S. airspace; and revokes Jet Route J–533 and VOR Federal Airway V–348. The FAA is taking this action due to the planned decommissioning of the Thunder Bay, Ontario (ON), Canada, VOR navigational aid (NAVAID). This action supports NAV CANADA’s NAVAID Modernization Program within Canada.

DATES: Effective date 0901 UTC, September 5, 2024. 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: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800

Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modifies the Air Traffic Service (ATS) route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2023–2326 in the **Federal Register** (88 FR 85519; December 8, 2023), proposing to amend VOR Federal Airways V–13, V–133, and V–300, and RNAV Route T–331; establish Canadian RNAV Routes Q–924, T–765, T–776, and T–810 in U.S. airspace; and revoke Jet Route J–533 and VOR Federal Airway V–348 due to the planned decommissioning of the Thunder Bay, ON, Canada, VOR NAVAID. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Differences From the NPRM

After publishing the NPRM in the **Federal Register**, the FAA identified an error in the V–300 proposed amendment discussed in The Proposal section of the preamble. In the paragraph addressing V–300 amendments, it stated the FAA proposed to remove the airway segment between the Victoria VOR/Distance Measuring Equipment (VOR/DME) and the Vancouver VOR/DME to match the airway segment removal action NAV CANADA is taking. However, at the end of the paragraph, it stated that as amended, the airway would be changed to extend between the Victoria VOR/DME and the Vancouver VOR/DME, in error. This action removes the V–300 airway segment between the Victoria VOR/DME and the Vancouver VOR/DME as it was published in the proposed regulatory text of the NPRM and is corrected in this final rule.

The FAA also identified an error in the proposed Canadian RNAV Route T–810 description in the proposed regulatory text of the NPRM. The CATGA, MI, Waypoint (WP) listed in the T–810 description incorrectly listed the latitude geographic coordinate for the WP as “lat. 46°28’11.51” N.” The correct latitude coordinate information for the CATGA WP is “lat. 46°28’11.52” N.” This action corrects the CATGA WP latitude geographic coordinate listed in the Canadian RNAV Route T–810 description in this final rule.

Additionally, subsequent publication of the NPRM, the FAA published a NPRM for Docket No. FAA–2023–2493 in the **Federal Register** (89 FR 1851; January 11, 2024), that also proposed to establish two Canadian RNAV Route T–765 segments in U.S. airspace due to NAV CANADA’s planned decommissioning of the Winnipeg, Manitoba (MB), Canada, VOR/Tactical Air Navigation (VORTAC) NAVAID. No substantive comments to that NPRM were received. The T–765 route segments in that action were to mitigate the removal of the VOR Federal Airway V–161 segments affected by the Winnipeg VORTAC decommissioning and to provide route continuity and cross border connectivity with the T–765 route segments being established by NAV CANADA within Canadian airspace. The FAA has decided to establish all of the proposed Canadian RNAV Route T–765 segments in a single docket action and selected Docket No. FAA–2023–2326 to accomplish that. Therefore, the T–765 route segment actions proposed in Docket No. FAA–2023–2493 have been removed from that docket and are included in this final rule.

Finally, prior to the NPRM, the FAA published a rule for Docket No. FAA–2023–0501 in the **Federal Register** (88 FR 30896; May 15, 2023), amending RNAV Route T–331 by renaming the Squaw Valley, CA, VOR/DME route point to become the Palisades, CA, VOR/DME. That editorial amendment, effective August 10, 2023, did not affect the T–331 route alignment or structure. In the NPRM for this action, the T–331 Palisades, CA, VOR/DME route point was incorrectly listed as the Squaw Valley, CA, VOR/DME. This rule corrects that error by listing the affected T–331 route point as the Palisades VOR/DME.

Incorporation by Reference

Jet Routes are published in paragraph 2004, Canadian Area Navigation Routes (Q-routes) are published in paragraph 2007, VOR Federal Airways are published in paragraph 6010(a), United

States Area Navigation Routes (T-routes) are published in paragraph 6011, and Canadian Area Navigation Routes (T-routes) are published in paragraph 6013 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by amending VOR Federal Airways V-13, V-133, and V-300, and United States RNAV Route T-331; establishing Canadian RNAV Routes Q-924, T-765, T-776, and T-810 in U.S. airspace; and revoking Jet Route J-533 and VOR Federal Airway V-348. This action is being taken due to the planned decommissioning of the Thunder Bay, ON, Canada, VOR by NAV CANADA in support of their NAVAID Modernization Program. The ATS route actions are described below.

J-533: Prior to this final rule, J-533 extended between the Duluth, MN, VORTAC and the U.S./Canada border via the Duluth to Thunder Bay, ON, direct radial. The Jet Route is removed in its entirety.

Q-924: Q-924 is a new Canadian RNAV route established within U.S. airspace extending between the Duluth, MN, VORTAC and the BEKRR, MI, WP that replaces the “MPCEG” Computer Navigation Fix (CNF) on the U.S./Canada border. The new RNAV route mitigates the J-533 revocation and provides route continuity and cross-border connectivity with the Q-924 route segment being established by NAV CANADA within Canadian airspace.

V-13: Prior to this final rule, V-13 extended between the Mc Allen, TX, VOR/DME and the Razorback, AR, VORTAC; between the Butler, MO, VORTAC and the Farmington, MN, VORTAC; and between the Duluth, MN, VORTAC and the Thunder Bay, ON, Canada, VOR/DME, excluding the airspace outside the United States. The airway segment between the Duluth VORTAC and the Thunder Bay VOR/DME is removed. As amended, the airway is changed to now extend between the Mc Allen VOR/DME and the Razorback VORTAC, and between

the Butler VORTAC and the Farmington VORTAC.

V-133: Prior to this final rule, V-133 extended between the intersection of the Charlotte, NC, VOR/DME 305° and Barretts Mountain, NC, VOR/DME 197° radials (LINCO Fix) and the Zanesville, OH, VOR/DME; and between the Saginaw, MI, VOR/DME and the Red Lake, ON, Canada, VOR, excluding the airspace within Canada. The airway segment between the Houghton, MI, VOR/DME and the International Falls, MN, VOR/DME is removed. As amended, the airway is changed to now extend between the Charlotte VOR/DME 305° and Barretts Mountain VOR/DME 197° radials (LINCO Fix) and the Zanesville VOR/DME, between the Saginaw VOR/DME and the Houghton VOR/DME, and between the International Falls VOR/DME and the Red Lake, ON, VOR. The airspace within Canada continues to be excluded.

V-300: Prior to this final rule, V-300 extended between the Victoria, British Columbia (BC), Canada, VOR/DME and the Vancouver, BC, Canada, VOR/DME; between the Thunder Bay, ON, Canada, VOR/DME and the Wiarton, ON, Canada, VOR/DME; and between the Sherbrooke, Quebec (PQ), Canada, VOR and the Fredericton, New Brunswick (NB), Canada, VORTAC, excluding the airspace within Canada. The airway segment between the Thunder Bay VOR/DME and the Sault Ste Marie, MI, VOR/DME is removed. Additionally, the airway segment between the Victoria VOR/DME and the Vancouver VOR/DME is removed to match the airway segment removal action NAV CANADA took and was effective November 30, 2023. Finally, the airway segment between the Sherbrooke VOR and the Fredericton VORTAC is removed due to NAV CANADA's actions removing the segments west and east of the portion of the airway segment within U.S. airspace and the previously existing cross-border connectivity no longer provided. As amended, the airway is changed to now extend between the Sault Ste Marie VOR/DME and the Wiarton, ON, VOR/DME. The airspace within Canada continues to be excluded.

V-348: Prior to this final rule, V-348 extended between the Thunder Bay, ON, Canada VOR/DME and the Sudbury, ON, Canada VOR, excluding the airspace within Canada. The airway segment between the Thunder Bay VOR/DME and the Sault Ste Marie, MI, VOR/DME is removed due to the planned decommissioning of the Thunder Bay VOR. Additionally, the airway segment between the Sault Ste Marie VOR/DME and the Sudbury VOR

is removed due to the Sudbury VOR having been decommissioned by NAV CANADA in 2021. The airway is removed in its entirety.

T-331: Prior to this final rule, T-331 extended between the FRAME, CA, Fix and the MECNU, MN, Fix. The route is extended northward to the BEKRR, MN, WP that replaces the “CFGDB” CNF on the U.S./Canada border and the MECNU Fix route point is removed from the route description. The MECNU Fix will remain charted and appear to be on the route but will not be listed as a route point in the part 71 route description. As amended, the route is changed to now extend between the FRAME Fix and the BEKRR WP and provides mitigation for the V-13 airway segment removal.

T-765: T-765 is a new Canadian RNAV route established within U.S. airspace extending between the Houghton, MI, VOR/DME and the BBLUE, MI, WP that replaces the “KJDRS” CNF on the U.S./Canada border; between the ASIXX, MN, WP that replaces the “KJDPL” CNF on the U.S./Canada border and the KORTY, MN, WP that replaces the “CFFQV” CNF on the U.S./Canada border, via the International Falls, MN, VOR/DME; and between the LCROS, MN, WP that replaces the “CFXDP” CNF on the U.S./Canada border and the CALDU, MN, WP that replaces the “CFZMG” CNF on the U.S./Canada border. The new RNAV route mitigates the V-133 airway segment removal due to the Thunder Bay VOR being decommissioned and the V-161 airway segment removal due to the Winnipeg, MB, Canada VORTAC being decommissioned as discussed in the Differences from the NPRM section. The new RNAV Route, T-765, segments in U.S. airspace provide route continuity and cross-border connectivity with the T-765 route segments being established by NAV CANADA within Canadian airspace.

T-776: T-776 is a new Canadian RNAV route established within U.S. airspace extending between the KAYCY, MI, WP that replaces the “CFZSV” CNF on the U.S./Canada border and the KMNGO, MI, WP that replaces the “CFXKN” CNF on the U.S./Canada border; between the NCOLY, MI, WP that replaces the “CWSKQ” CNF on the U.S./Canada border and the RRBEE, MI, WP that replaces the “KJSCR” CNF on the U.S./Canada border; and between the SKOWT, MI, WP that replaces the “KJSTL” CNF on the U.S./Canada border and the Sault Ste Marie, MI, VOR/DME. The new RNAV route mitigates the V-348 revocation and provides route continuity and cross-border connectivity with the T-776

route segments being established by NAV CANADA within Canadian airspace.

T-810: T-810 is a new Canadian RNAV route established within U.S. airspace extending between the BERDD, MI, WP that replaces the “KJNGG” CNF on the U.S./Canada border and the JEORG, MI, WP that replaces the “CFKJR” CNF on the U.S./Canada border; and between the CATGA, MI, WP that replaces the CATGA, MI, Fix on the U.S./Canada border and the Sault Ste Marie, MI, VOR/DME. The new RNAV route mitigates the V-300 airway segment removal and provides route continuity and cross-border connectivity with the T-810 route segments being established by NAV CANADA within Canadian airspace.

The NAVAID radials listed in the VOR Federal airway descriptions in the regulatory text of this final rule are unchanged and stated in degrees True north.

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 so 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 (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5i, which categorically excludes from further environmental impact review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have

a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 14 CFR 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 JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J-533 [Removed]

* * * * *

Paragraph 2007 Canadian Area Navigation Routes.

* * * * *

Q-924 Duluth, MN (DLH) to BEKRR, MN [New]

Duluth, MN (DLH)
BEKRR, MN

VORTAC
WP

(Lat. 46°48′07.79″ N, long. 092°12′10.33″ W).
(Lat. 48°00′25.78″ N, long. 089°55′39.40″ W).

* * * * *

Paragraph 6010(a) VOR Federal Airways.

* * * * *

V-13 [Amended]

From Mc Allen, TX; INT Mc Allen 060° radial and Corpus Christi, TX, 178° radials; Corpus Christi; INT Corpus Christi 039° and Palacios, TX, 241° radials; Palacios; Humble, TX; Lufkin, TX; Belcher, LA; Texarkana, AR; Rich Mountain, OK; Fort Smith, AR; INT Fort Smith 006° and Razorback, AR, 190° radials; to Razorback. From Butler, MO; Napoleon,

MO; Lamoni, IA; Des Moines, IA; Mason City, IA; to Farmington, MN.

* * * * *

V-133 [Amended]

From INT Charlotte, NC, 305° and Barretts Mountain, NC, 197° radials; Barretts Mountain; Charleston, WV; to Zanesville, OH. From Saginaw, MI; Traverse City, MI; Escanaba, MI; Sawyer, MI; to Houghton, MI. From International Falls, MN; to Red Lake, ON, Canada. The airspace within Canada is excluded.

* * * * *

V-300 [Amended]

From Sault Ste Marie, MI; to Wiarton, ON, Canada. The airspace within Canada is excluded.

* * * * *

* * * * *

V-348 [Removed]

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T-331 FRAME, CA to BEKRR, MN [Amended]

FRAME, CA
NTELL, CA
KARNN, CA
VINCO, CA
NORCL, CA

FIX
WP
FIX
FIX
WP

(Lat. 36°36′46.74″ N, long. 119°40′25.53″ W)
(Lat. 36°53′58.99″ N, long. 119°53′22.21″ W)
(Lat. 37°09′03.79″ N, long. 121°16′45.22″ W)
(Lat. 37°22′35.11″ N, long. 121°42′59.52″ W)
(Lat. 37°31′02.66″ N, long. 121°43′10.60″ W)

MOVDD, CA	WP	(Lat. 37°39'40.88" N, long. 121°26'53.53" W)
EVETT, CA	WP	(Lat. 38°00'36.11" N, long. 121°07'48.14" W)
TIPRE, CA	WP	(Lat. 38°12'21.00" N, long. 121°02'09.00" W)
Palisades, CA (SWR)	VOR/DME	(Lat. 39°10'49.16" N, long. 120°16'10.60" W)
TRUCK, CA	FIX	(Lat. 39°26'15.67" N, long. 120°09'42.48" W)
Mustang, NV (FMG)	VORTAC	(Lat. 39°31'52.60" N, long. 119°39'21.87" W)
Lovelock, NV (LLC)	VORTAC	(Lat. 40°07'30.95" N, long. 118°34'39.34" W)
Battle Mountain, NV (BAM)	VORTAC	(Lat. 40°34'08.69" N, long. 116°55'20.12" W)
TULIE, ID	WP	(Lat. 42°37'58.49" N, long. 113°06'44.54" W)
AMFAL, ID	WP	(Lat. 42°45'56.67" N, long. 112°50'04.64" W)
Pocatello, ID (PIH)	VOR/DME	(Lat. 42°52'13.38" N, long. 112°39'08.05" W)
VIPUC, ID	FIX	(Lat. 43°21'09.64" N, long. 112°14'44.08" W)
Idaho Falls, ID (IDA)	VOR/DME	(Lat. 43°31'08.42" N, long. 112°03'50.10" W)
SABAT, ID	FIX	(Lat. 44°00'59.71" N, long. 111°39'55.04" W)
Billings, MT (BIL)	VORTAC	(Lat. 45°48'30.81" N, long. 108°37'28.73" W)
EXADE, MT	FIX	(Lat. 47°35'56.78" N, long. 104°32'40.61" W)
JEKOK, ND	WP	(Lat. 47°59'31.05" N, long. 103°27'17.51" W)
FONIA, ND	FIX	(Lat. 48°15'35.07" N, long. 103°10'37.54" W)
Minot, ND (MOT)	VOR/DME	(Lat. 48°15'37.21" N, long. 101°17'13.46" W)
GICHI, ND	WP	(Lat. 48°06'54.20" N, long. 098°54'45.14" W)
Grand Forks, ND (GFK)	VOR/DME	(Lat. 47°57'17.40" N, long. 097°11'07.33" W)
Thief River Falls, MN (TVF)	VOR/DME	(Lat. 48°04'09.53" N, long. 096°11'11.31" W)
BLUOX, MN	FIX	(Lat. 47°34'33.13" N, long. 095°01'29.11" W)
Duluth, MN (DLH)	VORTAC	(Lat. 46°48'07.79" N, long. 092°12'10.33" W)
BEKRR, MN	WP	(Lat. 48°00'25.78" N, long. 089°55'39.40" W)

* * * * *

Paragraph 6013 Canadian Area Navigation Routes.

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T-765 Houghton, MI (CMX) to CALDU, MN [New]

Houghton, MI (CMX)	VOR/DME	(Lat. 47°10'12.94" N, long. 088°29'07.41" W)
BBLUE, MI	WP	(Lat. 48°01'10.44" N, long. 089°13'39.22" W)
and		
ASIXX, MN	WP	(Lat. 48°30'56.17" N, long. 092°37'34.98" W)
International Falls, MN (INL)	VOR/DME	(Lat. 48°33'56.87" N, long. 093°24'20.44" W)
KORTY, MN	WP	(Lat. 48°35'20.54" N, long. 093°27'59.55" W)
and		
LCROS, MN	WP	(Lat. 49°03'44.39" N, long. 094°44'18.17" W)
CALDU, MN	WP	(Lat. 49°12'42.53" N, long. 095°09'11.89" W)

* * * * *

T-776 KAYCY, MI to Sault Ste Marie, MI [New]

KAYCY, MI	WP	(Lat. 48°10'13.28" N, long. 088°51'36.53" W)
KMNGO, MI	WP	(Lat. 47°57'14.09" N, long. 087°27'15.24" W)
and		
NCOLY, MI	WP	(Lat. 47°01'58.21" N, long. 085°11'47.29" W)
RRBEE, MI	WP	(Lat. 46°45'54.88" N, long. 084°48'45.86" W)
and		
SKOWT, MI	WP	(Lat. 46°29'46.17" N, long. 084°25'57.74" W)
Sault Ste Marie, MI (SSM)	VOR/DME	(Lat. 46°24'43.60" N, long. 084°18'53.54" W)

* * * * *

T-810 BERDD, MI to Sault Ste Marie (SSM) [New]

BERDD, MI	WP	(Lat. 48°06'41.75" N, long. 089°00'14.29" W)
AVALI, MI	FIX	(Lat. 46°44'02.48" N, long. 085°07'59.96" W)
SRADE, MI	FIX	(Lat. 46°39'29.38" N, long. 084°56'42.98" W)
JEORG, MI	WP	(Lat. 46°32'50.81" N, long. 084°39'34.39" W)
and		
CATGA, MI	WP	(Lat. 46°28'11.52" N, long. 084°27'41.15" W)
Sault Ste Marie, MI (SSM)	VOR/DME	(Lat. 46°24'43.60" N, long. 084°18'53.54" W)

Issued in Washington, DC, on June 11, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024-13178 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 73**

[Docket No. FAA–2023–1972; Airspace
Docket No. 22–AGL–39]

RIN 2120–AA66

Modification of Restricted Areas R–4201A and R–4201B; Camp Grayling, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the designated altitudes of restricted area R–4201B, Camp Grayling, MI, by raising the restricted area ceiling from 9,000 feet mean sea level (MSL) to 23,000 feet MSL to match the ceiling of the adjacent restricted area R–4201A, Camp Grayling, MI. Additionally, this action adds a “tie-in” boundary point in the R–4201A boundaries description to ensure a shared R–4201A and R–4201B boundary. Lastly, this action makes minor administrative changes to the R–4201B time of designation information and the R–4201A and R–4201B using agency information to standardize the format of the information provided describing these restricted areas.

DATES: Effective date 0901 UTC, September 5, 2024.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 would modify the restricted area airspace at Camp Grayling, MI, to enhance aviation safety and accommodate essential U.S. Army training requirements.

History

The FAA published a NPRM for Docket No. FAA–2023–1972 in the **Federal Register** (88 FR 70915; October 13, 2023), proposing to raise the designated altitude ceiling of restricted area R–4201B, Camp Grayling, MI, from 9,000 feet MSL to 23,000 feet MSL, adding a “tie-in” boundary point in the R–4201A boundaries description to ensure a shared R–4201A and R–4201B boundary, and making minor administrative changes to the R–4201B time of designation information and the R–4201A and R–4201B using agency information. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. Two comments were received. Both comments supported the proposed restricted area amendment actions.

The Rule

This action amends 14 CFR part 73 by raising the designated altitudes ceiling of restricted area R–4201B, Camp Grayling, MI; adding a “tie-in” boundary point in the R–4201A boundaries description to ensure a shared R–4201A and R–4201B boundary; and making minor administrative changes to the existing R–4201B time of designation and the R–4201A and R–4201B using agency information.

The R–4201B ceiling is raised to 23,000 feet MSL to match the restricted area ceiling with the adjacent R–4201A ceiling and connect the eastern boundaries of the two restricted areas equally with two new MOAs proposed as part of a previously published non-rulemaking proposal to amend the Alpena Combat Readiness Training Center (CRTC) Airspace Complex.

An additional boundary point is added to the existing R–4201A southern boundary to ensure a shared boundary with the northern boundary of R–4201B. The additional boundary point located at latitude 44°47′00″ N, longitude 84°38′00″ W in the R–4201A description matches the geographic coordinates of the northwest corner of R–4201B and does not change the boundaries alignment for either restricted area.

The minor administrative change to the existing R–4201B time of designation does not change when the restricted area is available to be scheduled. Additionally, the administrative changes to the R–4201A and R–4201B using agency information prefaces the existing using agency information with “U.S. Army.” These administrative changes do not affect the

scheduling, use, or activities conducted within the restricted areas.

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 so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

In accordance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), the National Guard Bureau (NGB) and the Michigan Air National Guard (MIANG) prepared an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for Modification and Addition of Airspace at the Alpena Special Use Airspace (SUA) Complex, dated February 2, 2024. The EA considers the potential consequences to the human and natural environment associated with modification, expansion, and utilization of the Alpena SUA Complex, including the use of restricted areas R–4201A and R–4201B for NGB and MIANG aircraft exercises. The FAA is a cooperating agency for the NGB and MIANG EA since it has jurisdiction by law over the provision and use of the airspace in which the NGB and MIANG actions take place. In accordance with NEPA’s implementing regulations at 40 CFR part 1500 and FAA’s NEPA implementing regulations in FAA Order 1050.1F, paragraph 8–2, The Adoption of Other Agencies’ NEPA Documents, the FAA has adopted the NGB and MIANG EA and published its own FONSI for the establishment and use of the Alpena SUA Complex near Alpena, MI, dated April 17, 2024.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for 14 CFR part 73 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.

§ 73.42 Michigan (MI) [Amended]

■ 2. § 73.42 is amended as follows:

R-4201A Camp Grayling, MI [Amended]

Boundaries. Beginning at lat. 44°56'00" N, long. 084°29'00" W; to lat. 44°47'00" N, long. 084°29'00" W; to lat. 44°47'00" N, long. 084°38'00" W; to lat. 44°47'00" N, long. 084°39'00" W; to lat. 44°56'00" N, long. 084°39'00" W; to the point of beginning.

Designated altitudes. Surface to 23,000 feet MSL.

Time of designation. 0800–1600 local time, Tuesday–Saturday; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Army, Commander, Camp Grayling, Grayling, MI.

R-4201B Camp Grayling, MI [Amended]

Boundaries. Beginning at lat. 44°47'00" N, long. 084°29'00" W; to lat. 44°41'00" N, long. 084°29'00" W; to lat. 44°41'00" N, long. 084°40'00" W; to lat. 44°43'00" N, long. 084°40'00" W; to lat. 44°43'00" N, long. 084°38'00" W; to lat. 44°47'00" N, long. 084°38'00" W; to the point of beginning.

Designated altitudes. Surface to 23,000 feet MSL.

Time of designation. 0000–2359 local time, Saturday–Sunday; other times by NOTAM.

Controlling agency. FAA, Minneapolis ARTCC.

Using agency. U.S. Army, Commander, Camp Grayling, Grayling, MI.

* * * * *

Issued in Washington, DC, on June 12, 2024.

Frank Lias,

Manager, Rules and Regulations Group.
[FR Doc. 2024–13313 Filed 6–17–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Parts 91, 121, and 135**

[Docket No. FAA–2019–0360; Amdt. Nos. 91–375, 121–392 and 135–145]

RIN 2120–AL12

Removal of Check Pilot Medical Certificate Requirement

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

ACTION: Final rule.

SUMMARY: This action finalizes the substantive relief proposed in the notice of proposed rulemaking entitled *Removal of Check Pilot Medical Certificate Requirement*. It removes inconsistencies applicable to the qualification requirements for check pilots and flight instructors in domestic, flag, and supplemental operations and flight instructors in commuter and on-demand operations so that check pilots, check flight engineers, and flight instructors can continue to perform their functions in aircraft without a medical certificate unless they are serving as required flightcrew members. It also removes the medical certificate requirement for flight instructors in commuter and on-demand operations who perform their functions in aircraft and are not serving as required flightcrew members. Removing the conflicting medical certificate requirement enables the utilization of pilots who are otherwise qualified to function as check pilots, check flight engineers, and flight instructors in aircraft. Finally, this final rule updates related terminology.

DATES: This rule is effective July 18, 2024.

FOR FURTHER INFORMATION CONTACT: Joshua Jackson, Aviation Safety Inspector, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: 202–267–8166; email: joshua.jackson@faa.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary**

As discussed in the notice of proposed rulemaking (NPRM),¹ the regulations establishing the requirements for flight instructors and check airmen in parts 121 and 135 are

unclear regarding the medical certificate requirements when flight instructors or check airmen perform their duties in aircraft. The regulations indicate that flight instructors conducting flight training and check airmen administering checks in aircraft must hold a third-class medical certificate when not serving as a required flightcrew member. Elsewhere, however, the regulations also state that no medical certificate is required unless the flight instructor or check airman is serving as a required crewmember. Additionally, part 135 check pilots (aircraft) were held to different medical certification standards than part 121 check pilots and flight instructors and part 135 flight instructors.² This final rule resolves the discrepancy in the pertinent regulations by clarifying that flight instructors, check pilots, and check flight engineers (FEs) must hold the appropriate medical certificate only when serving as required flightcrew members in an aircraft. The final rule also includes nonsubstantive nomenclature changes and reorganizes certain sections of parts 121 and 135.

II. Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code (49 U.S.C.). Subtitle I, section 106 describes the authority of the FAA Administrator to promulgate rules and regulations. Subtitle VII of title 49, Aviation Programs, describes in more detail the scope of the FAA's authority.

This rulemaking is promulgated under the authority described in section 44701, General Requirements; section 44702, Issuance of Certificates; and section 44703, Airman Certificates. Under these sections, the FAA prescribes regulations and minimum standards for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. In addition, section 44701(d)(1)(A) specifically states the Administrator, when prescribing safety regulations, must consider the duty of an air carrier to provide service with the highest possible degree of safety in the public interest.

² Specifically, § 135.337(b)(5) states that a check airman (aircraft) must hold at least a third-class medical certificate unless serving as a required crewmember and the exception in § 135.337(e) that a check airman who does not hold the appropriate medical certificate may serve as a check airman, but not a required flightcrew member, applies only to check airmen (simulators). This differs from how the regulations treat part 121 check airmen and flight instructors and part 135 flight instructors.

¹ *Removal of Check Pilot Medical Certificate Requirement* notice of proposed rulemaking, 84 FR 25499 (Jun. 3, 2019).

III. Background

As discussed in the NPRM, all pilots serving in title 14 CFR part 121 and part 135 operations are required to complete certain flight training³ and checking⁴ on a regular basis to ensure each pilot's competency in operating the specific aircraft. The checks are conducted by check pilots:⁵ airmen approved by the FAA who have the appropriate knowledge, training, experience, and demonstrated ability to evaluate and to certify the knowledge and skills of other pilots. The role of the check pilot is to ensure that the flightcrew member has met competency standards in a particular aircraft before the check pilot releases the flightcrew member from training and that the flightcrew member maintains those standards while remaining in line service. Similar responsibilities and objectives exist for check FEs in part 121.⁶ Check pilot qualifications are set forth in §§ 121.411 and 135.337, as applicable. Check FE qualifications are set forth in § 121.411.

The flight training is conducted by a flight instructor who is designated by a part 121 or part 135 certificate holder and has the appropriate knowledge, training, experience, and demonstrated ability to instruct flightcrew members in a flight training segment of that certificate holder's training program. Flight instructor qualifications are set forth in §§ 121.412 and 135.338.

Under parts 121 and 135, flight training and checking can be accomplished in an aircraft or in a flight simulation training device (FSTD). As such, the qualification requirements for flight instructors, check pilots, and check FEs correspond to whether the training and checking is conducted in an aircraft or an FSTD. In an FSTD, flight instructors, check pilots, and check FEs typically do not occupy a flightcrew member station during training or checking. Rather, they typically occupy an instructor station from which they can oversee the simulation. Even when flight instructors, check pilots, or check FEs occupy a flightcrew member station in an FSTD, they are not subject to flightcrew member requirements that

apply to operations conducted in the national airspace.⁷

When performing flight instructor, check pilot, or check FE duties in an aircraft, that person may serve as a required flightcrew member. Specifically, a flight instructor, check pilot, or check FE is a required flightcrew member if (1) required by the regulations under which the flight is being conducted (e.g., when a safety pilot is required under part 91 or when a person receiving instruction is not qualified to act as pilot-in-command (PIC) and, therefore, the flight instructor acts as the PIC) or (2) required by the type certificate of the aircraft.⁸ In these scenarios, the person may serve as a required flightcrew member only if, in addition to meeting the requirements to hold the respective position of flight instructor, check airman, or check FE, the person is also qualified to serve in the flightcrew member position, which includes medical certificate requirements.

Prior to 1996, the FAA required medical certificates for flight instructors and check airmen⁹ performing such functions, even if they were not serving as required flightcrew members.¹⁰ This was largely because the primary means of training occurred in an aircraft until the implementation of significant changes in training methods (i.e., increased use of flight simulation) beginning in the late 1970s. With the increase in FSTD use, in 1996, the FAA, acknowledging that some experienced part 121 and part 135 airmen, who would otherwise qualify as flight instructors or check airmen but were not medically eligible to hold a medical certificate, were foreclosed by regulation from performing their functions even in FSTDs, revised the regulations.¹¹ Specifically, the final rule removed the medical certificate requirement altogether for flight instructors and check pilots in parts 135 and 121 who

perform their functions in FSTDs.¹² However, as noted earlier, the regulatory text ultimately introduced confusion as to the medical certificate requirement for flight instructors and check airmen who perform their functions in aircraft in parts 121 and 135 when not serving as required flightcrew members. Specifically, §§ 121.411, 121.412, 135.337, and 135.338 apply internally inconsistent medical certificate requirements to check airmen and flight instructors when performing their duties in an aircraft.

Recognizing the contradiction in the regulations, the FAA gave force and effect to the most relieving provision by not requiring flight instructors and check airmen performing their respective duties in aircraft to hold any medical certificate when not serving as a required flightcrew member.

IV. Discussion of Final Rule and Public Comments

A. Final Rule and Changes

On June 3, 2019, the FAA published an NPRM that proposed to update regulatory text to remove the inconsistencies applicable to check pilots and flight instructors in parts 121 and 135 to provide clarity to check pilots, check FEs, and flight instructors on the applicable medical certificate requirements when performing their functions in aircraft. Specifically, the NPRM proposed to keep and revise paragraph (b)(5) of §§ 121.411, 121.412, 135.337, and 135.338 to mandate medical certificate requirements only for those check pilots, check FEs, and flight instructors considered required flightcrew members. Thus, the proposal removed explicit requirements for check pilots, check FEs, and flight instructors who are not also serving as required flightcrew members. However, as proposed, the FAA would have kept language set forth in §§ 121.411(e), 121.412(e), 135.337(e), and 135.338(e) that specifically stated a person who did not hold a medical certificate may function as a check pilot, check FE, or flight instructor (as applicable), but could not serve as a required flightcrew member.

In response to comments received and additional analysis during the pendency of the rulemaking, the FAA recognizes

¹² *Id.* at 30735. Specifically for check airmen, the rule removed, first, the requirement to hold at least a Class III (third class) medical certificate in then-§ 121.411(a)(6) and, second, the requirements to hold a Class I, II, or III (first, second, or third class) medical certificate in then-§ 135.337(a). Additionally, the rule added §§ 121.412 and 135.338 to specifically speak to flight instructors and excepted those persons instructing in a simulator from holding a medical certificate.

³ See 14 CFR 121.433, 135.347, 135.351.

⁴ See 14 CFR 121.441, 135.293, 135.297.

⁵ The FAA notes that the NPRM proposed only to change verbiage in part 135 from "check airman" to "check pilot," as well as their plural forms. As discussed in section IV.D.1. of this preamble, the FAA is expanding this terminology change to include part 121. Therefore, for purposes of this preamble, the FAA uses the terms "check pilot" and "check flight engineer," as applicable, rather than "check airman" unless referring to past regulations that use "airman."

⁶ 14 CFR 121.419, 121.425.

⁷ Under § 1.1, a flightcrew member is "a pilot, flight engineer, or flight navigator assigned to duty in an aircraft during flight time."

⁸ Letter of Interpretation to Willmot White from Carl Schellenberg, Assistant Chief Counsel, Regulations and Enforcement Division (Oct. 5, 1978). Letter of Interpretation to Ivan Grau from Rebecca B. MacPherson, Assistant Chief Counsel for Regulations (Oct. 1, 2010); Letter of Interpretation to Louis Glenn from Rebecca B. MacPherson, Assistant Chief Counsel for Regulations (Dec. 1, 2009).

⁹ See footnote 5 of this preamble.

¹⁰ See e.g., Air Taxi Operators and Commercial Operators, 42 FR 43490 (Aug. 29, 1977) and Air Taxi Operators and Commercial Operators, 43 FR 46742, 46777 (Oct. 10, 1978).

¹¹ *Training and Qualification Requirements for Check Pilots and Flight Instructors* final rule, 61 FR 30734 (Jun. 17, 1996).

that the proposed revisions to the regulations were insufficient to achieve the goal of the rulemaking: elimination of medical certificate requirement confusion. Specifically, paragraph (b)(1) in each section (§§ 121.411, 121.412, 135.337, and 135.338) still would have required a person to hold all the “airman” certificates and ratings required to serve as a PIC in operations under that part, which would include the requisite medical certificate in exercising the privileges of a commercial or ATP certificate.¹³ Therefore, the FAA is adopting different language than proposed in the 2019 NPRM, accompanied by reorganization of the affected sections to reduce redundancy. To note, the substantive relief remains unchanged from that proposed in the 2019 NPRM and historical practice (*i.e.*, elimination of medical certificate requirements if not serving as a required flightcrew member).

Specifically, as it pertains to part 121, §§ 121.411(b)(1) and 121.412(b)(2) require a check pilot, check FE, and flight instructor to hold the airman certificates and ratings required to serve as a PIC or FE, as applicable, under part 121 operations. As written, “airman certificates” would include a medical certificate. Instead of relying on paragraph (b)(5) as an exception to paragraph (b)(1) in each section, as previously explained, this final rule revises each paragraph (b)(1) to specify that the requisite pilot or FE certificate and/or ratings are required. This revision, therefore, conveys that a medical certificate is not generally included in the required certificates to serve as a check pilot, check FE, or flight instructor. Therefore, while the NPRM proposed to revise §§ 121.411(b)(5) and 121.412(b)(5) from the regulations, this final rule would remove both paragraphs.¹⁴ Additionally, this final rule would remove existing §§ 121.411(e) and 121.412(e) and adopt a new paragraph (f) that concisely sets forth that a person who serves as a required flightcrew member while performing check pilot or check FE duties must meet all requirements for the duty position in which they are serving. This would include the requisite medical certificate for that duty position.

In summary, when not serving as a required flightcrew member, the check pilot, check FE, or flight instructor would be required to hold all certificates and ratings required to serve as PIC or FE under part 121, pursuant to §§ 121.411(b)(1) and 121.412(b)(1) except a medical certificate. Pursuant to new §§ 121.411(f) and 121.412(f), if the check pilot, check FE, or flight instructor was serving as a required flightcrew member, the person must also meet the requirements for the duty position in which they are serving.¹⁵

Additionally, while the FAA did not propose a reorganization of §§ 121.411 and 121.412 in the NPRM as it did in part 135, this final rule will revise certain provisions to eliminate redundancy in the regulations. First, § 121.411(b)(4) requires an airplane check pilot or check FE to satisfactorily complete the applicable training requirements of § 121.413, including inflight training and practice for initial and transition training. Similarly, § 121.412(b)(4) requires an airplane flight instructor to satisfactorily complete the applicable training requirements of § 121.414, including inflight training and practice for initial and transition training. The FAA finds these concluding phrases to be redundant because §§ 121.413 and 121.414 set forth the initial, transition, and recurrent training and checking requirements for check pilots, check FEs, and flight instructors, as applicable, and would control the scenarios under which the inflight training and practice for initial and transition training is required. Therefore, the FAA is removing the language in §§ 121.411(b)(4) and 121.412(b)(4) as redundant.

Second, § 121.411(b)(6) requires a check airman to satisfy the recency of experience requirements of § 121.439, as applicable. Section 121.439 sets forth the recent experience requirements for pilot qualification and applies specifically to required pilot flightcrew members in paragraph (a). In other words, § 121.439 would be rendered applicable only when a check pilot serves as a required flightcrew member. The recency of experience requirements of § 121.439 would, therefore, be required regardless of the specification of § 121.411(b)(6). The same principle

applies in § 121.412. Therefore, §§ 121.411(b)(6) and 121.412(b)(6) are removed in this final rule; however, the FAA emphasizes that this does not change the existing substantive recency of experience requirements. Additionally, §§ 121.411(f) and 121.412(f) would act as an umbrella provision for check pilots, check FEs, and flight instructors who serve as required flightcrew members, thereby subjecting a check pilot serving as a required flightcrew member to meet § 121.439.

In removing these revisions for redundancy (as well as §§ 121.411(b)(5) and 121.412(b)(5) as previously discussed), the requirements of § 121.411(b) for check pilot and check FE (airplane) are largely mirrored in § 121.411(c) for check pilot and check FE (FSTD). Similarly, the requirements of § 121.412(b) for flight instructor (airplane) are largely mirrored in § 121.412(c) for flight instructor (FSTD). Therefore, the FAA finds that the provisions in each paragraph, respectively, can be combined without losing any clarity or substantive requirements. Subsequently, the introductory language is revised to include both airplane and FSTD check pilots and check FEs, and paragraphs (b) and (c) are merged.¹⁶ Additionally, the reference to paragraphs (c)(2) through (4) in §§ 121.411(d) and 121.412(d) are removed, as those previous provisions will be covered under the reference to paragraphs (b)(2) through (4), which remain.

The same general revisions are made in part 135; however, part 135 does not contemplate FEs as part 121 does. Therefore, §§ 135.337(b)(1) and 135.338(b)(1) are revised to state that check pilots must hold the pilot certificates and ratings required to serve as a PIC in operations under part 135. Additionally, for the same reasons previously discussed for part 121, this final rule removes paragraphs (b)(5) and (b)(6)¹⁷ in each section, removes paragraph (e) in each section, and adds new paragraph (f), explicitly stating that each person who serves as a required flightcrew member while performing check pilot duties must meet the requirements for the duty position in

¹⁶ See section IV.B. of this preamble for section redesignation as an outgrowth of eliminated paragraphs.

¹⁷ For clarity, paragraph (b)(6) in §§ 135.337 and 135.338 require a check pilot or flight instructor to satisfy the recency of experience requirements of § 135.247. Section 135.247 applies to those pilots serving as PIC of an aircraft carrying passengers, which would apply regardless of duplicity in §§ 135.337 and 135.338. In other words, § 135.247 continues to control the conditions under which a person must meet recent experience requirements.

¹³ See 49 U.S.C. 44703(i)(2)(A)(i).

¹⁴ Paragraph restructuring is discussed in section IV.B. of this preamble. Additionally, the FAA notes that the NPRM proposed to change certain medical certificate terminology from Class I, II, and III to first-class, second-class, and third-class. With the elimination of these paragraphs, that proposal is rendered irrelevant.

¹⁵ For example, pursuant to 14 CFR 63.3, if a person is acting as a flight engineer of an aircraft, that person would be required to hold at least a second-class medical certificate or other documentation acceptable to the FAA. However, if the check flight engineer was only performing check duties, and was not acting as the flight engineer of the aircraft, the person would be exempted from holding the medical certificate.

which they are serving. This would include the appropriate medical certificate when serving as a required flightcrew member. The FAA acknowledges that there may be instances where a person is “assigned” to a part 135 operation. The FAA notes that if a check pilot or flight instructor is assigned duties, then they must be qualified as if they were required (*i.e.*, must be qualified for the operation for which the person is to be used), pursuant to § 135.95. Additionally, for the same reasons previously discussed in the part 121 revisions, the FAA is combining § 135.337 paragraph (c) with paragraph (b) and § 135.338(c) with (b).

In summary, these changes clarify that a person serving as a check pilot, check FE, or flight instructor under parts 121 or 135 would not be required to hold a medical certificate unless serving as a required flightcrew member. As previously discussed, a person is a required flightcrew member in two

scenarios: (1) where the operating rule requires the person to be a flightcrew member or (2) the aircraft’s type certificate requires the person to be a flightcrew member. In either scenario, the person would be required to hold a medical certificate in accordance with the privileges of the certificate they were exercising.¹⁸ For example, if a check pilot is performing a check but also serving as a safety pilot under § 91.109, that check pilot would be considered a required flightcrew member (due to the operating rule). Because under § 91.109(c)(1), the safety pilot/check pilot would be exercising the privileges of at least a private pilot certificate, the person must hold the requisite medical certificate: at least a third-class medical certificate.¹⁹ As another example, if the check pilot is conducting a check under part 135 in an aircraft that requires two pilots via type certificate and the check pilot is the second pilot, the check pilot would be

serving as a required flightcrew member under that part (due to type certificate). That check pilot would be serving as second in command, requiring at least a commercial pilot certificate and an instrument rating pursuant to § 135.4. Because the check pilot would be exercising the privileges of a commercial pilot certificate and instrument rating, that check pilot must hold at least a second-class medical certificate.²⁰ The same principle applies to part 121 operations, as well as flight instructors who would be considered required flightcrew members.

B. Redesignation of Affected Sections

As discussed in the previous section, the final rule revises and removes a number of existing paragraphs within §§ 121.411, 121.412, 135.337, and 135.338. The FAA provides the following tables to concisely detail the resulting redesignation within those sections.

TABLE 1—PART 121 REDESIGNATION

Current citation (14 CFR §)	Final rule action	Current citation (14 CFR §)	Final rule action
121.411(a)	Unchanged	121.412(a)	Unchanged.
121.411(b)	Incorporated paragraph (c)	121.412(b)	Incorporated paragraph (c).
121.411(c)	Merged into paragraph (b)	121.412(c)	Merged into paragraph (b).
121.411(d)	Redesignated as § 121.411(c)	121.412(d)	Redesignated as § 121.412(c).
121.411(e)	Removed	121.412(e)	Removed.
121.411(f)	Redesignated as § 121.411(d)	121.412(f)	Redesignated as § 121.412(d).
121.411(g)	Redesignated as § 121.411(e)	121.412(g)	Redesignated as § 121.412(e).

TABLE 2—PART 135 REDESIGNATION

Current citation (14 CFR §)	Final rule action	Current citation (14 CFR §)	Final rule action
135.337(a)	Unchanged	135.338(a)	Unchanged.
135.337(b)	Incorporated paragraph (c)	135.338(b)	Incorporated paragraph (c).
135.337(c)	Merged into paragraph (b)	135.338(c)	Merged into paragraph (b).
135.337(d)	Redesignated as § 135.337(c)	135.338(d)	Redesignated as § 135.338(c).
135.337(e)	Removed	135.338(e)	Removed.
135.337(f)	Redesignated as § 135.337(d)	135.338(f)	Redesignated as § 135.338(d).
135.337(g)	Redesignated as § 135.337(e)	135.338(g)	Redesignated as § 135.338(e).

C. Discussion of Comments

The FAA received and considered 12 comments to the NPRM, consisting of two from industry (Ameristar Air Cargo, Inc. and Harris Aircraft Services, Inc.) and 10 from individuals. The majority of commenters, including Ameristar Air Cargo, Inc. (Ameristar) and Harris Aircraft Services, Inc. (Harris), supported the rule. Only two individuals opposed the proposal, while

three commenters sought additional clarification on the proposal.

1. Support for the Rule

The majority of commenters supported the proposal. While some simply stated support for the proposal with no further rationale, several provided additional discussion as part of their support. Many supporters stated that the proposal helps to clarify an unsettled area of confusion for parts 121

and 135 operators. Supporters, including Harris and Ameristar, emphasized that adoption of the proposal would ensure operators could capitalize on the experience, ability, and expertise of retired or semi-retired pilots who may not be able to qualify for a medical certificate. Ameristar contended that utilizing the check airmen and instructors in a non-required flightcrew member role provides benefits, including, for

¹⁸ Section 61.3(c)(1) requires a person to hold the appropriate medical certificate if serving as a required pilot flightcrew member, subject to certain exceptions set forth in § 61.3(c)(2). Section 61.23

sets forth the class of medical certificate required for pilots, and § 63.3(b) requires a flight engineer to hold at least a current second-class medical certificate.

¹⁹ See 14 CFR 61.23(a)(3)(i).

²⁰ See 14 CFR 61.23(a)(2)(ii).

example, providing: (1) an additional person on the flight deck who understands the systems, procedures, and regulatory requirements and (2) an additional person to evaluate the improvement of teaching and checking techniques. Because that person is an additional and not a required flightcrew member, the lack of a medical certificate in that role would not necessarily degrade safety, as the person would not be in control of the aircraft. A couple of commenters went on to stress, though, that if check airmen or flight instructors were serving as required crewmembers, then they should possess the appropriate medical certificate to serve in the requisite capacity. Harris noted that the ability to utilize pilots for longer periods as check pilots would relieve the burden from the local Flight Standards District Office (FSDO).²¹

2. Requests for Clarifications and Suggestions

Several commenters suggested clarifications to the proposed regulatory text, asked specific questions and/or hypothetical scenarios to ensure understanding of the proposal, or requested additional relief for check pilots and flight instructors. This section responds to such comments.

First, one commenter asked the FAA to clarify when a check pilot would be a required flightcrew member. The commenter stated there are a number of operators who fly Caravan and Pilatus series aircraft in commercial operations, which are examples of specific aircraft that are certified to fly in commercial operations using a single pilot. The commenter further stated that if a check pilot were to give a check ride in one of these aircraft and the flight was flown under visual flight rules (VFR) flight with the applicant wearing a view limiting device, then the check pilot would be considered an essential flightcrew member even though the type certificate for the aircraft does not require a second pilot. The commenter asked for additional clarification to the regulation to explicitly allow a check pilot without a medical certificate to serve as a safety pilot while simultaneously conducting a check ride

in an aircraft certified to be used in commercial operations using a single pilot. The commenter explained that, if needed, the check ride could be conducted or mandated to be flown in VFR conditions if there was any concern with the applicant wearing a view-limiting device, adding that while the flight may be conducted while adhering to part 135 rules for the purposes of the check ride, the flight could be legally flown under part 91.

As discussed in section IV.A. of this preamble, a person is a required flightcrew member in two scenarios: where the operating rule or the aircraft's type certificate requires the person to be a required flightcrew member. In the commenter's hypothetical, the person would be required to hold a medical certificate in accordance with the privileges of the certificate they were exercising. Therefore, as the example provides in that section, the safety pilot would be exercising the privileges of a private pilot certificate and would require at least a third-class medical certificate. The FAA recognizes that the currently situated regulations indicate that, in this case, a safety pilot would be required to hold a first- or second-class medical certificate. As discussed, the FAA has removed that language in the adoption of this final rule; the pilot certificate that is required for the specific operation (whether that be by regulation or type certificate) controls what medical certificate is necessary for the pilot to hold.

The same commenter also asked the FAA to consider extending the rulemaking further to remove the general requirement that FAA aviation safety inspectors (ASIs) possess second-class medical certificates, as advertised by FAA ASI job solicitations. The commenter stated that ASI positions that involve simulator-only operations should be given the same consideration that check pilot, check FE, and flight instructor positions were given in this proposal (*i.e.*, to not require that they hold medical certificates). The commenter explained that an ASI is not normally acting as a required crewmember, and there is no need for an ASI to hold a medical certificate if the ASI is overseeing an airline designating a new check pilot or renewing a check pilot. The commenter asked if, assuming all the other requisites for that type of ASI job announcement are met, the FAA could consider removing the requirement that ASIs hold medical certificates for ASIs involving simulator operations so that the FAA could access the same highly experienced pilot pool as is discussed in

the proposal concerning check pilots and flight instructors.

The FAA acknowledges this comment, but changes to the FAA's hiring parameters and qualifications are outside the scope of this rulemaking. FAA requirements for ASIs are internal requirements specific to the FAA's employees rather than regulations on the public. Such internal FAA requirements are not subject to rulemaking nor public notice and comment.

Two individuals commented on requirements where a check pilot would be only occupying the jump seat. One of the individuals stated that the medical certification requirements should only be specific to or differentiate between the position of the check pilot: for example, a jump seat or a simulator. The FAA maintains that the differentiation between the requisite medical certificates should not be driven by the pilot's physical position in the aircraft but rather by their duties. The implementation of a rule only applicable to a certain location or seat could not be applicable to every contemplated aircraft that may be used in a part 121 or part 135 operation. Specifically, a check pilot may be checking a pilot in an aircraft that does not have a jump seat. Or, an aircraft may be type certificated for one pilot, and the regulations do not require more than one, in which case the check pilot could occupy the right seat to carry out the check. Therefore, it is inappropriate to regulate based solely on the physical location of the check pilot, check FE, or flight instructor and, for the reasons discussed in this preamble, more appropriate to ensure the pilot possesses the corresponding medical certificate required to perform the duties of the position that pilot is performing.

Next, one commenter asked whether a person would need to hold a medical certificate if that person was a check pilot or flight instructor who was the sole person on board with the ability to maintain the flight.

The FAA assumes that the commenter is alluding to a scenario in which a flight departs with a pilot serving as PIC in a single pilot operation with a check pilot on board conducting a check, subsequent to which the pilot experiences an incapacitating event and the check pilot is therefore required to fly the aircraft. While it is possible that a scenario such as the commenter raised could occur, the required flightcrew determination that check pilots rely on is made prior to takeoff based on the type certificate for the aircraft or the regulations governing the flight. In a hypothetical emergency situation, the

²¹ Checks may be given by the Administrator or an authorized check pilot; therefore, where a check pilot is unavailable, an FAA Aviation Safety Inspector (ASI) at a FSDO would give the appropriate check. The FAA notes that one commenter who supported the proposal as providing clarity and efficiency also questioned why check pilots must be approved or authorized by the Administrator. Because this responsibility is delegated to a person outside the FAA, the Administrator must ensure that the check pilot and flight instructors demonstrate the ability to perform check and instruction functions.

primary concern would be the safety of the persons on board the aircraft and landing the aircraft; a medical certificate (or lack thereof) should not prevent a check pilot or flight instructor from mitigating a safety situation. Therefore, the FAA does not intend to make amendments to the regulations beyond what was in the NPRM.

Ameristar requested clarification regarding the recency of experience and training requirements. Specifically, Ameristar asked that the FAA state whether a flight instructor who is not a required crewmember must meet the recency of experience requirements of § 121.412(b)(6). Ameristar believes that the instructor would not need to meet those requirements as long as he or she meets all of the other requirements of § 121.412.

Section 121.412 contains the qualification requirements for persons serving as flight instructors under part 121. Among these requirements, § 121.412(b)(6) requires part 121 flight instructors to, with respect to the airplane type involved, meet the recency of experience requirements of § 121.439, as applicable. The FAA notes that the same requirement would apply to check pilots and check FEs under part 121, as § 121.411 requires check pilots to meet the recency of experience requirements of § 121.439, as applicable. The recent experience requirements in § 121.439 apply only to “required pilot flightcrew members.” Therefore, for flight instructors, check FEs, and check pilots in aircraft who are not serving as required flightcrew members, the recency of flight experience requirements of § 121.439²² are not applicable. This same concept applies to the recency of flight experience requirements in part 135. In other words, for part 135, a certificate holder may only use a check airman or flight

instructor as a required flightcrew member serving as PIC carrying passengers if the person has satisfied the recency of experience requirements of § 135.247. Because these regulations set forth the conditions under which a pilot or FE must meet the recency of experience, the FAA does not find these provisions (*i.e.*, §§ 121.411(b)(6), 121.412(b)(6), 135.337(b)(6), and 135.338(b)(6)) required. The FAA expects these revisions to succinctly set forth the expectations for recency of experience. See section IV.A. of this preamble for additional discussion on the removal of these paragraphs.

Finally, Ameristar stated that it believed that the authorization to conduct training or checking without a medical certificate should be delineated to (1) line checks pursuant to § 121.440, where the PIC being checked is currently qualified as a pilot in command and is not out of currency, and (2) refresher training under § 121.434(h)(4)(ii) or other training required by a training program that requires an observation by an aircraft instructor or check pilot where the individual is otherwise qualified to be a required crewmember. Ameristar recommended limiting the allowance of checking or training without a medical certificate in part 121 to the line check requirement in § 121.440 and the refresher training in § 121.434 (or similar observational training) only. The FAA emphasizes that, as previously discussed, §§ 121.411 and 121.412 are currently implemented so as to not require a medical certificate when a check pilot or flight instructor is not serving as a required flightcrew member. This final rule merely clarifies, but does not change, the current implementation of those requirements. It is not the FAA’s intention to limit the authorization to conduct training or checking without a medical certificate further, nor does the FAA find it appropriate to do so. If the check pilot and flight instructor conducting their duties under § 121.440 or § 121.434 are not required crewmembers, then they would not be required to hold a medical certificate.

3. Opposition to Rule

Two anonymous commenters explicitly disagreed with the proposal. One commenter expressed a lack of understanding as to why check pilots should be exempt from medical certificate requirements, opining that it could be dangerous to other people on the flight if they relied on the check pilot and a medical situation were to happen. The second commenter believed that lowering the certifications

would add to general aviation community fears, especially as it pertained to flight paths of commuter aircraft.

As discussed in the NPRM, given the contradictory provisions in parts 121 and 135 regarding medical certification, the FAA currently implements §§ 121.411, 121.412, 135.337, and 135.338 under the least burdensome provision such that parts 121 and 135 check pilots and flight instructors are not required to hold a medical certificate unless serving as required flightcrew members. In other words, this final rule maintains the status quo of medical certificates in current practice. Given the length of time and lack of safety data to support more stringent medical certificate requirements on these persons, the FAA has no basis upon which to conclude that this final rule would create an adverse impact on safety. The required flightcrew, who are responsible for the safe conduct of the flight, will continue to hold the appropriate medical certificates as required by § 61.23.

Further, when a check pilot or flight instructor is serving as a required flightcrew member (*i.e.*, at the controls as required by regulation or type certificate), that check pilot or flight instructor must be fully qualified to serve as PIC²³ to include the requirement to hold a first- or second-class medical certificate, as appropriate, under § 61.23. In other words, they are not exempt from any medical certificate requirement. The only time a check pilot, check FE, or flight instructor is not required to hold a medical certificate is when they are not serving as a required flightcrew member; in that case, they are not needed for the conduct of the flight, and the person or persons operating the flight in that scenario would be fully qualified to conduct the operation. Eliminating the requirement that a check pilot, check FE, or flight instructor hold a medical certificate when they are not serving as a required flightcrew member will have no impact on risk to safety because aircraft will continue to operate using required flightcrew members who satisfy the necessary training and qualification requirements, including the requirement to hold an appropriate medical certificate. Therefore, while the FAA is revising some regulatory text from that proposed in the NPRM, as

²² The FAA notes that this may seem inconsistent with recency of experience requirements set forth in current §§ 121.411(f) and 121.412(f) (redesignated in this final rule as paragraph (d) for each section), which are required of simulator check airmen or flight instructors regardless of whether the person is a required crewmember or not. In other words, check pilots and flight instructors who are conducting checks or instruction in only simulators must meet certain recency requirements (*i.e.*, fly at least two flight segments as a required crewmember for the type of airplane in the 12 month period preceding the performance of any check airman duty in a full flight simulator (FFS) or satisfactorily complete a line-observation program within the period prescribed by that program preceding the performance of any check airman duty in an FFS). The recency of experience requirements for check airmen and flight instructors who only conduct operations in FFS ensure that these persons are adequately familiarized with a real-time flight environment. The same reasoning applies in part 135 (*i.e.*, current §§ 135.337(f) and 135.338(f)).

²³ See §§ 121.411(b)(1); 121.412(b)(1); 135.337(b)(1); and 135.338(b)(1). The FAA notes that a check pilot and flight instructor must hold the airman certificates and ratings required to serve as a PIC in operations under part 121 or 135, as applicable, regardless of whether they are a required flightcrew member.

explained in this preamble, the FAA is moving forward with the removal of certain inconsistent text to make clear no medical certificate is required for certain persons.

D. Miscellaneous Amendments

1. Part 121

The FAA notes that it did not propose changes to certain terminology in part 121 of the NPRM. However, given the proposed changes in part 135, the FAA finds that it would introduce confusion to have references to “check airmen” and “check pilots,” which could indicate the two have different meanings when that may not be the intent. Therefore, the FAA is adopting nonsubstantive rule terminology changes in part 121 of this final rule.

Specifically, “check airmen” is changed to “check pilot” and/or “check flight engineer” (as applicable²⁴) in the plural and singular. Currently, the term “check airmen” applies to both check pilots and check FEs. While there are similarities between the required training, qualification, and duties of check pilots and check FEs, there are many distinctive requirements. For example, a check pilot evaluates pilots operating the flight controls of an airplane, while a check FE evaluates FEs managing airplane systems. Using “check airmen” to describe both check pilots and check FEs can lead to confusion or misapplication of the regulations. Additionally, some provisions in subparts N and O of part 121 use the term “pilot check airman,”

while other provisions in subparts N and O use the term “check pilot.” The FAA considers these two terms synonymous, but using two different terms can create confusion and inconsistent application.

Additionally, the term “simulator” is changed to “FSTD.” Specifically, where the regulations reference a flight simulator or a flight training device together, the correct terminology is “flight simulation training device” or “FSTD,” given the definition of a flight simulation training device in 14 CFR 1.1.²⁵ This revision does not result in any substantive change to the regulations; rather, it simply condenses regulatory text. The following table sets forth the specific revised regulatory citations.

TABLE 3—TERMINOLOGY CHANGES IN PART 121

Revision	Affected regulations in this final rule (14 CFR)
“Check airman” to “check pilot” and/or “check flight engineer”.	§§ 121.401(a)(1), (c), and (e); 121.407(a)(5); 121.408(d) and (d)(1); 121.411(a)(1) and (2), (b), (b)(1) and (5), (d), (d)(1) and (2); 121.413(a), (a)(1), (c)(1), (d)(1) and (2); 121.414(a)(2); 121.434(d); 121.439(b)(1) and (e); 121.440(b)(1) and (c)(1); 121.441(b)(2); 121.445(d)(2); 121.915(b)(2)(iii); 121.919(e); appendix E to part 121, II.(f) and IV.(j); appendix F to part 121, V., freestanding paragraph after (d)(2); appendix H to part 121 3., 4., and 5.
“Check airmen” to “check pilots” and/or “check flight engineers”.	§§ 121.401(a)(4); 121.402(b)(4); 121.411 heading; 121.411(a)(3); 121.413 heading; 121.413(c), (c)(7), (d), (d)(2), (e), (e)(3) and (4), (g), and (h); appendix H to part 121 intro paragraph and 5.
“Simulator” to “FSTD”	§§ 121.411(a)(1) and (2), (d), (d)(1) and (2); 121.412(a)(1) and (2), (d), (d)(1) and (2); 121.413(a)(2), (c)(7) and (7)(iv), (d)(2) and (2)(iv), (f), (g)(1) and (2), and (h); and 121.414(a)(2), (c)(8) and (8)(iv), (d)(2) and (2)(iv), (f), (g), (g)(1) and (2), and (h).

2. Part 135

The FAA did not receive any comments on its proposed part 135 terminology changes as discussed in the

NPRM. Specifically, the FAA proposed to change “check airman” to “check pilot,” in the singular and plural, as well as changing “flight simulator” to

“FSTD,”²⁶ where appropriate, and adopts these revisions in this final rule. The following table sets forth the specific revised regulatory citations.

TABLE 4—TERMINOLOGY CHANGES IN PART 135

Revision	Affected regulations (14 CFR)
“Check airman” to “check pilot”	§§ 135.113; 135.297(c)(2); 135.323(a)(1) and (c); 135.337(a)(1), (a)(2), (b), (b)(1), (b)(6), (d), (d)(1), and (d)(2); 135.339(a), (a)(1), (c)(1), and (d); 135.340(a)(2).
“Check airmen” to “check pilots and check flight engineers”.	§§ 135.321(a)(2); 135.323(a)(4); 135.324(b)(4); 135.337 heading; 135.337(a)(3); 135.339 heading; 135.339(c), (d), (e), and (g).
“Simulator” to “FSTD”	§§ 135.323(a)(4); 135.337(a)(1), (a)(2), (d), (d)(1), and (d)(2); 135.338(a)(1), (a)(2), (d), (d)(1), and (d)(2); 135.339 heading; 135.339(g); and 135.340(g).

3. Removal of Certain Dated Provisions

During the pendency of this rulemaking, the FAA noted several provisions in parts 121 and 135 that direct action or remove action after a certain date that has since passed. As a result, these provisions are unnecessary

and may be removed without any substantive effect. The FAA notes that, while these removals were not included in the NPRM to this Final Rule, they are purely editorial revisions in nature that do not result in additional or lesser

requirements on the regulated community.

First, in December 1995, the FAA published the Air Carrier and Commercial Operator Training Programs final rule.²⁷ This created a rule (§ 121.404) with compliance

²⁴ There are certain instances in part 121 where “check airman” directs action only on a pilot or a flight engineer, not both. For example, § 121.413(e) sets forth initial and transition flight training specific to check pilots and check flight engineers. In these instances, the appropriate replacement is made.

²⁵ Specifically, an FSTD is defined as a full flight simulator or a flight training device. Additionally, the FAA notes that a flight simulation training device is abbreviated “FSTD” pursuant to 14 CFR 1.2.

²⁶ The FAA notes that the regulations refer to check pilot and flight instructor duties only in flight

simulator in § 135.337(f)(1) and (2) and § 135.338(f)(1) and (2). However, in practice, these regulations apply to any checking and instruction in flight training devices, as well.

²⁷ *Air Carrier and Commercial Operator Training Programs*, 60 FR 65940 (Dec. 20, 1995).

requirements for flight crewmembers, flight attendants, and aircraft dispatchers to have received Crew Resource Management (CRM) or Dispatch Resource Management (DRM) initial training by certain dates (*i.e.*, after March 19, 1998 and after March 19, 1999). Because these dates have passed, the FAA removes references to the expired compliance dates from § 121.404 in this final rule.

Next, in November 2013, the FAA issued the Qualification, Service, and Use of Crewmembers and Aircraft Dispatchers final rule.²⁸ That rule prescribed a compliance date of March 12, 2019, for certain provisions. Because March 12, 2019, has passed, the FAA is removing references to that expired compliance date, as well as certain requirements in part 121 subparts N and O that have expired. Specifically, the following paragraphs list a compliance date of March 12, 2019, as an outgrowth of that rule. Because these regulations are now in effect and do not require an explicit compliance date, the following paragraphs are revised or removed, as appropriate,²⁹ from the regulations:

- § 121.403(b)(2);
- § 121.407(e);
- § 121.408(f);
- § 121.409(b)(ii)(A);³⁰
- § 121.413(i);
- § 121.414(i);
- § 121.415(k);
- § 121.419(f);
- § 121.423(f);
- § 121.424(f);
- § 121.427(f);
- § 121.433(d);³¹
- § 121.441(a)(1);
- § 121.544;
- Appendix E to part 121, I.(c), I.(d), II.(c), and IV.(d)(2);
- Appendix F to part 121, I.(c), I.(d)(2), II.(c)(2), and V.(c)(2);

²⁸ *Qualification, Service, and Use of Crewmembers and Aircraft Dispatchers*, 78 FR 67800 (Nov. 12, 2013).

²⁹ Some paragraphs are only utilized to set forth the compliance date; these paragraphs are removed in their entirety (*e.g.*, § 121.413(i)). Other paragraphs set forth the compliance date among other text within the paragraph; these paragraphs are revised to remove only the compliance date phrasing (*e.g.*, § 121.407(e)).

³⁰ The compliance date for § 121.407(b)(2)(ii)(B)(6) has passed and, therefore, the requirement to provide an opportunity for each PIC to demonstrate leadership and command skills as part of LOFT is currently in effect. Therefore, the introductory text in paragraph (b)(2)(ii)(B) is rendered unnecessary, and the list of (b)(2)(ii)(B)(1) through (6) becomes (b)(2)(ii)(A) through (F).

³¹ The elimination of the compliance date in § 121.433 resulted in the removal of paragraph (d) in its entirety. As a result, § 121.433(e) is redesignated to § 121.433(d). In turn, this final rule makes a conforming amendment in § 121.427(e)(1)(ii)(B) to correct the cross-reference of § 121.433(e) to (d).

- Appendix H to part 121, 6.

Finally, in February 2020, the FAA issued the Pilot Professional Development final rule.³² That rule included April 27, 2022, or April 27, 2023, as a compliance date for certain provisions in part 121. For other provisions in part 121, the rule included April 27, 2022, as an expiration date. The FAA removes references to the April 27, 2022, compliance dates as well as any requirements in part 121 subpart N and appendix E to part 121 that expired on April 27, 2022. This revision includes the removal of reference to the April 27, 2022, compliance date in corresponding parts 91 and 135 that refer to part 121 certificate holders, specifically, §§ 91.1063 and 135.3. Furthermore, the FAA removes references to the April 27, 2023, compliance date, as air carriers are already in compliance with the provisions tied to that compliance date.

The following paragraphs are revised or removed, as appropriate,³³ from the regulations:

- § 91.1063(b)(2)(i) and (ii);
- § 121.409(b)(2)(ii)(B)(6);³⁴
- § 121.415(e)(2);
- § 121.419(c) and (g);
- § 121.420(c);
- § 121.424(b) and (g);
- § 121.426(d);
- § 121.429(a); and
- § 135.3(d)(1) and (2).

V. Regulatory Notices and Analyses

Federal agencies consider the impacts of regulatory actions under a variety of executive orders and other requirements. First, Executive Order 12866 and Executive Order 13563, as amended by Executive Order 14094 (“Modernizing Regulatory Review”), direct that each Federal agency propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements

³² *Pilot Professional Development*, 85 FR 10896 (Feb. 25, 2020).

³³ Some paragraphs are only utilized to set forth the compliance date; these paragraphs are removed in their entirety (*e.g.*, § 121.420(c)). Other paragraphs set forth the compliance date among other text within the paragraph; these paragraphs are revised to remove only the compliance date phrasing (*e.g.*, § 121.429(a)).

³⁴ To note, § 121.409(b)(2)(ii)(B)(6) is redesignated as § 121.409(b)(2)(ii)(F), as discussed in footnote 27 of this preamble. As a result of the redesignation, the FAA made a conforming amendment to § 135.3(d)(2) to revise the cross reference in that section to the updated citation of § 121.409(b)(2)(ii)(F).

Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include 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 or more (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is \$183 million using the most current (2023) Implicit Price Deflator for the Gross Domestic Product.

In conducting these analyses, the FAA has determined that this final rule will: (1) have savings and no additional costs, (2) not be an economically “significant regulatory action” as defined in section 3(f) of Executive Order 12866 as amended by Executive Order 14094, (3) not have a significant economic impact on a substantial number of small entities, (4) not create unnecessary obstacles to the foreign commerce of the United States, and (5) not impose an unfunded mandate on State, local, or Tribal governments, or on the private sector by exceeding the threshold identified above.

A. Regulatory Evaluation

As previously discussed, the FAA has determined the changes in this final rule will have no adverse impact on safety. The FAA has determined that allowing parts 121 and 135 check pilots and parts 121 and 135 flight instructors to perform their functions in an airplane without a medical certificate (unless they are required flightcrew members) has no negative effect on safety. Further, pilots serving as required flightcrew members must be fully qualified to serve as such and must have the appropriate medical certificate. If a check pilot or flight instructor is not a required flightcrew member, they are not necessary for the operation, and the flight may proceed whether or not they are present. The FAA’s current application of the regulations to allow check pilots, check FEs, and flight instructors to serve without medical certificates if not serving as required flightcrew members has caused no degradation in the safe operation of aircraft. Conversely, requiring a medical certificate for check pilots, check FEs, and flight instructors who are not serving as required flightcrew members would result in an unnecessary burden.

As of January 2020, there are approximately 1,069 part 135 check

pilots.³⁵ Of these 1,069 part 135 check pilots, there are roughly 532 part 135 check pilots who do not hold a medical certificate. In the NPRM, the FAA estimated cost savings from enabling check pilots who do not hold a medical certificate to perform their duties in an aircraft. The FAA requested additional information and data on the expanded opportunities for affected check pilots but did not receive additional information or data. The final rule instead clarifies that check pilots who are otherwise qualified and are not serving as required flightcrew are already exempt from having to hold a medical certificate as a matter of FAA policy (see section III. of this preamble, which explained that the FAA gave force and effect to the most relieving provision by not requiring flight instructors and check airmen performing their respective duties in aircraft to hold any medical certificate when not serving as a required flightcrew member). Since these check pilots can already perform their duties in an aircraft, the FAA does not estimate cost savings in this final rule but notes that the clarification could provide minimal cost savings.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) of 1980 (Pub. L. 96–354, codified at 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) and the Small Business Jobs Act of 2010 (Pub. L. 111–240), requires Federal agencies to consider the effects of the regulatory action on small entities and to minimize any significant economic impact. The term “small entities” includes 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.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify,

and a regulatory flexibility analysis is not required.

This final rule clarifies that part 135 check pilots who do not hold a current medical certificate but are otherwise qualified can function as check pilots, check FEs, and flight instructors in aircraft. This change could provide cost savings to a few part 135 check pilots without additional costs. The final rule also clarifies related FAA regulations without substantive effect. Thus, the expected outcome would be a small positive impact on any small entity affected by this rulemaking action.

Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that those international standards be the basis for U.S. standards. The FAA has assessed the potential effect of this rule and determined that it has only a domestic impact and, therefore, does not present any obstacle to foreign commerce of the United States.

D. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or Tribal government or the private sector to incur direct costs without the Federal government having first provided the funds to pay those costs. The FAA determined that this final rule will not result in the expenditure of \$183 million or more by State, local, or Tribal governments, in the aggregate, or the private sector, in any one year.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

The existing information collection associated with all check pilot and flight instructor medical certificates in parts 121 and 135 was approved under OMB control number 2120–0034. The information collection is used to collect medical certificate information to determine whether applicants are medically qualified to perform the duties associated with the class of medical certificate sought. The FAA has determined that removing the medical certificate requirement for part 135 check pilots (aircraft) who are currently eligible for a medical certificate but who may choose to allow their certificate to expire would result in a negligible reduction in the information collection, as pilots serving as a required flightcrew member would still need to maintain a valid medical certificate. The FAA has determined that there is no reduction in the information collection associated with part 121 check pilots and flight instructors and part 135 flight instructors. The FAA has also determined that there is no new requirement for information collection associated with this rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these regulations.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from the preparation of an environmental assessment or environmental impact statement under NEPA in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion

³⁵ National Vital Information Subsystem (NVIS) database, January 2020. All estimates of affected check pilots reported in this section are based on information from FAA's Air Transportation Division and the National Vital Information Subsystem (NVIS) database.

identified in paragraph 5–6.6f for regulations and that no extraordinary circumstances exist.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132. The FAA has determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, this rule will not have federalism implications.

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

Consistent with Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments,” and FAA Order 1210.20, American Indian and Alaska Native Tribal Consultation Policy and Procedures, the FAA ensures that Federally Recognized Tribes (Tribes) are given the opportunity to provide meaningful and timely input regarding Federal actions that have the potential to uniquely or significantly affect their respective Tribes. The FAA has not identified any unique or significant effects, environmental or otherwise, on Tribes resulting from this final rule.

C. Executive Order 13211, Regulations that Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this rule under Executive Order 13211. The FAA has determined that it is not a “significant energy action” under the Executive order and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

D. Executive Order 13609, Promoting International Regulatory Cooperation and International Trade Analysis

Under Executive Order 13609, Promoting International Regulatory Cooperation, agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, regulatory approaches developed through international cooperation can provide equivalent protection to standards developed independently while also minimizing

unnecessary differences. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609 and has determined that this action does not affect international regulatory cooperation.

VII. How To Obtain Additional Information

A. Electronic Access and Filing

A copy of the notice of proposed rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at <https://www.regulations.gov> using the docket number listed above. A copy of this rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register’s website at <https://www.federalregister.gov> and the Government Publishing Office’s website at <https://www.govinfo.gov>. A copy may also be found on the FAA’s Regulations and Policies website at https://www.faa.gov/regulations_policies.

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket, notice, or amendment number of this rulemaking.

All documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects

14 CFR Part 91

Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 121

Air carriers, Aircraft, Airmen, Aviation safety, Transportation.

14 CFR Part 135

Air taxis, Aircraft, Airmen, Aviation safety.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1063 by revising paragraphs (b)(2)(i) and (ii) to read as follows:

§ 91.1063 Testing and training: Applicability and terms used.

* * * * *

(b) * * *

(2) * * *

(i) Each program manager must include in upgrade ground training for pilots, instruction in at least the subjects identified in § 121.419(a) of this chapter, as applicable to their assigned duties; and, for pilots serving in crews of two or more pilots, instruction and facilitated discussion in the subjects identified in § 121.419(c) of this chapter.

(ii) Each program manager must include in upgrade flight training for pilots, flight training for the maneuvers and procedures required in § 121.424(a), (c), (e), and (f) of this chapter; and, for pilots serving in crews of two or more pilots, the flight training required in § 121.424(b) of this chapter.

* * * * *

PART 121—OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

■ 3. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40119, 41706, 42301 preceding note added by Pub. L. 112–95, sec. 412, 126 Stat. 89, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44729, 44732; 46105; Pub. L. 111–216, 124 Stat. 2348 (49 U.S.C. 44701 note); Pub. L. 112–95, 126 Stat 62 (49 U.S.C. 44732 note); Pub. L.

115–254, 132 Stat. 3186 (49 U.S.C. 44701 note).

■ 4. Amend § 121.401 by revising paragraphs (a)(1) and (4), (c), and (e) and removing the undesignated text following paragraph (e) to read as follows:

§ 121.401 Training program: General.

(a) * * *

(1) Establish and implement a training program that satisfies the requirements of this subpart and appendices E and F of this part and that ensures that each crewmember, aircraft dispatcher, flight instructor, check pilot, and check flight engineer is adequately trained to perform his or her assigned duties. Prior to implementation, the certificate holder must obtain initial and final FAA approval of the training program.

* * * * *

(4) Provide enough flight instructors and approved check pilots and check flight engineers to conduct the flight training and checks required under this part.

* * * * *

(c) Each instructor, supervisor, check pilot, or check flight engineer who is responsible for a particular ground training subject, segment of flight training, course of training, flight check, or competence check under this part shall certify as to the proficiency and knowledge of the crewmember, aircraft dispatcher, flight instructor, check pilot, or check flight engineer concerned upon completion of that training or check. That certification shall be made a part of the crewmember's or dispatcher's record. When the certification required by this paragraph is made by an entry in a computerized recordkeeping system, the certifying instructor, supervisor, check pilot, or check flight engineer must be identified with that entry. However, the signature of the certifying instructor, supervisor, check pilot, or check flight engineer is not required for computerized entries.

* * * * *

(e) A person who progresses successfully through flight training; is recommended by his instructor, check pilot, or check flight engineer; and successfully completes the appropriate flight check for a check pilot, check flight engineer, or the Administrator need not complete the programmed hours of flight training for the particular airplane. However, whenever the Administrator finds that 20 percent of the flight checks given at a particular training base during the previous 6 months under this paragraph are unsuccessful, this paragraph may not be used by the certificate holder at that

base until the Administrator finds that the effectiveness of the flight training there has improved.

■ 5. Amend § 121.402 by revising paragraph (b)(4) to read as follows:

§ 121.402 Training program: Special rules.

* * * * *

(b) * * *

(4) Has sufficient instructors, check pilots, and check flight engineers qualified under the applicable requirements of §§ 121.411 or 121.412 to provide training, testing, and checking to persons subject to the requirements of this subpart.

■ 6. Amend § 121.403 by revising paragraph (b)(2) to read as follows:

§ 121.403 Training program: Curriculum.

* * * * *

(b) * * *

(2) A list of all the training equipment approved under § 121.408 as well as other training aids that the certificate holder will use.

* * * * *

■ 7. Revise § 121.404 to read as follows:

§ 121.404 Crew and dispatcher resource management training.

No certificate holder may use a person as a flightcrew member, flight attendant, or aircraft dispatcher unless that person has completed approved crew resource management (CRM) or dispatcher resource management (DRM) initial training, as applicable, with that certificate holder or with another certificate holder.

■ 8. Amend § 121.407 by revising paragraphs (a)(5) and (e) to read as follows:

§ 121.407 Training program: Approval of flight simulation training devices.

(a) * * *

(5) Have a daily discrepancy log kept with each discrepancy entered in that log by the appropriate instructor, check pilot, or check flight engineer at the end of each training or check flight.

* * * * *

(e) An FFS approved under this section must be used instead of the airplane to satisfy the pilot flight training requirements prescribed in the extended envelope training set forth in § 121.423 of this part.

■ 9. Amend § 121.408 by:

■ a. Revising paragraphs (d) introductory text and (d)(1), and

■ b. Removing paragraph (f).

The revisions read as follows:

§ 121.408 Training equipment other than flight simulation training devices.

* * * * *

(d) All training equipment must have a record of discrepancies. The

documenting system must be readily available for review by each instructor, check pilot, check flight engineer, or supervisor prior to conducting training or checking with that equipment.

(1) Each instructor, check pilot, check flight engineer or supervisor conducting training or checking, and each person conducting an inspection of the equipment who discovers a discrepancy, including any missing, malfunctioning, or inoperative components, must record a description of that discrepancy and the date that the discrepancy was identified.

* * * * *

■ 10. Amend § 121.409 by revising and republishing paragraph (b)(2)(ii) to read as follows:

§ 121.409 Training courses using flight simulation training devices.

* * * * *

(b) * * *

(2) * * *

(ii) Line-oriented flight training (LOFT) that—

(A) Utilizes a complete flight crew;

(B) Includes at least the maneuvers and procedures (abnormal and emergency) that may be expected in line operations;

(C) Includes scenario-based or maneuver-based stall prevention training before, during or after the LOFT scenario for each pilot;

(D) Is representative of two flight segments appropriate to the operations being conducted by the certificate holder;

(E) Provides an opportunity to demonstrate workload management and pilot monitoring skills; and

(F) Provides an opportunity for each pilot in command to demonstrate leadership and command skills.

* * * * *

■ 11. Revise § 121.411 to read as follows:

§ 121.411 Qualifications: Check pilots and check flight engineers.

(a) For the purposes of this part:

(1) A check pilot (airplane) or check flight engineer (airplane) is a person who is qualified, and permitted, to conduct flight checks or instruction in an airplane for a particular type airplane.

(2) A check pilot (FSTD) or check flight engineer (FSTD) is a person who is qualified to conduct flight checks or instruction-only in an FSTD for a particular type airplane.

(3) Check pilots and check flight engineers are those persons who perform the functions described in § 121.401(a)(4).

(b) No certificate holder may use a person, nor may any person serve as a check pilot or check flight engineer in a training program established under this subpart unless, with respect to the airplane type involved, that person—

(1) Holds the pilot certificates and ratings required to serve as a pilot in command or a flight engineer certificate, as applicable, in operations under this part;

(2) Has satisfactorily completed the appropriate training phases for the airplane, including recurrent training, that are required to serve as a pilot in command or flight engineer, as applicable, in operations under this part;

(3) Has satisfactorily completed the appropriate proficiency or flight checks that are required to serve as a pilot in command or flight engineer, as applicable, in operations under this part;

(4) Has satisfactorily completed the applicable training requirements of § 121.413; and

(5) Has been approved by the Administrator for the check pilot or check flight engineer duties involved.

(c) Completion of the requirements in paragraphs (b)(2), (3), and (4) of this section, as applicable, shall be entered in the individual's training record maintained by the certificate holder.

(d) A check pilot (FSTD) and check flight engineer (FSTD) must accomplish the following—

(1) Fly at least two flight segments as a required crewmember for the type airplane involved within the 12-month period preceding the performance of any check pilot or check flight engineer duty in an FSTD; or

(2) Satisfactorily complete an approved line-observation program within the period prescribed by that program and that must precede the performance of any check pilot or check flight engineer duty in an FSTD.

(e) The flight segments or line-observation program required in paragraph (d) of this section are considered to be completed in the month required if completed in the calendar month before or in the calendar month after the month in which it is due.

(f) A person who serves as a required flightcrew member while performing check pilot or check flight engineer duties must also meet the requirements of this chapter for the duty position in which they are serving.

■ 12. Revise § 121.412 to read as follows:

§ 121.412 Qualifications: Flight instructors.

(a) For the purposes of this part:

(1) A flight instructor (airplane) is a person who is qualified to instruct in an airplane for a particular type airplane.

(2) A flight instructor (FSTD) is a person who is qualified to instruct only in an FSTD for a particular type airplane.

(3) Flight instructors are those instructors who perform the functions described in § 121.401(a)(4).

(b) No certificate holder may use a person nor may any person serve as a flight instructor in a training program established under this subpart unless, with respect to the airplane type involved, that person—

(1) Holds the pilot certificates and rating required to serve as a pilot in command or a flight engineer certificate, as applicable, in operations under this part;

(2) Has satisfactorily completed the appropriate training phases for the airplane, including recurrent training, that are required to serve as a pilot in command or flight engineer, as applicable, in operations under this part;

(3) Has satisfactorily completed the appropriate proficiency or flight checks that are required to serve as a pilot in command or flight engineer, as applicable, in operations under this part;

(4) Has satisfactorily completed the applicable training requirements of § 121.414.

(c) Completion of the requirements in paragraphs (b) (2), (3), and (4) of this section, as applicable, shall be entered in the individual's training record maintained by the certificate holder.

(d) A flight instructor (FSTD) must accomplish the following—

(1) Fly at least two flight segments as a required crewmember for the type of airplane within the 12-month period preceding the performance of any flight instructor duty in an FSTD; or

(2) Satisfactorily complete an approved line-observation program within the period prescribed by that program preceding the performance of any flight instructor duty in an FSTD.

(e) The flight segments or line-observation program required in paragraph (d) of this section is considered completed in the month required if completed in the calendar month before, or the calendar month after the month in which it is due.

(f) A person who serves as a required flightcrew member while performing flight instructor duties must also meet the requirements of this chapter for the duty position in which they are serving.

■ 13. Revise § 121.413 to read as follows:

§ 121.413 Initial, transition and recurrent training and checking requirements: Check pilots and check flight engineers.

(a) No certificate holder may use a person nor may any person serve as a check pilot or check flight engineer unless—

(1) That person has satisfactorily completed initial or transition check pilot or check flight engineer training, as applicable; and

(2) Within the preceding 24 calendar months, that person satisfactorily conducts a check or supervises operating experience under the observation of an FAA inspector or an aircrew designated examiner employed by the operator. The observation check may be accomplished in part or in full in an airplane and in an FSTD.

(b) The observation check required by paragraph (a)(2) of this section is considered to have been completed in the month required if completed in the calendar month before, or the calendar month after, the month in which it is due.

(c) The initial ground training for check pilots or check flight engineers must include the following, as applicable:

(1) Check pilot or check flight engineer duties, functions, and responsibilities.

(2) The applicable Code of Federal Regulations and the certificate holder's policies and procedures.

(3) The appropriate methods, procedures, and techniques for conducting the required checks.

(4) Proper evaluation of student performance, including the detection of—

(i) Improper and insufficient training; and

(ii) Personal characteristics of an applicant that could adversely affect safety.

(5) The appropriate corrective action in the case of unsatisfactory checks.

(6) The approved methods, procedures, and limitations for performing the required normal, abnormal, and emergency procedures in the airplane.

(7) For check pilots or check flight engineers who conduct training or checking in an FSTD, the following subjects specific to the device(s) for the airplane type:

(i) Proper operation of the controls and systems;

(ii) Proper operation of environmental and fault panels;

(iii) Data and motion limitations of simulation; and

(iv) The minimum airplane simulator equipment required by this part or part 60 of this chapter for each maneuver and procedure completed in an FSTD.

(d) The transition ground training for check pilots or check flight engineers must include the following:

(1) The approved methods, procedures, and limitations for performing the required normal, abnormal, and emergency procedures applicable to the airplane to which the check pilot or check flight engineer is transitioning.

(2) For check pilots or check flight engineers who conduct training or checking in an FSTD, the following subjects specific to the device(s) for the airplane type to which the check pilot or check flight engineer is transitioning:

(i) Proper operation of the controls and systems;

(ii) Proper operation of environmental and fault panels;

(iii) Data and motion limitations of simulation; and

(iv) The minimum airplane simulator equipment required by this part or part 60 of this chapter for each maneuver and procedure completed in an FSTD.

(e) The initial and transition flight training for check pilots (airplane) and check flight engineers (airplane) must include the following:

(1) The safety measures for emergency situations that are likely to develop during a check.

(2) The potential results of improper, untimely, or non-execution of safety measures during a check.

(3) For check pilots (airplane)—

(i) Training and practice in conducting flight checks from the left and right pilot seats in the required normal, abnormal, and emergency procedures to ensure competence to conduct the pilot flight checks required by this part; and

(ii) The safety measures to be taken from either pilot seat for emergency situations that are likely to develop during a check.

(4) For check flight engineers (airplane), training to ensure competence to perform assigned duties.

(f) The requirements of paragraph (e) of this section may be accomplished in full or in part inflight and in an FSTD, as appropriate.

(g) The initial and transition flight training for check pilots or check flight engineers who conduct training or checking in an FSTD must include the following:

(1) Training and practice in conducting flight checks in the required normal, abnormal, and emergency procedures to ensure competence to conduct the flight checks required by

this part. This training and practice must be accomplished in an FSTD.

(2) Training in the operation of FSTDs to ensure competence to conduct the flight checks required by this part.

(h) Recurrent ground training for check pilots or check flight engineers who conduct training or checking in an FSTD must be completed every 12 calendar months and must include the subjects required in paragraph (c)(7) of this section.

■ 14. Amend § 121.414 by:

■ a. Revising the section heading;

■ b. Revising paragraphs (a)(2), (c)(8) introductory text and (c)(8)(iv), (d)(2) introductory text and (d)(2)(iv), (f), (g), and (h), and

■ c. Removing paragraph (i).

The revisions read as follows:

§ 121.414 Initial, transition and recurrent training and checking requirements: Flight instructors.

(a) * * *

(2) Within the preceding 24 calendar months, that person satisfactorily conducts instruction under the observation of an FAA inspector, an operator check pilot, a check flight engineer, or an aircrew designated examiner employed by the operator, as appropriate. The observation check may be accomplished in part or in full in an airplane and an FSTD.

* * * * *

(c) * * *

(8) For flight instructors who conduct training in an FSTD, the following subjects specific to the device(s) for the airplane type:

* * * * *

(iv) The minimum airplane simulator equipment required by this part 121 or part 60 of this chapter for each maneuver and procedure completed in an FSTD.

(d) * * *

(2) For flight instructors who conduct training in an FSTD, the following subjects specific to the device(s) for the airplane type to which the flight instructor is transitioning:

* * * * *

(iv) The minimum airplane simulator equipment required by this part or part 60 of this chapter for each maneuver and procedure completed in an FSTD.

* * * * *

(f) The requirements of paragraph (e) of this section may be accomplished in full or in part inflight and in an FSTD, as appropriate.

(g) The initial and transition flight training for flight instructors who conduct training in an FSTD must include the following:

(1) Training and practice in the required normal, abnormal, and

emergency procedures to ensure competence to conduct the flight instruction required by this part. This training and practice must be accomplished in full or in part in an FSTD.

(2) Training in the operation of FSTDs to ensure competence to conduct the flight instruction required by this part.

(h) Recurrent flight instructor ground training for flight instructors who conduct training in an FSTD must be completed every 12 calendar months and must include the subjects required in paragraph (c)(8) of this section.

■ 15. Amend § 121.415 by:

■ a. Revising paragraph (e), and

■ b. Removing paragraph (k).

The revision reads as follows:

§ 121.415 Crewmember and dispatcher training program requirements.

* * * * *

(e) Upgrade training as specified in §§ 121.420 and 121.426 for a particular type airplane may be included in the training program for flightcrew members who have qualified and served as second in command pilot on that airplane.

* * * * *

■ 16. Amend § 121.419 by:

■ a. Revising paragraphs (c) and (f); and

■ b. Removing paragraph (g).

The revisions read as follows:

§ 121.419 Pilots and flight engineers: Initial, transition, conversion and upgrade ground training.

* * * * *

(c) In addition to the requirements in paragraph (a) or (b) of this section, as applicable, initial ground training for pilots in command must include instruction and facilitated discussion on the following:

* * * * *

(f) Initial programmed hours applicable to pilots as specified in paragraphs (d) and (e) of this section must include 2 additional hours to meet the requirements in paragraphs (a)(2)(xi) and (xii) of this section.

§ 121.420 [Amended]

■ 17. Amend § 121.420 by removing paragraph (c).

§ 121.423 [Amended]

■ 18. Amend § 121.423 by removing paragraph (f).

■ 19. Amend § 121.424 by:

■ a. Revising paragraph (b), and

■ b. Removing paragraphs (f) and (g).

The revision reads as follows:

§ 121.424 Pilots: Initial, transition, conversion, and upgrade flight training.

* * * * *

(b) In addition to the requirements in paragraph (a) of this section, initial flight training for pilots in command must include sufficient scenario-based training incorporating CRM and leadership and command skills to ensure the pilot's proficiency as pilot in command. The training required by this paragraph (b) may be completed inflight or in an FSTD.

§ 121.426 [Amended]

■ 20. Amend § 121.426 by removing paragraph (d).

■ 21. Amend § 121.427 by revising paragraphs (e)(1)(ii)(B) and (f) to read as follows:

§ 121.427 Recurrent training.

* * * * *

(e) * * *

(1) * * *

(ii) * * *

(B) Satisfactory completion of a proficiency check may be substituted for recurrent flight training as permitted in § 121.433(c) and (d).

* * * * *

(f) Recurrent programmed hours applicable to pilots as specified in paragraph (c)(1) of this section must include 30 additional minutes to meet the requirements in paragraph (e)(1)(i) of this section.

■ 22. Amend § 121.429 by revising the introductory text of paragraph (a) to read as follows:

§ 121.429 Pilots in command: Leadership and command and mentoring training.

(a) No certificate holder may use a pilot as pilot in command in an operation under this part unless the pilot has completed the following ground training in accordance with the certificate holder's approved training program:

* * * * *

■ 23. Amend § 121.433 by revising paragraph (d) and removing paragraph (e) to read as follows:

§ 121.433 Training required.

* * * * *

(d) Notwithstanding paragraph (c)(2) of this section, a proficiency check as provided in § 121.441 may not be substituted for the extended envelope training required by § 121.423 or training in those maneuvers and procedures set forth in a certificate holder's approved low-altitude windshear flight training program when that program is included in a recurrent flight training course as required by § 121.409(d).

■ 24. Amend § 121.434 by revising the introductory text of paragraph (d) to read as follows:

§ 121.434 Operating experience, operating cycles, and consolidation of knowledge and skills.

* * * * *

(d) A flight engineer must perform the duties of a flight engineer under the supervision of a check flight engineer or a qualified flight engineer for at least the following number of hours:

* * * * *

■ 25. Amend § 121.439 by revising paragraphs (b)(1) and (e) to read as follows:

§ 121.439 Pilot qualification: Recent experience.

* * * * *

(b) * * *

(1) Under the supervision of a check pilot, make at least three takeoffs and landings in the type airplane in which that person is to serve or in a Level B or higher FFS.

* * * * *

(e) A check pilot who observes the takeoffs and landings prescribed in paragraph (b)(1) of this section shall certify that the person being observed is proficient and qualified to perform flight duty in operations under this part and may require any additional maneuvers that are determined necessary to make this certifying statement.

* * * * *

■ 26. Amend § 121.440 by revising paragraphs (b)(1) and (c)(1) to read as follows:

§ 121.440 Line checks.

* * * * *

(b) * * *

(1) Be given by a check pilot who is currently qualified on both the route and the airplane; and

* * * * *

(c) * * *

(1) Be given by a check pilot who is currently qualified on the airplane; and

* * * * *

■ 27. Amend § 121.441 by revising paragraphs (a)(1)(i) and (ii) and (b)(2) to read as follows:

§ 121.441 Proficiency checks.

(a) * * *

(1) * * *

(i) A proficiency check within the preceding 12 calendar months in the aircraft type in which the person is to serve and,

(ii) In addition, within the preceding 6 calendar months, either a proficiency

check or the approved FFS course of training.

* * * * *

(b) * * *

(2) It must be given by the Administrator or a check pilot.

* * * * *

■ 28. Amend § 121.445 by revising paragraph (d)(2) to read as follows:

§ 121.445 Pilot in command airport qualification: Special areas and airports.

* * * * *

(d) * * *

(2) By flying over a route or area as pilot in command under the supervision of a check pilot using the special type of navigation system.

* * * * *

■ 29. Revise § 121.544 to read as follows:

§ 121.544 Pilot monitoring.

Each pilot who is seated at the pilot controls of the aircraft while not flying the aircraft must accomplish pilot monitoring duties as appropriate in accordance with the certificate holder's procedures contained in the manual required by § 121.133.

■ 30. Amend § 121.915 by revising paragraph (b)(2)(iii) to read as follows:

§ 121.915 Continuing qualification curriculum.

* * * * *

(b) * * *

(2) * * *

(iii) During the line checks required under paragraph (b)(2)(i) and (ii) of this section, each person performing duties as a pilot in command, second in command, or flight engineer for that flight must be individually evaluated to determine whether the person remains adequately trained and currently proficient with respect to the particular aircraft, crew position, and type of operation in which he or she serves; and the person has sufficient knowledge and skills to operate effectively as part of a crew. The evaluator must be a check pilot, check flight engineer, an APD, or an FAA inspector and must hold the certificates and ratings required of the pilot in command.

* * * * *

■ 31. Amend § 121.919 by revising paragraph (e) to read as follows:

§ 121.919 Certification.

* * * * *

(e) The applicant has been trained to proficiency on the certificate holder's approved AQP Qualification Standards as witnessed by an instructor, check pilot, check flight engineer, or APD and has passed an LOE administered by an APD or the FAA.

- (c) Crosswind landing with gusts, if practicable under existing meteorological, airport, and traffic conditions
- (d) * * *

B*

Notwithstanding the requirements of subparagraphs (d)(1) and (2) of this paragraph, for an SIC proficiency check, except for an SIC proficiency check for a type rating, the simulated loss of power may be only the most critical powerplant. In addition, a PIC may omit the maneuver required by subparagraph (d)(1) or (d)(2) of this paragraph during a required proficiency check or FFS course of training if the PIC satisfactorily performed that maneuver during the preceding proficiency check, or during the preceding approved FFS course of training under the observation of a check pilot, whichever was completed later.

* * * * *

- 34. In appendix H to part 121 amend the section Advanced Simulation Training Program by revising the introductory text and paragraphs 3., 4., 5., and 6. to read as follows:

Appendix H to Part 121—Advanced Simulation

Advanced Simulation Training Program

For a certificate holder to conduct Level C or D training under this appendix, all required FFS instruction and checks must be conducted under an advanced simulation training program approved by the Administrator for the certificate holder. This program must also ensure that all instructors, check pilots, and check flight engineers used in Appendix H training and checking are highly qualified to provide the training required in the training program. The advanced simulation training program must include the following:

* * * * *

3. Documentation that each instructor and check pilot has served for at least 1 year in that capacity in a certificate holder's approved program or has served for at least 1 year as a pilot in command or second in command in an airplane of the group in which that pilot is instructing or checking.

4. A procedure to ensure that each instructor, check pilot, and check flight engineer actively participates in either an approved regularly scheduled line flying program as a flightcrew member or an approved line observation program in the same airplane type for which that person is instructing or checking.

5. A procedure to ensure that each instructor, check pilot, and check flight engineer is given a minimum of 4 hours of training each year to become familiar with the certificate holder's advanced simulation training program, or changes to it, and to emphasize their respective roles in the program. Training for instructors, check pilots, and check flight engineers must include training policies and procedures, instruction methods and techniques, operation of FFS controls (including environmental and trouble panels), limitations of the FFS, and minimum equipment required for each course of training.

6. A special Line-Oriented Flight Training (LOFT) program to facilitate the transition from the FFS to line flying. This LOFT program must consist of at least a 4-hour course of training for each flightcrew. It also

must contain at least two representative flight segments of the certificate holder's operations. One of the flight segments must contain strictly normal operating procedures from pushback at one airport to arrival at another. Another flight segment must contain training in appropriate abnormal and emergency flight operations. The LOFT must provide an opportunity for the pilot to demonstrate workload management and pilot monitoring skills.

* * * * *

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

- 35. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 41706, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722, 44730, 45101–45105; Pub. L. 112–95, 126 Stat. 58 (49 U.S.C. 44730).

- 36. Amend § 135.3 by revising paragraphs (d)(1) and (2) to read as follows:

§ 135.3 Rules applicable to operations subject to this part.

* * * * *

(d) * * *

(1) *Upgrade training.* (i) Each certificate holder must include in upgrade ground training for pilots, instruction in at least the subjects identified in § 121.419(a) of this chapter, as applicable to their assigned duties; and, for pilots serving in crews of two or more pilots, instruction and facilitated discussion in the subjects identified in § 121.419(c) of this chapter.

(ii) Each certificate holder must include in upgrade flight training for pilots, flight training for the maneuvers and procedures required in § 121.424(a), (c), (e), and (f) of this chapter; and, for pilots serving in crews of two or more pilots, the flight training required in § 121.424(b) of this chapter.

(2) Initial and recurrent leadership and command and mentoring training. Certificate holders are not required to include leadership and command

training in §§ 121.409(b)(2)(ii)(F), 121.419(c)(1), 121.424(b) and 121.427(d)(1) of this chapter and mentoring training in §§ 121.419(c)(2) and 121.427(d)(1) of this chapter in initial and recurrent training for pilots in command who serve in operations that use only one pilot.

* * * * *

- 37. Revise § 135.113 to read as follows:

§ 135.113 Passenger occupancy of pilot seat.

No certificate holder may operate an aircraft type certificated after October 15, 1971, that has a passenger seating configuration, excluding any pilot seat, of more than eight seats if any person other than the pilot in command, a second in command, a company check pilot, or an authorized representative of the Administrator, the National Transportation Safety Board, or the United States Postal Service occupies a pilot seat.

- 38. Amend § 135.297 by revising paragraph (c)(2) to read as follows:

§ 135.297 Pilot in command: Instrument proficiency check requirements.

* * * * *

(c) * * *

(2) The instrument proficiency check must be given by an authorized check pilot or by the Administrator.

* * * * *

- 39. Amend § 135.321 by revising paragraph (a)(2) to read as follows:

§ 135.321 Applicability and terms used.

(a) * * *

(2) Each certificate holder for establishing and maintaining an approved training program for crewmembers, check pilots and instructors, and other operations personnel employed or used by that certificate holder; and

* * * * *

- 40. Amend § 135.323 by revising paragraphs (a)(1) and (4), and (c) to read as follows:

§ 135.323 Training program: General.

(a) * * *

(1) Establish and implement a training program that satisfies the requirements of this subpart and that ensures that each crewmember, aircraft dispatcher, flight instructor, and check pilot is adequately trained to perform his or her assigned duties. Prior to implementation, the certificate holder must obtain initial and final FAA approval of the training program.

* * * * *

(4) Provide enough flight instructors, check pilots, and FSTD instructors to conduct required flight training and flight checks and FSTD training courses allowed under this subpart.

* * * * *

(c) Each instructor, supervisor, or check pilot who is responsible for a particular ground training subject, segment of flight training, course of training, flight check, or competence check under this part shall certify as to the proficiency and knowledge of the crewmember, flight instructor, or check pilot concerned upon completion of that training or check. That certification shall be made a part of the crewmember's record. When the certification required by this paragraph is made by an entry in a computerized recordkeeping system, the certifying instructor, supervisor, or check pilot, must be identified with that entry. However, the signature of the certifying instructor, supervisor, or check pilot is not required for computerized entries.

* * * * *

■ 41. Amend § 135.324 by revising paragraph (b)(4) to read as follows:

§ 135.324 Training program: Special rules.

* * * * *

(b) * * *

(4) Has sufficient instructor and check pilots qualified under the applicable requirements of §§ 135.337 through 135.340 to provide training, testing, and checking to persons subject to the requirements of this subpart.

■ 42. Revise § 135.337 to read as follows:

§ 135.337 Qualifications: Check pilots.

(a) For the purposes of this part:

(1) A check pilot (aircraft) is a person who is qualified to conduct flight checks in an aircraft for a particular type aircraft.

(2) A check-pilot (FSTD) is a person who is qualified to conduct flight checks only in an FSTD for a particular type aircraft.

(3) Check pilots are those persons who perform the functions described in §§ 135.321(a) and 135.323(a)(4) and (c).

(b) No certificate holder may use a person, nor may any person serve as a check pilot in a training program established under this subpart unless, with respect to the aircraft type involved, that person—

(1) Holds the pilot certificates and ratings required to serve as a pilot in command in operations under this part;

(2) Has satisfactorily completed the appropriate training phases for the aircraft, including recurrent training, that are required to serve as a pilot in command in operations under this part;

(3) Has satisfactorily completed the proficiency or competency checks that are required to serve as a pilot in command in operations under this part;

(4) Has satisfactorily completed the applicable training requirements of § 135.339;

(5) Has been approved by the Administrator for the check pilot duties involved.

(c) Completion of the requirements in paragraphs (b)(2), (3), and (4) of this section, as applicable, shall be entered in the individual's training record maintained by the certificate holder.

(d) A check pilot (FSTD) must accomplish the following—

(1) Fly at least two flight segments as a required crewmember for the type, class, or category aircraft involved within the 12-month period preceding the performance of any check-pilot duty in an FSTD; or

(2) Satisfactorily complete an approved line-observation program within the period prescribed by that program and that must precede the performance of any check pilot duty in an FSTD.

(e) The flight segments or line-observation program required in paragraph (d) of this section are considered to be completed in the month required if completed in the calendar month before or the calendar month after the month in which they are due.

(f) A person who serves as a required flightcrew member while performing check pilot duties must also meet the requirements of this chapter for the duty position in which they are serving.

■ 43. Revise § 135.338 to read as follows:

§ 135.338 Qualifications: Flight instructors.

(a) For the purposes of this part:

(1) A flight instructor (aircraft) is a person who is qualified to instruct in an aircraft for a particular type, class, or category aircraft.

(2) A flight instructor (FSTD) is a person who is qualified to instruct only in an FSTD for a particular type, class, or category aircraft.

(3) Flight instructors are those instructors who perform the functions described in §§ 135.321(a) and 135.323(a)(4) and (c).

(b) No certificate holder may use a person, nor may any person serve as a flight instructor in a training program established under this subpart unless, with respect to the type, class, or category aircraft involved, that person—

(1) Holds the pilot certificates and ratings required to serve as a pilot in command in operations under this part;

(2) Has satisfactorily completed the appropriate training phases for the aircraft, including recurrent training, that are required to serve as a pilot in command in operations under this part;

(3) Has satisfactorily completed the proficiency or competency checks that are required to serve as a pilot in command in operations under this part;

(4) Has satisfactorily completed the applicable training requirements of § 135.340.

(c) Completion of the requirements in paragraphs (b)(2), (3), and (4) of this section shall be entered in the individual's training record maintained by the certificate holder.

(d) A flight instructor (FSTD) must accomplish the following—

(1) Fly at least two flight segments as a required crewmember for the type, class, or category aircraft involved within the 12-month period preceding the performance of any flight instructor duty in an FSTD; or

(2) Satisfactorily complete an approved line-observation program within the period prescribed by that program preceding the performance of any flight instructor duty in an FSTD.

(e) The flight segments or line-observation program required in paragraph (d) of this section are considered completed in the month required if completed in the calendar month before, or in the calendar month after, the month in which they are due.

(f) A person who serves as a required flightcrew member while performing flight instructor duties must also meet the requirements of this chapter for the duty position in which they are serving.

■ 44. Amend § 135.339 by revising paragraphs (a) introductory text, (a)(1), (c) introductory text, (c)(1), (d), (e) introductory text and (g) introductory text to read as follows:

§ 135.339 Initial and transition training and checking: Check pilots.

(a) No certificate holder may use a person nor may any person serve as a check pilot unless—

(1) That person has satisfactorily completed initial or transition check pilot training; and

* * * * *

(c) The initial ground training for check pilots must include the following:

(1) Check pilot duties, functions, and responsibilities.

* * * * *

(d) The transition ground training for check pilots must include the approved methods, procedures, and limitations for performing the required normal, abnormal, and emergency procedures applicable to the aircraft to which the check pilot is in transition.

(e) The initial and transition flight training for check pilots (aircraft) must include the following—

* * * * *

(g) The initial and transition flight training for check pilots (FSTD) must include the following:

* * * * *

■ 45. Amend § 135.340 by revising paragraph (a)(2) and paragraph (g) introductory text to read as follows:

§ 135.340 Initial and transition training and checking: Flight instructors.

(a) * * *

(2) Within the preceding 24 calendar months, that person satisfactorily conducts instruction under the observation of an FAA inspector, an operator check pilot, or an aircrew designated examiner employed by the operator. The observation check may be accomplished in part or in full in an aircraft, in a flight simulator, or in a flight training device.

* * * * *

(g) The initial and transition flight training for a flight instructor (FSTD) must include the following:

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), 44701(a)(5), and 44705 in Washington, DC.

Michael Gordon Whitaker,
Administrator, Federal Aviation Administration.

[FR Doc. 2024-12621 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31552; Amdt. No. 579]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: *Effective Date:* 0901 UTC, July 11, 2024.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to

the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

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

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC, on June 7, 2024.

Thomas J. Nichols,

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

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, 11 July 2024.

PART 95—IFR ALTITUDES

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113 and 14 CFR 11.49(b)(2)

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

Amendment 579 effective date July 11, 2024

FROM	TO	MEA
Color Routes		
§ 95.60 Blue Federal Airway B3 is Amended To Delete		
ANIAK, AK NDB	ANVIK, AK NDB	3700
		MAA—17500
ANVIK, AK NDB	NORTH RIVER, AK NDB	4600
		MAA—17500
NORTH RIVER, AK NDB	NORTON BAY, AK NDB	3000
		MAA—17500
NORTON BAY, AK NDB	HOTHAM, AK NDB	4500
		MAA—17500
HOTHAM, AK NDB	NOATAK, AK NDB/DME	3300
		MAA—17500

FROM	TO	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes			
§ 95.3206 RNAV Route T206 is Amended by Adding			
ZADEL, NC WP	LIBERTY, NC VORTAC	2800	17500
LIBERTY, NC VORTAC	SNOWS, NC FIX	2900	17500

§ 95.3258 RNAV Route T258 is Amended by Adding			
GMINI, NC WP	TWHYY, NC WP	2300	17500
TWHYY, NC WP	LANHO, NC FIX	3200	17500
LANHO, NC FIX	ZEBUL, NC FIX	2900	17500
ZEBUL, NC FIX	MEYER, NC FIX	2600	17500
MEYER, NC FIX	BOUSY, VA WP	2100	17500

§ 95.3287 RNAV Route T287 is Amended by Adding			
GMINI, NC WP	MMJAY, NC WP	2400	17500
MMJAY, NC WP	MERIL, NC FIX	2400	17500
MERIL, NC FIX	SNOWS, NC FIX	2500	17500
SNOWS, NC FIX	OXFRD, NC FIX	2600	17500
OXFRD, NC FIX	BOUSY, VA WP	2300	17500
BOUSY, VA WP	MANGE, VA FIX	2000	17500
MANGE, VA FIX	FLAT ROCK, VA VORTAC	2000	17500
FLAT ROCK, VA VORTAC	GORDONSVILLE, VA VORTAC	2300	17500
GORDONSVILLE, VA VORTAC	*DENNN, VA WP	2300	17500
*3200—MCA DENNN, VA WP, N BND			
TOMYD, PA WP	HAMRR, MD WP	2700	10000
HAMRR, MD WP	DANII, MD WP	*6000	17500
*3100—MOCA			
DANII, MD WP	OBWON, MD WP	*6000	17500
*2600—MOCA			
OBWON, MD WP	VYSOR, MD WP	1900	10000
VYSOR, MD WP	SPEAK, MD FIX	*2000	10000
*1500—MOCA			
SPEAK, MD FIX	WNSTN, NJ WP	2000	17500
WNSTN, NJ WP	AVALO, NJ FIX	1700	17500
AVALO, NJ FIX	BRIGS, NJ FIX	2000	17500
BRIGS, NJ FIX	MANTA, NJ FIX	*2500	17500
*1300—MOCA			
MANTA, NJ FIX	BEADS, NY FIX	*2500	17500
*1300—MOCA			
BEADS, NY FIX	ORCHA, NY WP	2000	17500
ORCHA, NY WP	PARCH, NY FIX	2000	17500
PARCH, NY FIX	TRAIT, NY FIX	1800	17500
TRAIT, NY FIX	WACKY, CT FIX	1900	17500
WACKY, CT FIX	ASHWY, RI FIX	*2000	17500
*1500—MOCA			
ASHWY, RI FIX	LAFAY, RI FIX	2100	17500
LAFAY, RI FIX	JIKUK, RI FIX	2300	17500
JIKUK, RI FIX	YBERA, RI FIX	2200	17500
YBERA, RI FIX	PROVIDENCE, RI VOR/DME	2000	17500
PROVIDENCE, RI VOR/DME	INNDY, MA FIX	2000	17500
INNDY, MA FIX	BURDY, MA FIX	2000	17500
BURDY, MA FIX	HAVNS, MA WP	2000	17500

FROM	TO	MEA	MAA
HAVNS, MA WP *1400—MOCA	GRGIO, MA WP	*2500	17500
GRGIO, MA WP	LBSTA, MA FIX	1900	17500
LBSTA, MA FIX	SILVE, NH FIX	1700	17500
SILVE, NH FIX	SEEDY, NH FIX	*1800	17500
*1300—MOCA			
SEEDY, NH FIX	KENNEBUNK, ME VOR/DME	*2400	17500
*1900—MOCA			
Is Amended To Read in Part			
REEES, PA WP *3700—MOCA	TOMYD, PA WP	*5000	10000
§ 95.3295 RNAV Route T295 Is Amended by Adding			
DUFFI, NC FIX	POORK, VA WP	2500	17500
POORK, VA WP	DOGWD, VA WP	2000	17500
DOGWD, VA WP	HOUKY, VA WP	1900	17500
Is Amended To Delete			
POORK, VA WP	KREGG, VA WP	2000	17500
KREGG, VA WP	HOUKY, VA WP	1900	17500
§ 95.3315 RNAV Route T315 Is Amended by Adding			
JIMUR, KY FIX	CALIF, KY FIX	2700	17500
CALIF, KY FIX	RHOMM, OH WP	2800	17500
RHOMM, OH WP	ZELID, KY WP	*3300	17500
*3000—MCA ZELID, KY WP, NW BND			
ZELID, KY WP	ILILE, OH WP	2700	17500
ILILE, OH WP	CROUP, OH FIX	2700	17500
CROUP, OH FIX	RULEY, WV WP	3200	17500
RULEY, WV WP	JARLO, WV WP	3600	17500
§ 95.3323 RNAV Route T323 Is Amended by Adding			
DACEL, KY WP *3300—MOCA	ZELID, KY WP	*4000	17500
ZELID, KY WP	ROHDE, OH WP	3300	17500
ROHDE, OH WP	VADUY, OH WP	2900	17500
VADUY, OH WP	APPLETON, OH VORTAC	3100	17500
§ 95.3370 RNAV Route T370 Is Amended To Delete			
BURBN, TX WP *3700—MCA ZUMKI, TX FIX, E BND	ZUMKI, TX FIX	*3000	17500
ZUMKI, TX FIX	RRORY, TX WP	4000	17500
RRORY, TX WP	RAKOC, TX FIX	2400	17500
RAKOC, TX FIX	TASEY, TX WP	2300	17500
TASEY, TX WP	SLOTH, TX WP	2000	17500
SLOTH, TX WP	LOCUS, AR FIX	2000	17500
LOCUS, AR FIX	HAMPT, AR FIX	1900	17500
HAMPT, AR FIX	RICKG, AR WP	2000	17500
RICKG, AR WP	EJKSN, MS WP	1900	17500
EJKSN, MS WP	IZAAC, MS WP	1800	17500
IZAAC, MS WP	TOMLN, MS FIX	*2000	17500
*2200—MCA TOMLN, MS FIX, E BND			
TOMLN, MS FIX	CLOUT, MS FIX	2500	17500
CLOUT, MS FIX	SKNRR, MS WP	2000	17500
SKNRR, MS WP	MINIM, AL FIX	2000	17500
MINIM, AL FIX	BESOM, AL FIX	2300	17500
BESOM, AL FIX	NESTS, AL WP	*2500	17500
*2000—MOCA			
NESTS, AL WP	VLKNN, AL WP	2500	17500
§ 95.3398 RNAV Route T398 Is Amended by Adding			
GMINI, NC WP	JIMYV, NC WP	2300	17500
JIMYV, NC WP	ACUTE, NC WP	2200	17500
ACUTE, NC WP	RALEIGH/DURHAM, NC VORTAC	2300	17500
RALEIGH/DURHAM, NC VORTAC	AIMHI, NC WP	2300	17500
AIMHI, NC WP	BOUSY, VA WP	2200	17500
BOUSY, VA WP	THHMP, VA WP	2000	17500

FROM	TO	MEA	MAA
THHMP, VA WP	SVILL, VA WP	1900	17500
SVILL, VA WP	TAPPA, VA FIX	1900	17500
§ 95.3480 RNAV Route T480 Is Added To Read			
GREENSBORO, NC VORTAC	REIDE, NC FIX	2700	17500
REIDE, NC FIX	YANCE, NC FIX	2500	17500
YANCE, NC FIX	MCDON, VA WP	2400	17500
MCDON, VA WP	DOGWD, VA WP	2300	17500
DOGWD, VA WP	MAZON, VA FIX	1900	17500
MAZON, VA FIX	COUPN, VA WP	1800	17500
COUPN, VA WP	DRONE, NC FIX	1800	17500
DRONE, NC FIX	ELIZABETH CITY, NC VOR/DME	2000	17500
ELIZABETH CITY, NC VOR/DME	NORTN, NC FIX	1700	17500
NORTN, NC FIX	RTBRO, NC WP	*1800	17500
*1300—MOCA			
RTBRO, NC WP	ZOLMN, NC FIX	2000	17500
§ 95.3482 RNAV Route T482 Is Added To Read			
MEYER, NC FIX	DUFFI, NC FIX	*2500	17500
*2200—MCA DUFFI, NC FIX, W BND			
DUFFI, NC FIX	GUMBE, NC FIX	2100	17500
GUMBE, NC FIX	COUPN, VA WP	1900	17500
§ 95.3486 RNAV Route T486 Is Added To Read			
BURBN, TX WP	ZUMKI, TX FIX	*3000	17500
*3700—MCA ZUMKI, TX FIX, E BND			
ZUMKI, TX FIX	RRORY, TX WP	4000	17500
RRORY, TX WP	RAKOC, TX FIX	2400	17500
RAKOC, TX FIX	TASEY, TX WP	2300	17500
TASEY, TX WP	SLOTH, TX WP	2000	17500
SLOTH, TX WP	LOCUS, AR FIX	2000	17500
LOCUS, AR FIX	HAMPT, AR FIX	1900	17500
HAMPT, AR FIX	RICKG, AR WP	2000	17500
RICKG, AR WP	EJKSN, MS WP	1900	17500
EJKSN, MS WP	IZAAC, MS WP	1800	17500
IZAAC, MS WP	TOMLN, MS FIX	*2000	17500
*2200—MCA TOMLN, MS FIX, E BND			
TOMLN, MS FIX	CLOUT, MS FIX	2500	17500
CLOUT, MS FIX	HRISN, MS WP	2000	17500
HRISN, MS WP	MINIM, AL FIX	2000	17500
MINIM, AL FIX	BESOM, AL FIX	2300	17500
BESOM, AL FIX	NESTS, AL WP	*2500	17500
*2000—MOCA			
NESTS, AL WP	VLKNN, AL WP	2500	17500
§ 95.3488 RNAV Route T488 Is Added To Read			
TAR RIVER, NC VORTAC	RMACK, NC FIX	2100	17500
RMACK, NC FIX	ALGTR, NC FIX	*4000	17500
*2700—MOCA			
ALGTR, NC FIX	RTBRO, NC WP	2000	17500
§ 95.4000 High Altitude RNAV Routes			
§ 95.4030 RNAV Route Q30 Is Amended To Read in Part			
IZAAC, MS WP	HRISN, MS WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
HRISN, MS WP	VLKNN, AL WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
§ 95.4140 RNAV Route Q140 Is Amended by Adding			
ARRKK, NY WP	TOTHH, NY WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
TOTHH, NY WP	YODAA, NY FIX	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			

FROM	TO	MEA	MAA
Is Amended To Delete			
ARRKK, NY WP *18000—GNSS MEA *DME/DME/IRU MEA	RODYY, NY WP YODAA, NY FIX	*18000 *18000	45000 45000
Is Amended To Read in Part			
U.S. CANADIAN BORDER *18000—GNSS MEA *DME/DME/IRU MEA	MEDAV, NY WP AHPAH, NY WP	*18000 *18000	45000 45000
§ 95.6001 VICTOR Routes-U.S			
§ 95.6003 VOR Federal Airway V3 Is Amended To Read in Part			
MODENA, PA VORTAC MAZIE, PA FIX	MAZIE, PA FIX SOLBERG, NJ VOR/DME		3000 MAA—17500 2500 MAA—17500
§ 95.6020 VOR Federal Airway V20 Is Amended To Read in Part			
SOUTH BOSTON, VA VORTAC *2400—MOCA	MELIA, VA FIX		*3000 MAA—17500
§ 95.6029 VOR Federal Airway V29 Is Amended To Read in Part			
SMYRNA, DE VORTAC	DUPONT, DE VORTAC		1800 MAA—17500
§ 95.6044 VOR Federal Airway V44 Is Amended To Delete			
FALMOUTH, KY VOR/DME YORK, KY TACAN	YORK, KY TACAN PARKERSBURG, WV VOR/DME		3300 MAA—17500 3300 MAA—17500
§ 95.6069 VOR Federal Airway V69 Is Amended To Read in Part			
HILLE, AR FIX *3100—MOCA WALNUT RIDGE, AR VORTAC	WALNUT RIDGE, AR VORTAC FARMINGTON, MO VORTAC		*4000 MAA—17500 4000 MAA—17500
§ 95.6077 VOR Federal Airway V77 Is Amended To Read in Part			
WICHITA, KS VORTAC *3600—MOCA WILSY, KS FIX *2900—MOCA	WILSY, KS FIX HEYDN, KS FIX		*5000 MAA—17500 *5000 MAA—17500
§ 95.6097 VOR Federal Airway V97 Is Amended To Read in Part			
AMAPO, GA FIX *6000—MCA WILMS, GA FIX, N BND *2000—MOCA *2500—GNSS MEA WILMS, GA FIX *6000—MCA PRATZ, GA FIX, S BND *2200—MOCA *2500—GNSS MEA	*WILMS, GA FIX *PRATZ, GA FIX. N BND S BND		**3000 MAA—17500 **6000 **3000 MAA—17500
§ 95.6120 VOR Federal Airway V120 Is Amended To Read in Part			
DUPREE, SD VOR/DME	PIERRE, SD VORTAC		*4300

FROM	TO	MEA
*3800—MOCA PIERRE, SD VORTAC	MITCHELL, SD VOR/DME	MAA—17500 3900 MAA—17500
§ 95.6128 VOR Federal Airway V128 Is Amended To Delete		
CINCINNATI, KY VORTAC	CALIF, KY FIX	2600 MAA—17500
CALIF, KY FIX	YORK, KY TACAN	4000 MAA—17500
YORK, KY TACAN	CROUP, OH FIX	*3300 MAA—17500
*2300—MOCA	RULEY, WV WP.	
CROUP, OH FIX	NW BND	3600
	SE BND	3300
		MAA—17500
RULEY, WV WP	CHARLESTON, WV VOR/DME	3600 MAA—17500
§ 95.6131 VOR Federal Airway V131 Is Amended To Delete		
OKMULGEE, OK VOR/DME	TULSA, OK VORTAC	3200 MAA—17500
TULSA, OK VORTAC	TYROE, KS WP	3000 MAA—17500
TYROE, KS WP	CHANUTE, KS DME	2800 MAA—17500
CHANUTE, KS DME	TOPEKA, KS VORTAC	2900 MAA—17500
§ 95.6132 VOR Federal Airway V132 Is Amended To Delete		
HUTCHINSON, KS VOR/DME	WAIVE, KS FIX	4000 MAA—17500
WAIVE, KS FIX	*FLOSS, KS FIX	3300 MAA—17500
*5000—MCA FLOSS, KS FIX, SE BND		
FLOSS, KS FIX	CHANUTE, KS DME	*5000 MAA—17500
*2800—MOCA	NALLY, KS WP.	
CHANUTE, KS DME	W BND	2800
	E BND	4500
		MAA—17500
NALLY, KS WP	SPRINGFIELD, MO VORTAC	*4500 MAA—17500
*2800—MOCA		
*3000—GNSS MEA		
§ 95.6190 VOR Federal Airway V190 Is Amended To Read in Part		
MITBEE, OK VORTAC	CARON, OK FIX.	
	SW BND	*6000
	NE BND	*8000
*4100—MOCA		MAA—17500
CARON, OK FIX	FIRET, OK FIX	*8000 MAA—17500
*3100—MOCA		
§ 95.6252 VOR Federal Airway V252 Is Amended To Read in Part		
GENESEO, NY VOR/DME	GIBBE, NY FIX	4500 MAA—17500
GIBBE, NY FIX	BINGHAMTON, NY VOR/DME.	
	SE BND	3800
	NW BND	4500
		MAA—17500
§ 95.6307 VOR Federal Airway V307 Is Amended To Delete		
CHANUTE, KS DME	EMPORIA, KS VORTAC	3000 MAA—17500
§ 95.6350 VOR Federal Airway V350 Is Amended To Delete		
WICHITA, KS VORTAC	CHANUTE, KS DME	3600 MAA—17500

FROM	TO	MEA
§ 95.6419 VOR Federal Airway V419 Is Amended To Read in Part		
MODENA, PA VORTAC	MAZIE, PA FIX	3000
		MAA—17500
MAZIE, PA FIX	SOLBERG, NJ VOR/DME	2500
		MAA—17500
§ 95.6431 VOR Federal Airway V431 Is Amended To Read in Part		
REVER, MA FIX	GARDNER, MA VOR/DME	3700
		MAA—17500
§ 95.6493 VOR Federal Airway V493 Is Amended To Delete		
LEXINGTON, KY VOR/DME	BEAER, KY WP	3000
		MAA—17500
BEAER, KY WP	YORK, KY TACAN	3300
		MAA—17500
YORK, KY TACAN	TARTO, OH FIX	3300
		MAA—17500
TARTO, OH FIX	APPLETON, OH VORTAC	3000
		MAA—17500
§ 95.6518 VOR Federal Airway V518 Is Amended To Read in Part		
TWINE, CA FIX	*LANGE, CA FIX	**7000
*11000—MCA LANGE, CA FIX, NE BND		
**6000—MOCA		MAA—17500
LANGE, CA FIX	PALMDALE, CA VORTAC	*11000
		MAA—17500
*7500—MOCA		
§ 95.6506 Alaska VOR Federal Airway V506 Is Amended by Adding		
KOTZEBUE, AK VOR/DME	SETUP, AK FIX.	
	N BND	2000
	S BND	7000
		MAA—17500
SETUP, AK FIX	BAIME, AK FIX	*7000
*5700—MOCA		MAA—17500
*6000—GNSS MEA		
BAIME, AK FIX	NOME, AK VOR/DME.	
	S BND	6000
	N BND	7000
		MAA—17500
NOME, AK VOR/DME	DACIA, AK FIX.	
	N BND	*4000
	S BND	*8000
		MAA—17500
*3200—MOCA	JOHNI, AK FIX	*8000
DACIA, AK FIX		MAA—17500
*3200—MOCA		
*4000—GNSS MEA		
JOHNI, AK FIX	MARSI, AK FIX	*16000
*3200—MOCA		MAA—17500
*4000—GNSS MEA		
*MEA IS ESTABLISHED WITH A GAP IN NAVIGATION		
SIGNAL COVERAGE.		
MARSI, AK FIX	BETHEL, AK VORTAC.	
	E BND	2000
	W BND	16000
		MAA—17500
BETHEL, AK VORTAC	CAYON, AK FIX.	
	W BND	4000
	E BND	8000
		MAA—17500
CAYON, AK FIX	KOWOK, AK FIX	*8000
*7000—MOCA		MAA—17500
*7000—GNSS MEA		
KOWOK, AK FIX	KING SALMON, AK VORTAC	*3000
*2400—MOCA		MAA—17500
Is Amended To Delete		
CJAYY, AK FIX	KODIAK, AK VOR/DME	4000
		MAA—17500

FROM	TO	MEA
KODIAK, AK VOR/DME	BREMI, AK FIX	*12000
*9900—MOCA		MAA—17500
*10000—GNSS MEA		
BREMI, AK FIX	KING SALMON, AK VORTAC.	
	E BND	12000
	W BND	5000
		MAA—17500
KING SALMON, AK VORTAC	KOWOK, AK FIX	*3000
*2400—MOCA		MAA—17500
KOWOK, AK FIX	CAYON, AK FIX	*8000
*7000—MOCA		MAA—17500
*7000—GNSS MEA		
CAYON, AK FIX	BETHEL, AK VORTAC.	
	E BND	8000
	W BND	4000
		MAA—17500
BETHEL, AK VORTAC	MARSI, AK FIX.	
	W BND	16000
	E BND	2000
		MAA—17500
MARSI, AK FIX	JOHNI, AK FIX	*16000
*3200—MOCA		MAA—17500
*4000—GNSS MEA		
*MEA IS ESTABLISHED WITH A GAP IN NAVIGATION SIGNAL COVERAGE.		
JOHNI, AK FIX	DACIA, AK FIX	*8000
*3200—MOCA		MAA—17500
*4000—GNSS MEA		
DACIA, AK FIX	NOME, AK VOR/DME.	
*3200—MOCA	S BND	*8000
	N BND	*4000
		MAA—17500
NOME, AK VOR/DME	BAIME, AK FIX.	
	N BND	7000
	S BND	6000
		MAA—17500
BAIME, AK FIX	SETUP, AK FIX	*7000
*5700—MOCA		MAA—17500
*6000—GNSS MEA		
SETUP, AK FIX	KOTZEBUE, AK VOR/DME.	
	S BND	7000
	N BND	2000
		MAA—17500
KOTZEBUE, AK VOR/DME	HOTHAM, AK NDB	2000
		MAA—17500
HOTHAM, AK NDB	SHOKK, AK WP	*6000
*5000—MOCA		MAA—17500
*5000—GNSS MEA		
SHOKK, AK WP	MEADE, AK FIX	*10000
*7000—MOCA		MAA—17500
*8000—GNSS MEA		
MEADE, AK FIX	BARROW, AK VOR/DME.	
	S BND	*10000
	N BND	*2000
*1100—MOCA		MAA—17500

Airway Segment	Changeover Points		
FROM	TO	DISTANCE	FROM
§ 95.8003 VOR Federal Airway Changeover Point V20 Is Amended To Add Changeover Point			
SOUTH BOSTON, VA VORTAC	RICHMOND, VA VORTAC	46	SOUTH BOSTON.
V128 is Amended To Delete Changeover Point			
CINCINNATI, KY VORTAC	YORK, KY VORTAC	38	CINCINNATI.
YORK, KY VORTAC	CHARLESTON, VA VORTAC	29	YORK.
Alaska V506			
KODIAK, AK VOR/DME	KING SALMON, AK VORTAC	55	KODIAK.

Airway Segment	Changeover Points		
	FROM	TO	DISTANCE
HOTHAM, AK NDB	BARROW, AK VOR/DME	186	HOTHAM.

Alaska V506 Is Amended To Modify Changeover Point

KOTZEBUE, AK VOR/DME	NOME, AK VOR/DME	95	KOTZEBUE.
BETHEL, AK VORTAC	KING SALMON, AK VORTAC	96	BETHEL.

[FR Doc. 2024–13342 Filed 6–17–24; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0496]

RIN 1625–AA00

Safety Zones; Fourth of July Events for the Los Angeles Long Beach Captain of the Port Zone.

AGENCY: Coast Guard, DHS.
ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones around five separate 4th of July firework display platforms. The safety zones will encompass the navigable waters within a 1000-foot radius of the pyrotechnic platforms located offshore in the following locations: Bel Air Bay, Pacific Palisades, CA; Newport Beach, CA; Carnival Cruise Terminal dock, Long Beach, CA; Three Arch Bay, South Laguna, CA, and Two Harbors, Catalina Island, CA. The safety zones are needed to protect personnel, vessels, and the marine environment from potential hazards created by the firework show. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the Captain of the Port, Sector Los Angeles—Long Beach.

DATES: This rule is effective from July 3, 2024, through July 6, 2024, from 08:00 p.m. to 11:00 p.m. during the listed dates and specified locations.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0496 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 about this rule, call or email LCDR Kevin Kinsella, U.S. Coast Guard Sector Los Angeles—Long

Beach; telephone (310) 521–3861, email D11-SMB-SectorLALB-WWM@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 under authority in 5 U.S.C. 553(b)(B). This statutory 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.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it would be impracticable to publish a NPRM within the required time frame to ensure publish safety.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to ensure navigational safety amidst the potential safety hazards associated with the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Los Angeles–Long Beach (COTP) has determined that potential hazards associated with the fireworks shows occurring from July 3, 2024 through July 6, 2024 will be a safety concern for anyone within a 1000-foot radius of the pyrotechnics platforms. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters before, during and after the scheduled firework events within the designated safety zones.

IV. Discussion of the Rule

This rule establishes a safety zone from 8 p.m. until 11 p.m. on July 3, 2024 through July 6, 2024. The safety zones will cover all navigable waters within 1000 feet of the pyrotechnics platforms located in the follow areas on the indicated dates: Bel Air Bay on July 3, 2024 located in position 34°02′08.3″ N/118°32′44.5″ W; Newport Beach on July 4, 2024, located in position 33°35′28.4″ N/117°53′17.8″ W; Long Beach Carnival Cruise Terminal Dock, located in position 33°45′06.8″ N 118°11′13.7″ W; Three Arch Bay on July 5, 2024 located in position 33°29′08.7″/117°44′21.2″ W; and Two Harbors on July 6, 2024, located in position 33°26′45.4″ N/118°29′37.1″ W. The duration of the zones is intended to protect personnel, vessels, and the marine environment in these navigable waters before, during, and after the scheduled events. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). 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, duration, and time-of-day of the safety zone. The Coast Guard will be issuing Broadcast

Notice to Mariners via VHF-FM marine channel 16 about the zones, 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 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 five safety zone lasting only 3 hours each that will prohibit entry within 1000 feet of the pyrotechnics platform used for the firework events. 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. 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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

- 2. Add § 165.T11–0496 to read as follows:

§ 165.T11–0496 Safety Zones; Fourth of July Events for the Los Angeles Long Beach Captain of the Port Zone.

(a) *Location.* The following areas are a safety zone: All waters from surface to bottom, within a 1000-foot radius of the designated firework display platforms located in the following locations. Bel Air Bay on July 3, 2024 located in approximate position 34°02′08.3″ N/118°32′44.5″ W; Newport Beach on July 4, 2024, located in approximate position 33°35′28.4″ N/117°53′17.8″ W; Long Beach Carnival Cruise Terminal Dock on July 4, 2024, in approximate position 33°45′06.8″ N 118°11′13.7″ W; Three Arch Bay on July 5, 2024 located in approximate position 33°29′08.7″ /117°44′21.2″ W; and Two Harbors on July 6, 2024, located in approximate position 33°26′45.4″ N/118°29′37.1″ W. These coordinates are based on the North American Datum of 1983.

(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 and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Los Angeles-Long Beach (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) To seek permission to enter, contact the PATCOM, the COTP's

representative, by VHF–FM Channel 13 (156.65 MHz) or 16 (156.8 MHz). Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced during the following dates and times: July 3, 2024, Pacific Palisades in Bel Air Bay, CA from 8:00 p.m. to 11:00 p.m.; July 4, 2024, Newport Beach, CA from 8:00 p.m. to 11:00 p.m.; July 4, 2024, Long Beach Carnival Cruise Terminal from 8:00 p.m. to 11:00 p.m.; July 5, 2024, South Laguna in Three Arch Bay, CA from 8:00 p.m. to 11:00 p.m.; And July 6, 2024, Catalina Island in Two Harbors, CA from 8:00 p.m. to 11:00 p.m.

Dated: June 12, 2024.

S.L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles—Long Beach.

[FR Doc. 2024–13341 Filed 6–17–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AR95

Exemption of “Diversity and Equal Employment Opportunity (EEO) Program Records” (203VA08)

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final, with one change, a proposed rule to exempt the system of records titled, “Diversity and Equal Employment Opportunity (EEO) Program Records” (203VA08) from certain provisions of the Privacy Act, in order to, prevent interference with harassment and sexual harassment administrative investigations.

DATES: This final rule is effective July 18, 2024.

FOR FURTHER INFORMATION CONTACT:

Larry Holman, Program Analyst, Office of Resolution Management, Diversity and Inclusion (ORMDI), Department of Veterans, 810 Vermont Avenue NW, Washington, DC 20420, 901–456–8148 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On June 9, 2023, VA published a proposed rule in the *Federal Register* (88 FR 37839) to add a new exemption to § 1.582 of title 38 Code of Federal Regulations (CFR) exempting certain Harassment Prevention Program (HPP) records from the Privacy Act of 1974, as amended, 5 U.S.C. 552a. The exempted records

include management notifications; investigator and coordinator findings; determinations as to whether harassment occurred; preventive or corrective action taken; and related correspondence, exhibits, and written follow-up documents. VA believes disclosure of these records would cause sources to refrain from disclosing information due to fear of reprisal and that disclosure would compromise guarantees of anonymity and confidentiality, therefore compromising VA's ability to conduct investigations and obtain information necessary to support an effective HPP.

VA provided a 60-day comment period, which ended on August 8, 2023. VA received seventy-one comments on the proposed rule. One comment was supportive of the rule, and we thank the commenter for their support. The remaining seventy comments opposed the proposed Privacy Act exemptions. VA addresses the non-supportive comments below, which have been grouped together by theme. VA adopts the proposed rule as final with one minor technical change described below.

Fifteen commenters raised concerns with the proposed rulemaking, stating that it will make it harder for employees to prevail in EEO cases and will negatively affect the outcome of HPP investigations. VA disagrees because EEO investigations are separate and independent investigations from HPP. HPP does not require a basis and does not make determinations of discrimination nor unlawful harassment, rather, HPP is focused on ensuring that harassment is expediently addressed and stopped. VA is committed to transparency in its investigative processes and believes the Privacy Act exemptions are necessary to maintain the confidentiality and integrity of the HPP. The Privacy Act exemptions will protect the identities of sources wishing to remain anonymous for fear of retaliation, harassment, intimidation, and other attempts to improperly influence outcomes of investigations. Since some comments appear to confuse the HPP and EEO processes, VA reiterates that the HPP and EEO process are distinct, and individuals can file both EEO and HPP complaints on the same underlying issue. Exempting HPP records will not impact the release of EEO reports of investigation because they are different processes. HPP investigations do not make legal determinations of unlawful harassment or discrimination. These investigations are designed to stop harassing behaviors before they become unlawful. EEO investigations are

conducted by independent third-party investigators, while HPP complaints are investigated by factfinders in the facility where the incident occurred. VA makes no changes to the rule based on these comments.

Seventeen commenters expressed concerns that labor-management relations will deteriorate if the proposed Privacy Act exemptions are implemented. VA believes labor-management relations will not be impacted because VA protects individuals who participate in harassment investigations from retaliation, harassment, intimidation, and other attempts to improperly influence outcomes of investigations. Additionally, under current VA policy, there is an existing prohibition regarding providing HPP records to individuals filing HPP complaints as well as negotiated grievance procedures that only apply to the subject of the investigation. The rule will allow Union representatives to request HPP records using the VA Freedom of Information Act (FOIA) procedures, contained in 38 CFR 1.550 through 1.562, where identities of sources are redacted. VA makes no changes to the rule based on these comments.

Thirty-four commenters expressed concerns that if these Privacy Act exemptions are implemented, ORMDI and local EEO offices would be flooded with complaints, which would result in complaints not being resolved at the lowest level. VA shares the concern for resolving complaints at the lowest level and is committed to holding those who engage in harassment accountable. VA will continue to offer multiple paths to report harassment, thereby allowing individuals to choose the path with which they are most familiar and provide increased safeguards to protect confidential sources from reprisal. VA believes revealing of HPP records will infringe upon the confidentiality of the program and threaten the privacy of the witnesses who are required to cooperate in the process. Individuals wishing to review the report will continue to be able to request the report through a FOIA request.

Nineteen commenters expressed concern that the proposed rule would inhibit transparency. To reiterate, VA is committed to transparency in its investigative processes, but believes these Privacy Act exemptions are necessary to maintain the confidentiality and integrity of the HPP. These Privacy Act exemptions will protect the identities of sources wishing to remain anonymous from retaliation, harassment, intimidation, and other attempts to improperly influence

outcomes of investigations. VA makes no changes to the rule based on these comments.

Seven commenters were generally opposed to the rule and expressed concerns that exempting HPP records from disclosure under the Privacy Act would make it difficult to track repeat offenders, would show a lack of concern for harassment prevention by VA, and would be harmful to all. Implementing these Privacy Act exemptions will not conceal the existence of HPP records but will categorize these records as investigative documents necessary to carry out the HPP. As such, these Privacy Act exemptions will minimize the potential of altering investigative records, as well as safeguard the identity of witnesses, individuals who report the allegations, and other sources necessary to the investigative process. As mentioned previously, this rulemaking will not hinder the ability to request copies of redacted HPP records using VA's FOIA process. VA makes no changes to the rule based on these comments.

Change Not Based on Comments

In the proposed rule, VA proposed adding the new Privacy Act exemptions for HPP records in paragraph (d) of 38 CFR 1.582. This was a technical error, as current paragraph (d) contains exemptions for certain police and security records and there should be no change to that paragraph. In this final rule, VA makes a minor technical change to correct the paragraph for the HPP Privacy Act exemptions to paragraph (e).

Executive Orders 12866, 13563 and 14094

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), and Executive Order 13563 of January 18,

2011 (Improving Regulation and Regulatory Review). The Office of Information and Regulatory Affairs has determined that this rulemaking is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601 through 612). The operations and administrative processes associated with this final rule consist of internal VA management officials and non-bargaining unit individuals (internal VA Human Resource or VA Quality Assurance staff). Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will not have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 through 3521).

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not satisfying the criteria under 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Claims, Freedom of information, Government employees, Penalties, Privacy, Reporting and recordkeeping requirements, Security measures.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on June 12, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 1 as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 38 U.S.C. 5101, and as noted in specific sections.

■ 2. Amend § 1.582 by adding paragraph (e) to read as follows:

* * * * *

(e) *Exemption of Harassment Prevention Program Records.* The Department of Veterans Affairs provides limited access to Harassment Prevention Program (HPP) records as indicated.

(1) The system of records is exempted pursuant to the provisions of 5 U.S.C. 552a(k)(2) from subsections (c)(3), (d), (e)(1), (e)(4), (G), (H), (I), and (f): Diversity and Equal Employment Opportunity (EEO) Program Records (203VA08).

(2) This exemption applies to the extent that information in these systems is subject to exemption pursuant to 5 U.S.C. 552a(k)(2).

(3) For the reasons set forth, the system of records listed above is exempted under 5 U.S.C. 552a(k)(2) from the following provisions of 5 U.S.C. 552a:

(i) 5 U.S.C. 552a(c)(3) requires that an agency make available to the individual to whom the records pertain upon request an accounting of disclosures of records that includes the date, nature and purpose of each disclosure of the record and the name and address of the recipient. Providing an individual with an accounting of disclosures of HPP records could reveal the existence of an investigation of alleged harassment and the allegations being investigated and therefore result in the alternation or destruction of evidence, improper influencing of witnesses, and other activities that could impede or compromise the investigation.

(ii) 5 U.S.C. 552a(d), (e)(4), (G), (H), and (f) relate to an individual's right to be notified of the existence of records

pertaining to such individual; requirements for identifying an individual who requests access to records; and the agency procedures relating to access to records and the contest of information contained in such records. Providing an individual with notification of, access to, or the right to seek amendment of HPP records could disclose the identity of confidential sources, reveal investigative techniques, and interfere with enforcement proceedings.

(iii) 5 U.S.C. 552a(e)(4)(I) requires the publication of the categories of sources of records in each system of records. Revealing the sources of information in HPP records could discourage such sources from cooperating with investigations of alleged harassment for fear of reprisal. In addition, the disclosure of VA's investigative techniques and procedures and compromise the ability to conduct impartial investigations into workplace and sexual harassment allegations.

(iv) 5 U.S.C. 552a(e)(1) requires each agency to maintain in its records only such information about an individual that is relevant and necessary to accomplish a purpose of the agency required by statute or Executive Order. The relevance or necessity of specific information in HPP records often cannot be detected in the early stages of an investigation and can only be established after the information is evaluated. Further, a thorough and complete investigation could involve information that at first appears incidental but ultimately becomes critical to the investigation.

(Authority: 5 U.S.C. 552a(j) and (k); 38 U.S.C. 501)

[FR Doc. 2024–13384 Filed 6–17–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AR98

VA Health Professional Scholarship Program

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final, without changes, a proposed rule to amend its regulations that govern the VA Health Professional Scholarship Program (HPSP) by implementing the mandates of the Consolidated Appropriations Act, which would expand the number of scholarships available to those who are

pursuing degrees or training in occupations providing care within mental health programs. This rule also adopts as final technical corrections under the Paperwork Reduction Act section to correct an approved Office of Management and Budget (OMB) control number.

DATES: This rule is effective July 18, 2024.

FOR FURTHER INFORMATION CONTACT: Nicole Nedd, Director, Scholarships and Clinical Education, Workforce Management and Consulting Office, 810 Vermont Ave. NW, Washington, DC 20420. ((504) 881–4036). (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** (FR) on August 14, 2023, VA proposed to revise its VA Health Professional Scholarship Program (HPSP) regulations. The purpose of the HPSP is to award scholarships to students pursuing a course of study leading to a degree in certain health care occupations, listed in 38 U.S.C. 7401(1) and (3). See § 17.600. The HPSP allows VA to provide scholarship awards to facilitate recruitment and retention of employees in several hard-to-fill health care occupations. Id. In the proposed rule we stated that we would amend the HPSP to reflect statutory changes made by section 104(a) of Division V of the Consolidated Appropriations Act (the Act), Public Law 117–328, which expanded HPSP by requiring VA to specifically award scholarships to applicants pursuing degrees or training in mental health disciplines, including advanced practice nursing (with a focus on mental health or substance use disorder), psychology, and social work. Section 104(a) of the Act also required that VA provide no fewer than an additional 50 awards (as compared to academic year 2021, which provided 33 awards) to such applicants per academic year starting in academic year 2022. 88 FR 54972. The rule also proposed to make a technical edit to the HPSP regulations to correct an approved Office of Management and Budget (OMB) control number. Id.

VA provided a 60-day comment period, which ended on October 13, 2023. VA received 13 comments on the proposed rule. One comment supported the proposed rule and will not be further addressed in this final rule. The remaining comments are summarized and addressed in the discussion below.

Public Comments

Physician Assistants

VA received 11 comments regarding physician assistants (PAs). The

comments suggested or supported the inclusion of PAs as mental health care professionals eligible to receive scholarships under proposed § 17.603(b)(2). For instance, a commenter suggested that generally PAs should receive scholarships under proposed § 17.603(b)(2) and another stated that PAs are a core mental health profession. VA does not make any changes based on these comments.

PAs are eligible to apply for and receive HPSP scholarships for mental health disciplines under proposed § 17.603(b)(2). Consistent with section 104(a) of Division V of the Act, VA proposed to revise § 17.603(b)(2) to expand HPSP to applicants who are pursuing degrees or training in mental health disciplines, including advanced practice nursing (with a focus on mental health or substance use disorder), psychology, and social work. As noted in the proposed rule, this is not an exhaustive list and merely mirrors section 104(a) of Division V of the Act. 88 FR 54974. VA acknowledges that PAs' training includes core mental health training and mandatory psychiatry clinical rotations, and they may provide mental health care. Thus, PAs are eligible to apply for and may receive HPSP scholarships for mental health disciplines under proposed § 17.603(b)(2) once this rule is final and effective.

Other commenters suggested that PAs be listed in proposed § 17.603(b)(2) as a mental health profession eligible for a HPSP scholarship pursuant to the Act. Relatedly, one commenter stated that VA should provide an exhaustive list of health care professions that may be awarded the HPSP scholarship under proposed § 17.603(b)(2). We do not make changes to the rule based on these comments.

As VA explained in the proposed rule, the list of mental health disciplines in proposed § 17.603(b)(2) is not an exhaustive list, as there are other mental health disciplines not included in the Act. (See 88 FR 54974). Other mental health disciplines may include licensed professional mental health counselor, marriage and family therapist, and rehabilitation counseling. The list in proposed § 17.603(b)(2) was merely meant to mirror the statutory language and is not exclusionary of other mental health care professions. VA determined that it should maintain a non-exhaustive list in the regulation to permit flexibility so that new mental health professions can be included without the need to amend the regulations. Therefore, other occupations not listed in proposed § 17.603(b)(2) that may provide clinical care in mental health programs may,

and are encouraged to, apply for and receive HPSP scholarships.

One commenter recommended that VA expand HPSP scholarships to mandate inclusion for PAs. We are not making any changes based on this comment.

To the extent that the commenter is suggesting that VA mandate that PAs be prioritized over other potential applicants, VA cannot mandate that PAs be selected over other health care professions. Under 38 U.S.C. 7612(D), VA may provide scholarships with a preference for applicants who are veterans. VA does not have any other preferential statutory authority. The awarding of HPSP scholarships is based on VA recruitment needs. As previously stated in this rulemaking, an HPSP scholarship will be awarded only when necessary to assist VA in alleviating shortages or anticipated shortages of personnel in the health professions.

One commenter raised concerns that the HPSP website indicates that existing HPSP scholarships are limited to only those PAs with veteran status. VA is not making any changes to the rule based on this comment.

VA acknowledges that its HPSP website previously indicated that the PA scholarship is only open to those that have veteran status. VA has since updated its HPSP website to ensure it clearly explains that all PA students are allowed to apply for an HPSP scholarship, but that a preference may be given to veterans, consistent with § 17.605. While the eligibility criteria for HPSP does not require that applicants have any military experience (see § 17.602), if there are a larger number of equally qualified applicants than there are awards to be made, VA will first select veterans, then use a random method as the basis for further selection. See § 17.605(a). This provision applies to all health care professions eligible for HPSP scholarships, not just PAs.

Awarding HPSP Scholarships in Academic Year 2023

One commenter encouraged VA to issue the 50 additional awards in the 2023 academic year, as increasing access to mental health care is critical.

Consistent with section 104(a) of Division V of the Act, VA proposed to provide no fewer than an additional 50 awards (as compared to academic year 2021) to applicants who are pursuing degrees or training in mental health disciplines per academic year starting in academic year 2022. See proposed § 17.603(b)(2) and 88 FR 54973. However, VA will not be able to implement this regulation until this final rule is published and effective,

which will be after the start of the 2023 academic year. VA notes that under the current regulations, VA is authorized to provide HPSP scholarships to disciplines that provide clinical care within mental health programs and in academic year 2023, VA offered 87 scholarships for professions providing clinical care within mental health programs, which is more than the required 83 scholarships for mental health professions as required under the Act. VA is not making any changes based on this comment.

Chaplains

While not entirely clear, one commenter appeared to request chaplains be eligible for HPSP scholarships since they should be considered mental health professionals who are eligible under the changes VA proposed to make to § 17.603(b)(2) in the proposed rule. VA is not making changes based on this comment.

VA considers chaplains to be an integral part of the veteran's mental health and individuals who are pursuing a degree that leads to placement as a chaplain may be eligible to receive HPSP scholarships under §§ 17.603(b)(2) and (3) as revised and made final in this rule. However, in order to be eligible under § 17.603(b)(2) the criteria in § 17.603(b)(1) still needs to be met, which provides that an HPSP scholarship will be awarded only when necessary to assist VA in alleviating shortages or anticipated shortages of personnel in the health professions stated in paragraph (b) of this section. These occupations are identified in OIG's Determination of Veterans Health Administration's Severe Occupational Staffing Shortages Fiscal Year 2023. However, the OIG's report did not list the chaplain occupation as one of the severe shortage occupations within VA. Therefore, VA cannot award HPSP scholarships to individuals who are pursuing a degree leading to a position as a VA chaplain at this time. VA may offer HPSP scholarships to these individuals in the future should there be a shortage of VA chaplains.

Employment in a Mental Health Care Profession

A commenter questioned whether HPSP participants would be guaranteed placement in positions in VA that are mental health related if they are earning a degree that could be used to provide either mental health care or a different type of health care. VA is not making any changes based on this comment.

Pursuant to § 17.607(a), each participant is obligated to provide service as a Department of Veterans

Affairs employee in full-time clinical practice in the participant's discipline in an assignment or location determined by the Secretary. Consistent with § 17.607, individuals who are awarded an HPSP scholarship under § 17.603(b)(2), as revised and made final in this rule, will be placed in positions that are mental health related.

Comments That Are Beyond the Scope of the Proposed Rule

Several comments were beyond the scope of the proposed rule. For instance, one commenter indicated that health care professionals need more mental health training. Another commenter requested changes be made to other VA directives and policies to better incorporate PAs as mental health providers. As these comments are beyond the scope of the rulemaking, we will not address them further.

Based on the rationale set forth in the proposed rule and in this final rule, VA is adopting the proposed rule as final with no changes.

Executive Orders 12866, 13563, and 14094

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Executive order on Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), and Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review). The Office of Information and Regulatory Affairs has determined that this rulemaking is not a significant regulatory action under Executive Order 12866, as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant

economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This final rule will solely be operated and administered within VA and will only affect individuals who apply and are awarded an HPSP scholarship. On this basis, the Secretary certifies that the adoption of this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act. Therefore, under 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

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

Paperwork Reduction Act

Although this final rule contains an increase in the provisions constituting a collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), this increase is already captured in an existing collection of information. The collection of information for 38 CFR 17.602 is currently approved by the Office of Management and Budget (OMB) and has been assigned OMB control number 2900–0793. However, § 17.602 incorrectly reflects OMB control number 2900–0352. VA is correcting this technical error in this rulemaking by updating the reference in § 17.602 to OMB control number 2900–0793.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not satisfying the criteria under 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Health care, Health facilities, Health professions, Scholarships and fellowships.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on June 12, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,
Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

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

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended by adding an entry for §§ 17.600 through 17.612, in numerical order, to read as follows:

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

* * * * *

Sections 17.600 through 17.612 are also issued under 38 U.S.C. 7601–7619, 7633, 7634, 7636, and sec. 104(a), div. V, Public Law 117–328.

* * * * * **COM020*

§ 17.602 [Amended]

■ 2. Amend § 17.602 by revising the parenthetical at the end of the section to read as follows:

§ 17.602 Eligibility.

* * * * *

(Approved by the Office of Management and Budget under control number 2900–0793)

§ 17.603 [Amended]

■ 3. Amend § 17.603 by:
■ a. Redesignating paragraph (b)(2) as new paragraph (b)(3); and
■ b. Adding new paragraph (b)(2) to read as follows:

§ 17.603 Availability of HPSP scholarships.

* * * * *

(b) * * *

(2) *Mental health disciplines.*

Notwithstanding paragraphs (b)(1) and (3) of this section, VA will award not less than 83 HPSP scholarships each year to individuals who are accepted for or are enrolled in a program of education or training leading to employment in a mental health discipline, including, but limited to, advanced practice nursing (with a focus on mental health or substance use disorder), psychology, or social work.

* * * * *

[FR Doc. 2024–13367 Filed 6–17–24; 8:45 am]

BILLING CODE 8320–01–P

POSTAL SERVICE

39 CFR Part 20

Known Mailer and Exceptions

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is revising the *Mailing Standards of the United States Postal Service*, International Mail Manual (IMM®) to remove the “known mailer” definition and exceptions for customs declarations.

DATES: Effective September 29, 2024.

FOR FURTHER INFORMATION CONTACT: Vlad Spanu at (202) 268–4180 or Kathy Frigo at (202) 268–4178.

SUPPLEMENTARY INFORMATION: On May 12, 2023, the Postal Service published a notice of proposal (88 FR 30689) to remove IMM section 123.62 regarding known mailers and other related information in the IMM associated with known mailers to align postal regulations with current customs policy. In response to the proposed rule, the Postal Service received formal comments from two commenters as follows:

Comment: One commenter responded on behalf of the industry for multiple mailing services, noting that this industry represents the vast majority of the Postal Service’s outbound commercial volume and revenue. The commenter indicated it would be challenging for this industry, especially for nonprofit and publication mailers, to remove the “known mailer” definition and exceptions for customs declarations, in that the change would end the current allowances whereby a good of nominal value (less than \$1.00) can accompany a document mailed as a letter or flat without a customs form.

Response: Under the Acts of the Universal Postal Union (UPU), small packets containing goods must bear customs declarations, regardless of the minimal value of the goods. All goods require disclosure of details using the Customs Forms and Advance Electronic Data (AED) also known as Electronic Advance Data (EAD) outside of the United States, and as these items are traveling via international means, they must follow international rules for content and disclosure of contents.

Comment: The commenter further indicated that it would eliminate the current exception that also allows a document that exceeds the dimensions of a flat to be mailed as a packet without a customs declaration if it is poly-wrapped, noting that the exceptions were created a decade ago.

Response: Similar to the response above, under the Acts of the UPU, small packets containing goods must bear customs declarations, regardless of the minimal value of the goods. With respect to documents that are sent as bulky letters, the Postal Service does not have operational systems in place to separate such pieces from small packets containing goods. Consequently, a customs declaration is required for letter-post pieces that are entered as bulky letters *i.e.*, that are items containing documents and are not eligible as letter-post letters or flats.

Comment: The commenter also indicated that, in 2017, similar comments of support to retain the known mailer exceptions were provided in response to a Notice of Proposed Rulemaking on International Mailing Service, citing that those comments are essentially unchanged, and are even more resonant today given the sizeable decline in the Postal Service's outbound volumes and revenue over the past five years. The commenter further noted that the Postal Service should not be adding any obstacles that make it harder for mailers to do business with it, especially given the highly competitive outbound market in which the Postal Service operates.

Response: The reduction of mail volumes and revenue, or other business concerns, while significant to the Postal Service, do not excuse the Postal Service and mailers from following international requirements for customs declarations and AED.

Comment: The commenter indicated that requiring a customs declaration form and accompanying electronic data for goods of a nominal value will be a costly adjustment to make for many current users, including among nonprofit organizations with which such items are most popular, in that it would require significant adjustments to their processes and increase their costs to accommodate the customs declaration form and data, most likely causing clients to consider the cost-effectiveness of sending future mailings, curtailing international fundraising mail. The commenter further indicated that adding the burden of the customs declaration form would make advertising mail with a giveaway cost-prohibitive for nonprofits.

Response: The cost effectiveness of this change does not dictate whether customs declarations are required by international law. This is not a change made with intent to shift burden or cost to the mailing or nonprofit industry; it is solely for consistency with mandatory international regulations.

Comment: Another notable challenge provided by the commenter is the proposed requirement that documents mailed as a packet due to size restrictions, such as publications, include a customs declaration form and associated electronic data. Any additional obstacles for publishers are likely to have an impact on outbound volumes.

Response: Similar to the response above, the impacts should be limited to an additional form placed on the package and associated AED transmission, and should not impact mail preparation or packaging unless the size of the item does not allow for a label that is 4 inches in length by 6 inches in height—in which case the package size may need to change or a smaller form may need to be designed and passed by the approving officials at the Postal Service for custom designed customs forms.

Comment: The commenter added that another problem with this proposed change is that confusion remains about whether publications and magazines sent as documents are “goods” that require a customs form. Some publications are free circulation, so customers do not pay for them and thus they have no monetary value to the customer, therefore presumably fitting the category of documents for which no customs declaration form is required. The commenter also contended that the importing country sets its own regulations determining whether publications are considered goods or documents and that it is not consistent across the board, with some countries treating publications as documents and others as goods. The commenter questioned whether the Postal Service would require a customs declaration form for all publications, even if the destination country considers them to be documents.

Response: In accordance with the UPU Convention and its Regulations, items containing goods require customs declarations. Documents generally consist of any written, drawn, printed, or digital information, excluding objects of merchandise, whose physical specifications lie within certain limits; goods generally consist of any tangible and movable objects other than money, including objects of merchandise, which do not fall under the definition of documents. Current IMM section 123.63 (here being renumbered as section 123.62) provides guidance on what items are generally considered documents and what items are generally considered merchandise. Customs declaration forms are required for magazines (periodicals) as merchandise.

Comment: The commenter also indicated that eliminating the known mailer exceptions adds another layer of complexity to the export compliance process, especially for shared partners that have worked closely with the Postal Service to meet the necessary export compliance requirements to ensure safety, security, and accountability in the international mailstream. The commenter further stated that these hurdles seem to tip the scale in favor of the Postal Service's competitors and that elimination of the known mailer exceptions adds one more weight to the scale.

Response: The Postal Service cannot choose whether or not items with goods require customs declarations as a matter of international law, regardless of whether competitors insist on customs forms for private shipments. Customs forms are typically required for goods shipped as private cargo.

Comment: The other commenter requested that the subsections containing “official mail” exceptions for customs declarations remain and not be amended. The commenter indicated that general descriptions are utilized to deter rifling and theft and that removing the known mailer definition would compromise classified and secret or sensitive materials and equipment, hinder investigations, and create stagnancy for the nation's trusted workforce, resulting in adverse impacts to government agencies and ultimately prevent the mailing of classified materials.

Response: Under binding international law, there is no general exception for customs declarations for “official mail.” At the same time, the Postal Service considers the security of all mail for which it is responsible to be of paramount importance.

The Postal Service is removing IMM section 123.62 in its entirety and revising associated IMM section 123.61a, Exhibit 123.61, and section 272.4 to remove known mailer references.

We believe these revisions are necessary to align postal policy with current customs and international mail regulations applicable to the United States and other countries. The Postal Service adopts the described changes to *Mailing Standards of the United States Postal Service*, International Mail Manual (IMM), incorporated by reference in the Code of Federal Regulations. We will publish an appropriate amendment to 39 CFR part 20 to reflect these changes.

In a separate rule, the Postal Service will also revise associated revisions to the DMM.

List of Subjects in 39 CFR Part 20

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 20 is amended as follows:

PART 20—[AMENDED]

■ 1. The authority citation for 39 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 407, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the *Mailing Standards of the United States Postal Service*, International Mail Manual (IMM) as follows:

Mailing Standards of the United States Postal Service, International Mail Manual (IMM)

* * * * *

1 International Mail Services

* * * * *

120 Preparation for Mailing

* * * * *

123 Customs Forms and Online Shipping Labels

* * * * *

123.6 Required Usage**123.61 Conditions**

* * * * *

[Revise item a. to read as follows:]

a. Mailers may use the hard copy PS Form 2976–R and present it at a USPS retail service counter, or use an electronic PS Form 2976, PS Form 2976–A, or PS Form 2976–B as described in Exhibit 123.61.

* * * * *

Exhibit 123.61

Customs Declaration Form Usage by Mail Category

* * * * *

[In the section “First-Class Package International Service Packages (Small Packets), as well as IPA Packages (Small Packets) and ISAL Packages (Small Packets),” remove the second row (beginning with “All package-size items. . .”) in its entirety; also in Exhibit 123.61, revise all references of 123.63 to 123.62.]

* * * * *

[Remove section 123.62, “Known Mailers,” in its entirety, renumbering current sections 123.63 and 123.64 to be 123.62 and 123.63, respectively.]

* * * * *

2 Conditions for Mailing

* * * * *

270 Free Matter for the Blind

* * * * *

272 Eligibility

* * * * *

272.4 Customs Form Required

[Revise the text to read as follows (removing the second sentence):]

When required (see *Exhibit 123.61*), the mailer must affix a fully completed electronically generated PS Form 2976 or 2976–A to each item.

Colleen Hibbert-Kapler,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2024–13264 Filed 6–17–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 679**

[Docket No. 240612–0158; RTID 0648–XD877]

Fisheries of the Exclusive Economic Zone off Alaska; Cook Inlet; Final 2024 Harvest Specifications for Salmon

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

ACTION: Final rule; harvest specifications.

SUMMARY: NMFS announces the final 2024 harvest specifications for the salmon fishery of the Cook Inlet exclusive economic zone (EEZ) Area. This action is necessary to establish harvest limits for salmon during the 2024 fishing year and to accomplish the goals and objectives of the Fishery Management Plan for Salmon Fisheries in the EEZ off Alaska (Salmon FMP). The intended effect of this action is to conserve and manage the salmon resources in Cook Inlet EEZ Area in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Harvest specifications and closures are effective at 0700 hours, Alaska local time (A.l.t.), June 17, 2024, until the effective date of the final 2025 harvest specifications for the Cook Inlet EEZ Area.

ADDRESSES: A plain language summary of this rule is available at <https://www.regulations.gov/docket/NOAA-NMFS-2024-0028>.

Electronic copies of the Environmental Assessment (EA)/Regulatory Impact Review/Social Impact Review (collectively, the Analysis) for amendment 16 to the Salmon FMP are available from <https://www.regulations.gov> or from the NMFS Alaska Region website at <https://www.fisheries.noaa.gov/action/amendment-16-fmp-salmon-fisheries-alaska>. The final 2024 Stock Assessment and Fishery Evaluation (SAFE) report for Cook Inlet salmon is available on the Alaska Region website at <https://www.fisheries.noaa.gov/alaska/population-assessments/alaska-stock-assessments>.

FOR FURTHER INFORMATION CONTACT:

Adam Zaleski, 907–586–7228, adam.zaleski@noaa.gov.

SUPPLEMENTARY INFORMATION:**Background**

NMFS prepared the Salmon FMP under the authority of the Magnuson-Stevens Act (16 U.S.C. 1801 *et seq.*). Regulations governing U.S. fisheries and implementing the Salmon FMP appear at 50 CFR parts 600 and 679.

Section 679.118(b)(2) requires that NMFS consider public comment on the proposed harvest specifications and publish the final harvest specifications in the **Federal Register**. The proposed 2024 harvest specifications for the Cook Inlet EEZ Area were published in the **Federal Register** on April 12, 2024 (89 FR 25857). Comments were invited and accepted through May 13, 2024. NMFS received 21 letters and 19 distinct comments during the public comment period for the proposed 2024 Cook Inlet EEZ Area harvest specifications. NMFS responses are addressed in the Response to Comments section below. After considering public comments submitted for the proposed rule (89 FR 25857, April 12, 2024), NMFS is implementing the final 2024 harvest specifications for the salmon fishery of the Cook Inlet EEZ Area consistent with the Scientific and Statistical Committee’s (SSC) fishing level recommendations and that account for the significant management uncertainty associated with this new fishery.

Final 2024 Overfishing Levels (OFL), Acceptable Biological Catch (ABC), and Total Allowable Catch (TAC) Specifications

The final 2024 SAFE report contains a review of the latest scientific analyses and estimates of biological parameters for five salmon species, and because harvest specifications must be in place before the fishery begins, the SAFE report relies on forecasts of the coming

year's salmon runs. The 2024 forecasted returns, and, consequently, the OFLs, ABCs, and TACs were developed by NMFS and reviewed by the SSC. Status determination criteria (SDC) and harvest specifications are calculated in terms of potential yield for the Cook Inlet EEZ Area. The potential yield is the total forecasted run size minus the number of salmon required to achieve spawning escapement targets and the estimated mortality from other sources including in other fisheries. For the final 2024 SAFE report, NMFS developed suitable alternative forecasts based on historical data for some stocks and used fishery catch in prior years for other stocks and stock complexes to inform the 2024 harvest specifications.

Amendment 16 to the Salmon FMP specifies the tiers used to calculate OFLs and ABCs. The tiers applicable to a particular stock or stock complex are determined by the level of reliable information available. This information is categorized into a successive series of three tiers to define OFLs and ABCs, with Tier 1 representing the highest level of information quality available and Tier 3 representing the lowest level of information quality available. NMFS used this tier structure to calculate OFLs and ABCs for each salmon stock or stock complex (a stock complex is an aggregate of multiple stocks of a species).

The SSC, Advisory Panel (AP), and North Pacific Fishery Management Council (Council) reviewed NMFS's preliminary 2024 SAFE report for the Cook Inlet EEZ Area salmon fishery in February 2024. From these data and analyses, the SSC recommended an OFL

and ABC for each salmon stock and stock complex. The SSC further recommended changing the buffers that reduce ABC from the OFL for aggregate Chinook, aggregate pink, and aggregate chum salmon to be sufficiently precautionary. For each stock and stock complex, the SSC made recommendations regarding OFLs and ABCs and the AP recommended TACs, but after NMFS's consultation with the Council, the Council took no action to recommend Cook Inlet EEZ Area salmon harvest specifications. NMFS is implementing the OFLs and ABCs recommended by the SSC and TACs consistent with the SSC's fishing level recommendations and that account for the significant management uncertainty associated with this new fishery. In making its motion at the February Council meeting, NMFS discussed the sources of scientific and management uncertainty in detail.

Following the February SSC and Council meeting, NMFS updated the 2024 SAFE report to include SSC recommendations (see **ADDRESSES**). The final specifications are based on the final 2024 SAFE report, which represents the best scientific information available on the biological condition of salmon stocks in Cook Inlet and other social and economic considerations.

The recommended specifications of OFL, ABC, and TAC are consistent with the harvest strategy outlined in the Salmon FMP, the biological condition of salmon as described in the final 2024 SAFE, SSC recommendations, and with National Standard 1. ABC is less than or equal to the OFL for each stock and

stock complex. TACs are established for species rather than stocks or stock complexes because it is not possible to differentiate among stocks of the same species through catch accounting during the fishing season. TACs for each species are set less than the aggregate ABC for each component stock and stock complex, and these TACs account for the assumed contribution of each stock or stock complex to total catch to ensure ABC is not exceeded for any stock and stock complex.

NMFS is publishing the final 2024 harvest specifications after: (1) considering comments received within the comment period (see **DATES**); (2) considering information presented in the Analysis (see **ADDRESSES**); and (3) considering information presented in the final 2024 SAFE report prepared for the 2024 Cook Inlet EEZ Area salmon fisheries (see 50 CFR 679.118(b)(2)).

The final 2024 OFLs, ABCs, and TACs are based on the best scientific information available. The SAFE report was subject to peer review by the SSC, which recommended ABCs in table 1, as is consistent with §§ 600.310(f)(3) and 600.315(c)–(d). The TACs are adjusted to account for other relevant biological and social and economic considerations presented in the resource assessment documents (*i.e.*, the 2024 SAFE report) (see 50 CFR 679.118(a)(2)), including to account for management uncertainty for this new fishery, the estimated contribution of each stock or stock complex to total catch of a species, and to prevent catch in the Cook Inlet EEZ Area from exceeding the ABC for any stock or stock complex.

TABLE 1—FINAL 2024 COOK INLET EEZ AREA SALMON OFLs, ABCs, AND TACs IN NUMBERS OF FISH

Stock ¹	OFL	ABC	TAC
Kenai River Late-Run sockeye salmon	902,000	431,100	492,100
Kasilof River sockeye salmon	541,100	375,500	
Aggregate other sockeye salmon	887,500	177,500	
Aggregate Chinook salmon	2,700	270	240
Aggregate coho salmon	357,700	35,800	25,000
Aggregate chum salmon	441,700	110,400	99,400
Aggregate pink salmon	270,400	135,200	121,700

¹The TAC for sockeye salmon is combined for Kenai River Late-Run, Kasilof River, and aggregate other sockeye salmon because of the mixed stock fishery.

Response to Comments

NMFS published its proposed harvest specifications on April 12, 2024 (89 FR 25857) and accepted public comment for 31 days, closing on May 13, 2024. NMFS received 21 letters with 19 distinct comments during the public comment. The comments were from individuals, environmental groups, local governments, commercial fishing

organizations, tribes and tribal members, individual drift gillnet fishermen, and the United Cook Inlet Drift Association.

Scope of the Harvest Specifications

Comment 1: NMFS needs to revise the Cook Inlet EEZ Area salmon fishery management measures implemented under amendment 16, including the use

of a TAC, fishing dates and times, net length, recordkeeping and reporting, vessel monitoring systems, authority to issue Emergency Orders, refusal to honor Commercial Fisheries Entry Commission (CFEC) limited entry permits, research, a tribal fishery, and tribal engagement on amendment 16.

Response: These comments address topics outside the scope of the harvest

specifications. Responses to any of these comments that were submitted regarding amendment 16 were addressed in the Comments and Responses section of the amendment 16 final rule (starting on page 34724 at 89 FR 34718, April 30, 2024). The comment period for amendment 16 ended on December 18, 2023. The rulemaking for the proposed and final harvest specifications sets the OFLs, ABCs, and TACs for the salmon fisheries of the Cook Inlet EEZ Area, and this action does not change any of the fishery management policies adopted under amendment 16.

Many of these comments asserted that the use of a TAC is not appropriate for salmon. As stated in the previous paragraph, the use of TACs was established by amendment 16 and its implementing regulations. These harvest specifications establish the amount of the TACs for salmon during the 2024 fishing year to accomplish the goals and objectives of the Salmon FMP. Therefore, any comments related to the use of a TAC are outside the scope of the harvest specifications.

Also, NMFS will monitor the fishery daily and use inseason management measures and adjust the TAC, if practicable and supported by the best scientific information available, to ensure that catch amounts are appropriate for the realized run strength. NMFS determined the TACs for the Cook Inlet EEZ Area are suitably precautionary to avoid overfishing.

Total Allowable Catch (TAC) Amounts

Comment 2: The TACs proposed by NMFS for the Cook Inlet EEZ Area are set too low and will cause foregone harvest and over-escapement. Additionally, the 2024 forecast from State of Alaska Department of Fish and Game (ADF&G) is for 3.72 million sockeye, minus 1 million for the dip net/recreational fishery, which would leave about 2.7 million sockeye theoretically available for commercial harvest. There is no east side set net fishery again in 2024. There should be 2.7 million sockeye available for commercial users, only drift gillnet gear type is authorized for those commercial users, and 65 percent of the catch occurs in the EEZ, so the TAC would need to be set at least 1.7 million sockeye. For sockeye salmon, the TAC of 492,100 sockeye is too low as a result of buffers that are disproportionately conservative relative to other salmon stocks given their high abundance.

Response: NMFS disagrees that the 2024 Cook Inlet EEZ Area TAC of 492,100 sockeye salmon is too low and disproportionately conservative. NMFS

also disagrees that the TAC should be 1.7 million sockeye salmon. The commenter's proposed TAC of 1.7 million sockeye salmon relies on incorrect assumptions of historical EEZ harvests, is not based on the preseason forecast method described in the final 2024 SAFE report, does not account for scientific uncertainty in reducing the pre-season OFL to the resulting ABCs recommended by the SSC, and does not account for management uncertainty in setting the TAC less than the combined ABCs.

NMFS disagrees with the commenter's characterization of the methodology used in the Federal harvest specifications for setting OFLs, ABCs, and TACs. As described in section 4.5.1.2.3 of the Analysis, the best available estimates of historical harvests indicate that, contrary to the commenter's contention, 47 percent (not 65 percent) of the Cook Inlet drift gillnet harvest have occurred in EEZ waters. Thus, the commenter overstates the proportions of historical harvests that are estimated to have occurred in Cook Inlet EEZ Area and, as a result, overestimated the number of sockeye salmon available for harvest by the drift gillnet fleet as described in the final 2024 SAFE report and determined by the Federal TAC setting process. In addition, the ADF&G preseason harvest estimate of 3.72 million sockeye salmon (across all fisheries) that is referenced by the commenter—which the commenter alleges should leave 2.7 million sockeye available for commercial harvest—was not available in time to be included in the final 2024 SAFE report for review by the SSC at the February 2024 Council meeting. Further, even assuming these numbers were accurate, the 2.7 million sockeye the commenter argues should be available for commercial harvest represents something akin to an OFL (*i.e.*, the maximum number of fish theoretically available for harvest before accounting for scientific and management uncertainty) and does not represent a scientifically-defensible ceiling for total commercial harvest. The combined 2024 OFL for sockeye under these harvest specifications is 2.33 million fish prior to accounting for scientific and management uncertainty, and the OFLs were based on the best scientific information available in time for SSC review. And as described in the final 2024 SAFE report, historical harvests, not total run size was used to set harvest specifications for the Tier 3 aggregate other sockeye salmon stock complex. Therefore, the combined preseason harvest estimate provided by

the commenter, in addition to being erroneously inflated for the reasons described previously, is not directly comparable to estimates of total run size and OFL described in the final 2024 SAFE report.

As described in section 5 of the final 2024 SAFE report, for Tier 1 stocks of sockeye salmon (*i.e.*, Kenai and Kasilof river stocks), preseason total run size forecasts, which were based on the best scientific information available in time for SSC consideration, were reduced by the SSC-recommended spawning escapements and likely ADF&G harvests to result in OFLs of 901,932 sockeye salmon for the Kenai River and 541,084 sockeye salmon for the Kasilof River (1,443,016 fish combined for Tier 1 stocks). For the Tier 3 aggregate other stock, the SSC recommended an OFL of 887,500 fish by relying on estimated maximum historical annual catch.

After defining OFL for each stock or stock complex, the SSC recommends ABCs consistent with section 302(g) of the Magnuson-Stevens Act. An ABC is “a level of a stock or stock complex’s annual catch, which is based on an ABC control rule that accounts for the scientific uncertainty in the estimate of [OFL], any other scientific uncertainty, and the Council’s risk policy” (50 CFR 600.310(f)(1)(ii)). After considering scientific uncertainty in the calculation of OFLs for the Tier 1 stocks, including the historical accuracy of the estimates of run size and ADF&G harvests, the SSC recommended ABCs of 431,123 sockeye salmon for the Kenai River and 375,512 sockeye salmon for the Kasilof River (806,635 combined ABC for Tier 1 stocks). As described in section 5 of the final 2024 SAFE report, for the data-poor Tier 3 aggregate other sockeye salmon stock complex, the SSC recommended a higher buffer to account for the greater scientific uncertainty and significant data gaps for this stock complex, and ultimately recommended an ABC of 177,493 sockeye salmon. Thus, even prior to NMFS considering management uncertainty in setting a TAC for sockeye salmon, the sum of the 2024 SSC-recommended ABCs for sockeye salmon in the Cook Inlet EEZ Area (984,128 sockeye salmon) is considerably lower than the TAC recommended by the commenter (1.7 million sockeye salmon).

TAC is reduced from ABC to account for management uncertainty, which includes “[l]ate catch reporting; misreporting; underreporting of catches; lack of sufficient inseason management, including inseason closure authority; or other factors.” (50 CFR 600.310(f)(1)(v); see also 50 CFR 600.310(g)(4)). NMFS set the combined sockeye salmon TAC

below the SSC's recommended ABCs to account for management uncertainty for this new fishery and to prevent catch in the EEZ from exceeding the annual catch limit, consistent with the Magnuson-Stevens Act and National Standard 1 guidelines (see 50 CFR 600.310(g)(4), providing that TACs should account "for management uncertainty in controlling the catch at or below the [annual catch limit]," which is equal to ABC for this fishery). In particular, NMFS considered the uncertainty associated with the efficacy and timeliness of catch reporting in a new fishery and the uncertainty associated with managing a mixed stock fishery in which certain weak stocks are at risk of missing their spawning escapement goals. At present, weak stocks' relative contribution to total EEZ harvest remains an estimate. The management uncertainty associated with the achievement of escapement targets for weak stocks is a separate consideration from the scientific uncertainty that was explicitly addressed in the SSC-recommended buffers that reduced the ABC from the OFL (*i.e.*, uncertainty of total run size estimate and uncertainty of ADF&G harvests).

For the Tier 3 aggregate other sockeye salmon stock complex, NMFS considered the management uncertainty associated with the achievement of the escapement goals for the indicator stocks in the stock complex. For that stock complex, NMFS determined that a 50 percent buffer of the ABC would result in harvests of the stock complex that approximate those estimated to have occurred during recent years (*e.g.*, compared with recent 5-year and 10-year averages) and, as such, that this level of harvest would generally also allow the achievement of spawning escapements to the indicator systems of the stock complex. However, as some indicator systems for this stock have not always achieved their spawning escapement targets during recent years, NMFS was justified in applying a buffer that did not result in a large increase in the amount of harvest for this stock in the EEZ, especially during the first year of the fishery. Due to the mixed-stock nature of the Cook Inlet EEZ Area fishery, the 50 percent buffer was applied to all stocks of sockeye salmon because the fleet cannot target any of the stocks in isolation, and NMFS must manage to ensure no harm is done to the stock complex that is most vulnerable to missing its escapement goals. NMFS cannot differentiate among stocks of the same species inseason, and NMFS is relying on estimates of relative

sockeye stock contributions to total harvest in setting a combined TAC. NMFS must therefore account for considerable management uncertainty, justifying a 50 percent buffer to ensure no stock exceeds its ACL (equal to ABC). The combined TAC of 492,100 sockeye salmon is somewhat higher than recent levels of sockeye harvest in the EEZ (recent 10-year average estimated EEZ harvest of approximately 397,393 sockeye salmon).

Fishing in the Cook Inlet EEZ Area targets mixed stocks of salmon that have varying levels of abundance and surplus yield. Conservation measures to prevent overfishing on salmon stocks that are less abundant and/or for which there is less available information to assess run strength are a primary driver of foregone yield to the more abundant stocks. Allowing a higher TAC to harvest surplus yield for more abundant stocks in the EEZ would create a significant risk of not meeting escapement goals for less abundant stocks and reduce or eliminate the harvestable surplus of these stocks available to all other salmon users. The 2024 TACs are appropriate for a new Cook Inlet EEZ Area fishery and will prevent harvest from exceeding the ABC, as required by the Magnuson-Stevens Act and National Standard guidelines (50 CFR 600.310(f)(1), (2), (3)).

The Magnuson-Stevens Act has no prohibition against foregone harvest, explicitly mandates that NMFS prevent overfishing, and states that foregone harvest is necessary when additional harvest of an abundant stock would also result in harvest of species for which there is a conservation concern. Therefore, in determining harvest limits for a mixed stock fishery, NMFS cannot look at the more abundant stocks in isolation. Crucially, the commercial drift gillnet fleet has no means of targeting only one specific stock of salmon while fishing, so harvest limits must account for the assumed contribution of each stock to total harvest. Additionally, harvest limits are appropriately limited to EEZ waters (where NMFS has management authority) and defined so as to identify the amount of cumulative harvest of all co-occurring EEZ stocks that both provides harvest opportunity to the greatest extent practicable while preventing overfishing (supported by the best available scientific information). This is consistent with NMFS's approach to salmon management on the West Coast where "weak stock" management is required to avoid exceeding limits for the stocks with the most constraining limits.

In addition, Federal regulations for setting salmon TACs provide that the Council and NMFS should consider (1) the biological condition of salmon stocks and (2) social and economic considerations (50 CFR 679.118(a)(2)). For these harvest specifications, NMFS fully evaluated the biological condition of salmon stocks and social and economic considerations in specifying TACs. This information is extensively described in Section 2.5.2.2 of the Analysis, with additional relevant biological information on each stock provided in the Stock Status Summaries section of the 2024 SAFE report (*Tier determination and resulting OFL and ABC determination for 2024*) and the sources NMFS references within the SAFE Report.

Each year when setting harvest specifications, NMFS will evaluate the potential harvest available in the Cook Inlet EEZ Area and will work to provide harvest opportunities to the extent possible, subject to the constraints of scientific and management uncertainty. As the information available to NMFS to manage salmon fishing in the Cook Inlet EEZ Area improves through implementation of this new Federal fishery management regime, it is possible that harvest levels could increase in the future.

At this time there is not available information for NMFS to manage specific sockeye salmon stocks inseason and therefore NMFS will manage all sockeye salmon stocks inseason with a single TAC that includes harvests from the Kasilof, Kenai, and aggregate other sockeye salmon stocks. NMFS sets the combined sockeye salmon TAC after considering the best scientific information available on the relative contribution of each stock to the total catch. While there are currently no State of Alaska stocks of concern for sockeye salmon in Upper Cook Inlet, there are significant data gaps. For example, the lack of timely escapement data for the smaller spawning systems that make up the aggregate other sockeye salmon stocks—for which there is significant harvest—necessitates a precautionary approach to managing the fishery given the management and data limitations described above. These considerations are described throughout sections 2.5 and 3.1 of the Analysis. Preventing overfishing on all stocks within the fishery is consistent with NMFS's mandate under the Magnuson-Stevens Act and National Standard 1.

Comment 3: The TAC for the aggregate other sockeye salmon stock complex may have a larger impact on the weaker sockeye stocks and is not conservative enough.

Response: NMFS set a combined TAC for all sockeye salmon in the Cook Inlet EEZ Area, including for the stock complex it refers to in the harvest specifications as “aggregate other sockeye salmon.” Drift gillnet fishing in the Cook Inlet EEZ Area harvests multiple sockeye salmon stocks originating from systems throughout Cook Inlet. There is no information currently available for NMFS managers to utilize to determine genetic stock composition during the fishing season (*i.e.*, how many sockeye from each system are caught each day). Therefore, NMFS must manage using a combined sockeye salmon stock TAC as a conservation measure to prevent overfishing on less abundant co-occurring salmon stocks. However, NMFS did use the historical genetic catch composition data that is available post-season to set TACs that avoid exceeding the SSC’s recommendation for each component stock. Given this information, NMFS does not expect that the ABC for “aggregate other sockeye salmon” (which includes the weakest sockeye salmon stocks in Cook Inlet) will be exceeded if the combined sockeye salmon TAC is fully harvested. The TAC amount includes an additional reduction between ABC and TAC to account for management uncertainty (see the response to comment 2 for more detail).

Comment 4: The proposed TAC of 25,000 coho salmon is appropriate based on the available, although extremely limited, information.

Response: NMFS agrees. Compared to other stocks, the 2024 SAFE report supports, and the SSC recommended, a relatively conservative buffer for aggregate coho salmon during 2024 due to the lack of information necessary to estimate total run size and associated status determination criteria for the aggregate coho stock complex, and genetic evidence showing that significant proportions of the coho salmon harvested by the drift gillnet fleet are likely bound for Northern Cook Inlet drainages where indicator stocks have not consistently achieved spawning escapement goals during recent years. Therefore, in order to help ensure that spawning escapement goals are achieved, and allow for at least some harvestable surplus for other users, NMFS selected a sufficiently conservative coho salmon TAC.

In addition, the 2024 SAFE report also considered potential concerns about the salmon prey available to endangered Cook Inlet beluga whales. This endangered species occupies Northern Cook Inlet, including the far reaches of

the Inlet when coho salmon runs are present.

Comment 5: NMFS should reduce the TAC amounts in the 2024 harvest specifications based on recommendations from the Council’s AP, the full Council, and public comment.

Response: NMFS acknowledges the support for the TAC amounts based on the OFLs and ABCs recommended by the SSC and the TACs recommended by the AP. However, the Council ultimately did not recommend any harvest specifications. NMFS did consider all feedback received at the February 2024 Council meeting when establishing these harvest specifications.

Comment 6: NMFS violates the National Environmental Policy Act (NEPA) by failing to consider alternatives other than its chosen TAC.

Response: NMFS disagrees. The Analysis analyzed the harvest specifications process and expected outcomes, including the likely TAC amounts which were expected to be near existing harvest levels, as well as alternatives to these TACs. These harvest specifications are consistent with that analysis. TACs are the result of a scientifically driven process following the National Standard 1 guidelines for determining OFL and ABC. TACs are then set below the OFL and ABC to ensure that the ABC and ACL are not exceeded after accounting for management uncertainty, as well as other social, economic, and ecological factors (50 CFR 600.310(g)(4), 679.118(a)(2)). Prior to selecting TAC amounts for each Cook Inlet salmon stock or stock complex, NMFS considered values between zero and ABC, as well as the specific proposal provided by the Council’s AP at the February 2024 Council meeting.

NMFS also considered alternative methods to establish the SDC in the Analysis, which are the measurable and objective factors (*e.g.*, maximum fishing mortality threshold, OFL, and minimum stock size threshold) that NMFS uses to determine if overfishing has occurred, or if the stock or stock complex is overfished. The harvest specifications implement the preferred alternative from the Analysis (see section 2.5: Alternative 3, Federal management). Further, NMFS followed the harvest specifications process analyzed as an alternative in the Analysis by providing a draft SAFE report to the SSC for their consideration in establishing the SDC. The SSC recommended ABCs for each stock or stock complex and, after the Council failed to take action in recommending TACs, NMFS proposed TACs in consideration of public

testimony and based on the tier system described in both the Analysis (section 2.5.2.2) and the final 2024 SAFE report. NMFS is publishing these final harvest specifications after consideration of public comment and consistent with the process established under amendment 16 and implementing regulation (50 CFR 679.118(a)(b)). The responses to comments 2, 11, and 12 include discussion of the tier system used to establish TACs in further detail.

Comment 7: The TAC is much lower than the usual harvest in the Cook Inlet EEZ Area and will make the fishery economically unviable. The projected TAC is so low that it could be caught in just a few openers.

Response: NMFS disagrees that the TAC amounts in these harvest specifications are much lower than the usual harvest in the Cook Inlet EEZ Area and will make fishing economically inviable. The salmon TACs NMFS approves in these harvest specifications are commensurate with, if not slightly higher than, the recent 10-year average of EEZ harvests. For example, the 10-year average harvest of sockeye salmon in the EEZ is estimated to be approximately 397,393 fish while the proposed EEZ TAC of sockeye salmon is 492,100 fish. The appendices in the 2024 SAFE detail total catch, estimated EEZ catch, and cumulative EEZ catch for each stock or aggregate stock.

Further, given the ADF&G’s current conservation measures for depressed stocks of Chinook and coho salmon, it is expected that continued State of Alaska management of commercial fishing in the Cook Inlet EEZ would have resulted in similar or lower catch amounts in the EEZ area for this fishing year in order to meet escapement goals and provide some harvestable surplus to the greatest range of users. Thus, compared to baseline conditions—*i.e.*, salmon management in the Cook Inlet EEZ by the State of Alaska—these EEZ harvest limits are not expected to have adverse economic impacts. Further, NMFS cannot authorize harvests above these limits without a serious risk that weaker stocks would miss their escapement goals, possibly resulting in overfishing, as well as serious economic impacts to other users also dependent on these salmon stocks after they have moved through the Cook Inlet EEZ Area.

Comment 8: NMFS is interpreting “conservative management” as solely based on a TAC rather than recognizing the importance of harvest rates in conjunction with net length, run timing, and the Conservation Corridor as components of conservative management.

Response: NMFS disagrees. As described in the response to comments 3 and 7, the TACs were established with conservative buffers accounting for scientific and management uncertainty in the context of the management measures implemented by amendment 16 in Federal regulations. NMFS expects that the TACs implemented in these harvest specifications are attainable, while also protective of weaker stocks, based on the best scientific available information (e.g., run timing) and based on expected effort under the regulations established by amendment 16 (e.g., net size). Other management measures and the rationale for selecting them is described in the final rule implementing amendment 16, but are outside the scope of this rule.

Comment 9: The harvest specifications violate the Magnuson-Stevens Act by providing the commercial fishing sector with an insufficient percentage of total available salmon for harvest in the Cook Inlet EEZ.

Response: NMFS disagrees. The Magnuson-Stevens Act does not require that NMFS allocate a specific percentage of the harvest to the commercial fishing sector. Nonetheless, NMFS expects that over 99.9 percent of the salmon harvested in Cook Inlet EEZ Area will be harvested by the commercial salmon fishery sector, consistent with historical trends and all applicable Magnuson-Stevens Act requirements. Further, the TACs will provide fishermen an opportunity to harvest salmon commensurate with, if not slightly higher than, the recent 10-year average of EEZ harvests, as explained in the response to comment 7.

Stock Assessment and Fishery Evaluation (SAFE)

Comment 10: NMFS should work with ADF&G to develop indicator stocks to determine strength in the Susitna River drainages.

Response: NMFS acknowledges that there are information gaps for management of Cook Inlet salmon stocks, however this rule is based on the best scientific information currently available, consistent with the Magnuson-Stevens Act (16 U.S.C. 1851(a)(2)). As with all other federally-managed fisheries, NMFS will work with stakeholders, other government agencies, Alaska Native Tribes, and academic institutions to improve the level of scientific information available to manage this fishery over time to the extent practicable.

Comment 11: Not adding in the number of fish counted over the upper escapement goal which entered the river

each year into any data formula for a TAC is an unacceptable oversight.

Response: The comment does not describe or recommend a formula by which escapements beyond the upper bound of the escapement goal should be considered in setting a TAC, whether such a count should be used to re-evaluate a TAC inseason, or whether the commenter wishes for such a count to be applied to TAC setting in future years. As described in the final 2024 SAFE report, for Tier 1 stocks, the SAFE report does consider the total run size, including harvests and escapement, of each salmon stock in determining the OFL and the SSC's recommended ABC, which formed the basis of TAC in the proposed harvest specifications. In setting harvest limits for the Cook Inlet EEZ Area, NMFS considers escapement in prior years in the stock assessment, which informs the SAFE's forecast of total run size for the current fishing year, and the expected impact of each salmon fishery. This addresses the expected impact of escapement values, including those in excess of escapement goals, on future run sizes, as well the impact of management on fishery harvests of each salmon stock. While this approach does indicate that some stocks may be able to support additional harvest, NMFS must also consider the uncertainty associated with all of this information and account for weaker stocks that would also be harvested concurrently. Data on total returns, harvest, and escapement for the 2024 fishing season will be considered in the 2025 harvest specifications to improve management and utilization, subject to the constraints of uncertainty as well as ensuring a harvestable surplus for other salmon users.

For Tier 2 stocks the SAFE report identifies these as salmon stocks that would be managed as a stock complex, where specific tributaries or drainages serve as indicator stocks to estimate stock-specific harvest levels. However, the SAFE report did not recommend any stock or stock complex be designated as Tier 2, because there may be many tributaries for which spawning escapements are not assessed or are assessed with methods for which the total numbers of spawners cannot be estimated with high precision. Tier 2 may be used in future years as the Federal fishery develops and management is able to improve with additional years of data.

There are currently no reliable estimates of total number of spawners or total run size for the entire stocks and stock complexes in Tier 3; therefore, historical harvest data were used in determining the OFLs for Tier 3 stocks

and stock complexes as described in the final 2024 SAFE report and Salmon FMP. The ABC for Tier 3 was reduced from the OFL by a scientifically-informed buffer, which is conservative due to the lack of reliable information for Tier 3 stocks. The buffers are discussed further in response to comment 2. The methodology of using historical harvest for data-limited stocks is consistent with the calculation of OFL for data-limited stocks managed under other FMPs (e.g., the FMPs for groundfish), as is the use of conservative buffers (e.g., up to 75% reduction from OFL in setting ABC) for the calculation of ABC (e.g., crab species managed under the FMP for Bering Sea/Aleutian Islands King and Tanner Crabs).

Comment 12: We urge NMFS to use the mid-range of escapement goals instead of the low-end and consider trends in weak stocks when setting their TAC.

Response: For Tier 1 stocks, NMFS had originally recommended using the lower bound of the escapement goal to calculate SDC and associated harvest specifications to the SSC at the February 2024 Council meeting. Under section 302(h)(B) of the Magnuson-Stevens Act, the SSC provides recommendations for ABC and OFL that prevent overfishing. The SSC reviewed all available information and instead recommended that SDC and harvest specifications for the 2024 fishing season be based on the number of spawners necessary to achieve maximum sustainable yield (S_{MSY}). Using S_{MSY} resulted in a lower (more conservative) ABC for Tier 1 stocks than if the lower bound of the escapement goals were used. NMFS then set the TACs below the ABCs recommended by the SSC.

For Tier 2 stocks that are managed as a stock complex, escapement is an index of spawners that may represent an unknown portion of the overall escapement. However, the SAFE report did not recommend any stock or stock complex be designated as Tier 2 (see response to comment 11). For Tier 3 stocks, escapement data is poor and NMFS currently cannot produce reliable estimates of abundance and instead relies of historical harvest rates when recommending the OFL. ABCs for Tier 3 stocks are reduced from OFL based on an appropriate buffer that accounts for scientific uncertainty. NMFS then set the TACs for Tier 3 stocks below the ABCs recommended by the SSC.

Escapement

Comment 13: The proposed TACs will continue the trend of gross over-escapements resulting in fewer fish returning in subsequent years, reduced

future returns, wasted foregone yield that is a National food source, a waste of interstate commerce, and an economic disaster for fisherman and the communities.

Response: NMFS disagrees that escapements that exceed the current goals are certain or will necessarily lead to negative impacts on the ecosystem. The majority of Cook Inlet salmon harvests occur within State of Alaska waters and management. In establishing harvest specifications, NMFS considers the scientific and management uncertainty present, and the risk that the number of returning salmon will be lower than forecasted. Because salmon fishing in the Cook Inlet EEZ Area harvests target salmon runs before all other users in Cook Inlet, it is essential to ensure that enough salmon of all stocks can pass through the Cook Inlet EEZ Area to meet escapement goals, while also accounting for all subsequent mortality. Any salmon surplus to escapement goals may still be harvested in State of Alaska waters after moving through the Cook Inlet EEZ Area. Moreover, NMFS disagrees that escapement in excess of current goals will necessarily negatively impact future salmon abundance.

In appendix 14 of the Analysis, the Kenai and Kasilof sections of the 2024 SAFE report, and responses to comments in the amendment 16 final rule address the topic of whether sockeye salmon spawning escapements above the upper bound of the escapement goal (*i.e.*, “over-escapements”) result in fewer returning adult fish in subsequent years (*i.e.*, density dependent effects, otherwise known as overcompensation). Sockeye salmon spawning escapements above the upper bound of the spawning escapement goals were included in spawner-recruitment analyses in the Analysis and the SAFE. These larger spawning escapements have generally resulted in substantial yields of adult sockeye salmon in future years, and, therefore, do not suggest that “over-escapement” has resulted in density dependent effects. NMFS will continue to monitor spawner-recruitment trends and will adjust its status determination criteria and harvest specifications recommendations to the SSC if density dependent effects become evident.

National Standards

Comment 14: The proposed harvest specifications do not meet National Standard 1 requirements to manage the fishery based on maximum sustainable yield (MSY) or that optimum yield (OY) will be achieved on a continuous basis.

Response: NMFS disagrees. National Standard 1 states that conservation and management measures shall prevent overfishing while achieving, on a continuing basis, the OY from each fishery for the United States fishing industry. Under the National Standard 1 guidelines, OY is prescribed on the basis of MSY. NMFS defined both OY and MSY under amendment 16; neither are annual management targets and both definitions are outside the scope of these harvest specifications. However, these harvest specifications are consistent with National Standard 1 because they will prevent overfishing while remaining consistent with NMFS’s obligation to achieve OY on a continuing basis over the long term. NMFS established these harvest specifications to prevent overfishing while considering all salmon stocks harvested, the limitations of weak stock management, scientific uncertainty, management uncertainty, and harvest in other salmon fisheries, as well as social, economic, and other ecological factors.

While the SSC’s harvest level recommendations account for scientific uncertainty, they do not account for management uncertainty. NMFS must account for an additional layer of management uncertainty through a reduction in harvest between ABC and TAC, as required by National Standard 1 (50 CFR 600.310(f)(1)(v), (g)(4)). As a result of this combination of factors, NMFS appropriately set TAC amounts for each species.

Further, the summed TAC amounts across all species fall within the OY range established by amendment 16 and can be achieved by the management measures implemented by amendment 16. This action does not modify OY. To the extent this comment is asserting that MSY and OY are improperly established, that is outside of the scope of this action and is addressed in the amendment 16 final rule.

Comment 15: The harvest specifications do not comply with the decisions of the U.S. Court of Appeals for the Ninth Circuit and the U.S. District Court for the District of Alaska, the 10 National Standards of the Magnuson-Stevens Act, or other applicable laws.

Response: NMFS disagrees. NMFS developed amendment 16 to comply with the decisions of the Ninth Circuit Court of Appeals and the U.S. District Court for the District of Alaska, the Magnuson-Stevens Act, and other applicable Federal law. NMFS considered all Magnuson-Stevens Act requirements for FMPs and balanced the competing demands of the National Standards in section 301(a) of the

Magnuson-Stevens Act when developing amendment 16. NMFS found amendment 16 to be consistent with all 10 National Standards, as detailed in section 5.1 of the Analysis and further addressed in responses to comments on the amendment 16 final rule under the National Standard headings.

The harvest specifications are required to implement amendment 16 and allow a fishery to open. NMFS cannot open a fishery without harvest specifications. NMFS has determined that the harvest specifications comply with the National Standards. These harvest specifications result in harvest limits that fall within the OY range established for the Cook Inlet EEZ Area, can be achieved, and are expected to prevent overfishing on all stocks. The response to comment 14 provides additional detail on consistency with National Standard 1.

Consistent with National Standard 2 and as described in section 1 of the 2024 SAFE, the data, estimates, and analyses used to conduct stock assessment analyses are based upon the best scientific information available, including a rigorous scientific stock assessment and review process. Furthermore, tier selection for all stocks, methods used to determine harvest specifications, MSY, OFL, and ABC were reviewed by the SSC and incorporated their recommendations on fishing levels. The response to comment 18 provides additional discussion of the scientific basis of these harvest specifications.

Consistent with National Standard 3, this action manages all salmon fishing in the Cook Inlet EEZ Area under NMFS’s jurisdiction, while considering all other fishing and management, to ensure that no stocks are subject to overfishing or are overfished, and to achieve OY.

Consistent with National Standard 4, these harvest specifications do not discriminate between residents of different states. The specifications do not allocate or assign any fishing privileges among fishermen, as only one sector may commercially harvest salmon in the Cook Inlet EEZ Area. Regardless, these harvest specifications are fair and equitable to all fishery participants by maintaining historical harvest proportions and levels, are reasonably calculated to promote conservation by avoiding overfishing, and ensure that no entity acquires an excessive share of harvest privileges.

National Standard 5 states that conservation and management measures shall, where practicable, consider efficiency in the utilization of fishery

resources; except that no such measure shall have economic allocation as its sole purpose. This action allows for efficient and historically-consistent commercial drift gillnet harvest of nearly all salmon stocks in the Cook Inlet EEZ Area, subject to the constraints of scientific/management uncertainty, weak stock management, allowing for escapement needs, and allowing for a harvestable surplus for other users.

Consistent with National Standard 6, these harvest specifications account for and allow for variations among, and contingencies in, fisheries, fishery resources, and catches and—as required by the National Standard 6 guidelines—provide “a suitable buffer in favor of conservation” in light of significant scientific and management uncertainties (see 50 CFR 600.335(c)).

These harvest specifications impose no costs and are not duplicative of any other management measures and are therefore consistent with National Standard 7.

Consistent with National Standard 8, these harvest specifications maintain historical access to the resource for all fishing communities in Cook Inlet, consistent with current conservation conditions. This includes maintaining conditions for fishing communities dependent on salmon fishing in the Cook Inlet EEZ Area as well as salmon fishing within State of Alaska waters.

Consistent with National Standard 9, this action minimizes bycatch and bycatch mortality by establishing salmon TACs that can be achieved without additional or different fishing effort that would increase bycatch.

Consistent with National Standard 10, this action promotes safety by establishing TACs that can be achieved during the summer period of relatively good weather.

Comment 16: The Ninth Circuit Court said to not use ADF&G’s data to determine a TAC as it has parochial concerns. All of the years used for data to set the TACs were negatively affected by political management and should not legally be used for science.

Response: NMFS is not relying on ADF&G’s data to determine TACs for any salmon stocks in the Cook Inlet EEZ Area, but rather is making determinations based on the best scientific data available as described in the SAFE report and the Analysis (see response to comment 15). The SAFE report generally uses catch and escapement data from 1999 to 2023 because the data from these years are representative of the current biological and environmental conditions affecting salmon productivity. Also, the data from

these years are representative of how the salmon fisheries throughout Cook Inlet have developed and changed over time. This is also the period for which high quality and comparable data for all Cook Inlet salmon fisheries was available. The Analysis considers harvest and management data back to 1966. This is consistent with the SAFE report and harvest specification approach for all other federally-managed fisheries in the Alaska Region, which have changed over time in response to biological, environmental, social, and economic factors. In addition, the catch and escapement data used in the SAFE report and Analysis were peer reviewed and approved by the SSC, which agreed that the data constitutes the best scientific information available. Ultimately, data on past catch and escapement represents facts about the catch and escapement that occurred during those years. No political decisions are relevant to the reliability of data regarding total run sizes or escapement or other indices of abundance during the selected time series. Finally, the commenter identified no other sources of data that NMFS could have used.

Comment 17: This rule as presented simply adds to the long-term negative impact on the health of the Alaska Native communities around Cook Inlet.

Response: NMFS acknowledges the importance of salmon to Alaska Native communities and citizens in the Cook Inlet, and when there are declines in salmon abundance, it results in adverse impacts to Alaska Native communities and citizens. As described in the response to comment 7, these harvest specifications are expected to maintain salmon harvests in the Cook Inlet EEZ Area near recent historical levels. They are also expected to maintain existing salmon harvest opportunities in State of Alaska waters throughout Cook Inlet. To the extent this comment is referring to the impacts of amendment 16, these are addressed under the Tribal Summary Impact Statement and Tribal Comments headings of the amendment 16 final rule. For discussion of the potential economic impacts on communities from this action, see sections 4.7.1.3 to 4.7.1.4 and section 4.6.4 of the Analysis.

Comment 18: NMFS proposes that it applies the best scientific information available, the unfortunate fact is that there is very limited science available. ADF&G tracks what is caught in Cook Inlet, but there has been no effort to track what is caught specifically in Federal EEZ waters, or when, or how many vessels and permits have been applied to the catch effort. The proposed harvest specifications are not

based on the best scientific information or in fact any scientific information or data.

Response: NMFS used the best scientific information available to inform estimates of previous harvests within the Cook Inlet EEZ Area, which includes comprehensive fish ticket data including locale codes. It is always possible to develop better information, but NMFS must make management decisions based on the best scientific information *available* rather than the best scientific information *possible*. The National Standard 2 guideline instructs NMFS to account for the risks associated with scientific uncertainty and data gaps—which it did here—and acknowledges simpler methodologies or greater proxies may be needed for data-poor fisheries (50 CFR 600.315(a)(2)–(3)). Previously, data regarding harvests, landings, and statistical areas in Upper Cook Inlet were not required to and did not differentiate between State of Alaska and Federal waters. Therefore, NMFS had to develop a methodology to estimate historical salmon harvest in the Cook Inlet EEZ Area. The methodology used to develop harvest estimates for the Cook Inlet EEZ Area is presented in section 4.5.1.2.3 of the Analysis, along with a description of the associated uncertainties. This method and the results were peer reviewed and approved by the SSC, which agreed that the Analysis and harvest specification process rely on the best scientific information available. NMFS received no comments providing additional data to estimate EEZ harvest and no suggested alternate methodologies. NMFS cannot arbitrarily increase the attribution of historical harvest to the EEZ in the absence of any supporting data. Therefore, NMFS determined that the estimates presented in the Analysis constitute the best scientific information available. See the response to comment 15 for additional discussion on National Standard 2.

The 2024 SAFE report describes the State of Alaska’s stock definitions, including the data, estimates, and analyses used to conduct stock assessments are: (1) accurate, thorough, and complete (including documenting when escapement estimates were partial or missing due to various circumstances); and (2) based upon the best scientific information available, including a rigorous scientific stock assessment and review process. The 2024 SAFE report also describes that, given the stock assessment results, the resulting escapement targets represent ranges that are likely to result in sustainable returns for all stocks, and maximum yield (at the stock level) for

those stocks with available spawner-recruitment information. The equations used to propose SDC and harvest specifications for the 2024 SAFE report include escapement targets and—for Tier 1 stocks—associated point estimates of the number of spawners likely to result in the MSY. These equations are consistent with National Standard 1 and 2 guidelines. The Federal stock definitions in the 2024 SAFE report are based on several considerations, including: (1) the availability and specificity of preseason forecasts; (2) the practical limitations, including current genetics limitations, of monitoring and accounting for the harvest of specific stocks of the same species in a mixed-stock fishery; (3) the relative quality of the historical harvest records estimated to have occurred in the Cook Inlet EEZ Area during previous years; and (4) other considerations. Data collected by NMFS during the 2024 and future fishing years are expected to improve the scientific information available for management of Cook Inlet salmon stocks. NMFS will collect the landings information needed to directly and precisely determine EEZ harvests. NMFS will review the information available to manage Cook Inlet salmon stocks each year, including any data gaps and uncertainties. As data are collected on harvest that occurs solely within the Cook Inlet EEZ Area, NMFS will include that information in its ongoing assessment of what constitutes best available science for future management decisions.

Comment 19: In its 2024 SAFE report, NMFS fails to mention OY even once, demonstrating that the chosen OY metric is not even scientifically significant when discussing yield and harvest specifications. Rather than discussing the chosen metric of OY, NMFS uses the term “potential yield,” which appears closer to an actual Magnuson-Stevens Act compliant definition of optimum yield for the “fishery.” NMFS’s SAFE also clearly demonstrates the wasted yield that could be potential yield in the EEZ. The SAFE appendix A1.1 shows the potential yield—after escapement, State of Alaska waters catch, and EEZ catch—in the EEZ for the last two decades.

Response: This action does not modify OY. To the extent this comment is asserting that MSY and OY are improperly established, that is outside of the scope of this action and addressed in the amendment 16 final rule.

OY is not an annual management target that is addressed in a SAFE report, but rather is a long-term objective (50 CFR 600.310(e)(3)(ii)). Consistent with SAFE reports for all

other federally-managed fish and shellfish stocks in the North Pacific, there is limited or no discussion of OY in the Cook Inlet salmon SAFE report. SAFE reports summarize the best scientific information available concerning the past, present, and possible future condition of the stocks, marine ecosystems, and fisheries that are managed under Federal regulation. It provides information to the Council and NMFS for recommending and implementing, respectively, annual harvest levels from each stock, documenting significant trends or changes in the resource, marine ecosystems, and fishery over time, and assessing the relative success of existing State of Alaska and Federal fishery management programs. A SAFE report can provide important information to NMFS or a Council in determining whether the management regime can achieve OY as defined in an FMP, or whether changes to management measures or the OY may be warranted, consistent with the National Standard 1 guidelines. Under the Magnuson-Stevens Act and based on the best available scientific information, NMFS and the Council can revise as appropriate an OY, but such changes are outside the scope of these harvest specifications.

For 2024, the sum of the final TAC amounts across all species, under these final harvest specifications, fall within the OY range established by amendment 16, and can be achieved by the management measures implemented by amendment 16. However, as stated above, OY remains a long-term objective, but is not an annual requirement (50 CFR 600.310(e)(3)(ii)).

Changes From Proposed to Final Rule

NMFS undertook a thorough review of the relevant comments received during the public comment period. However, for reasons described in the preceding section, NMFS made no changes to the proposed rule.

Classification

NMFS is issuing this final rule pursuant to section 305(d) of the Magnuson-Stevens Act. The NMFS Assistant Administrator has determined that this final rule is consistent with the Magnuson-Stevens Act, the Salmon FMP, and other applicable laws.

This action is exempt from review under Executive Order 12866 because it only implements annual catch limits for the Cook Inlet EEZ Area salmon fishery.

NMFS prepared an EA for amendment 16 to the Salmon FMP, which included analysis of the Cook Inlet EEZ Area salmon harvest specifications process

and expected harvest levels (see **ADDRESSES**) and made it available to the public (see the amendment 16 final rule at 89 FR 34718, April 30, 2024; see also the proposed rule at 88 FR 72314, October 19, 2023). The final EA analyzes the environmental, social, and economic consequences of the amendment 16, including the salmon harvest specifications, on resources in the action area. In the final rule implementing amendment 16, NMFS considered and addressed the public comments received during the comment period for the amendment 16 proposed rule, as is consistent with the Magnuson-Stevens Act, the Salmon FMP, and other applicable law, and a final EA and finding of no significant impact, as is consistent with the National Environmental Policy Act and implementing regulations, prior to the publication of the final harvest specifications.

Directed Fishing Closures and Inseason Adjustments

In accordance with 50 CFR 679.118(c)(1)(i), NMFS will prohibit fishing for salmon in the Cook Inlet EEZ Area if NMFS determines that any salmon TAC has been or may be reached for any salmon species or stock. NMFS may also make adjustments to a TAC for any salmon species or stock, or open or close a season, in the Cook Inlet EEZ Area, if necessary to prevent underharvest of a TAC or to prevent overfishing, consistent with § 679.25. Changes to the salmon fisheries in the Cook Inlet EEZ Area will be posted at the following website under the Alaska filter for Management Areas: <https://www.fisheries.noaa.gov/rules-and-announcements/bulletins>.

Final Regulatory Flexibility Analysis

A final regulatory flexibility analysis (FRFA) was prepared for this action. Section 604 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 604) requires that, when an agency promulgates a final rule under 5 U.S.C. 553, after being required by that section or any other law, to publish a general notice of proposed rulemaking, the agency shall prepare a FRFA. The following constitutes the FRFA prepared for these final 2024 harvest specifications.

Section 604 of the RFA describes the required contents of a FRFA: (1) a statement of the need for, and objectives of, the rule; (2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed

rule as a result of such comments; (3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments; (4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available; (5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and (6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency that affect the impact on small entities was rejected.

A description of this action, its purpose, and its legal basis are included at the beginning of the preamble in the Background section to this final rule and are not repeated here.

NMFS published the proposed rule on April 12, 2024 (89 FR 25857). NMFS prepared an Initial Regulatory Flexibility Analysis (IRFA) to accompany the proposed action, and included the IRFA in the proposed rule. The comment period closed on May 13, 2024. No comments were received on the IRFA or on the economic impacts of the rule on a general level.

The Chief Counsel for Advocacy of the Small Business Administration did not file any comments on the proposed rule.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (North American Industry Classification System (NAICS) code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates) and has combined annual gross receipts not in excess of 11 million dollars for all its affiliated operations worldwide. In addition, the Small Business Administration has established a small business size standard

applicable to charter fishing vessels (NAICS code 713990) of 9 million dollars.

This final rule directly regulates commercial salmon fishing vessels that operate in the Cook Inlet EEZ Area, and charter guides and charter businesses fishing for salmon in the Cook Inlet EEZ Area. Because NMFS expects the State of Alaska to maintain current requirements for commercial salmon fishing vessels landing any salmon in upper Cook Inlet to hold a CFEC S03H permit, NMFS does not expect participation from non-S03H permit holders in the federally-managed salmon fishery in the Cook Inlet EEZ Area. Therefore, the number of S03H permit holders represents the maximum number of directly regulated entities for the commercial salmon fishery in the Cook Inlet EEZ Area. From 2018 to 2022, there was an average of 567 S03H permits in circulation, with an average of 325 active permit holders, all of which are considered small entities based on the 11 million dollar threshold. The evaluation of the number of directly regulated small entities and their revenue was conducted via custom query by staff of the Alaska Fish Information Network utilizing both ADF&G and Fish Ticket revenue data and the CFEC permits database. Similarly, the Analysis prepared for amendment 16 provides the most recent tabulation of commercial charter vessels that could potentially fish for salmon within the Cook Inlet EEZ Area (see **ADDRESSES**).

The commercial fishing entities directly regulated by the salmon harvest specifications are the entities operating vessels with Salmon Federal fisheries permits (SFFPs) catching salmon in Federal waters. For purposes of this analysis, NMFS assumes that the number of small entities with SFFPs that are directly regulated by the salmon harvest specifications is the average number of S03H permits in circulation (*i.e.*, 567 permits). This may be an overstatement of the number of directly-regulated small entities since some entities may hold more than one permit.

The commercial charter fishing entities directly regulated by the salmon harvest specifications are the entities that hold commercial charter licenses and that choose to fish for salmon in the Cook Inlet EEZ Area where these harvest specifications will apply. Salmon charter operators are required to register with the State of Alaska annually and the numbers of registered charter operators in the Cook Inlet area varies. Available data indicates that, from 2015 to present, the total number of directly regulated charter vessel small

entities that have participated in the Cook Inlet EEZ Area has been as high as 91. However, from 2019 to 2021, there was an average of 58 charter guides that fished for salmon at least once in the Cook Inlet EEZ Area. All of these entities, if they choose to fish in the Cook Inlet EEZ Area, are directly regulated by this action and all are considered small entities based on the 9 million dollar threshold.

This action does not modify recordkeeping or reporting requirements or duplicate, overlap, or conflict with any Federal rules.

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

The action under consideration is the final 2024 harvest specifications for the Cook Inlet EEZ Area salmon fishery. The TAC is set to reduce the risk of overfishing without the benefit of inseason harvest data but remains commensurate with or slightly above the recent 10-year average estimated EEZ harvest.

This action is necessary to establish harvest limits for Cook Inlet salmon harvested within the EEZ during the 2024 fishing years and is taken in accordance with the Salmon FMP pursuant to the Magnuson-Stevens Act. The establishment of the harvest specifications is governed by the process for determining harvest levels for salmon in the Cook Inlet EEZ Area in the FMP. Under this process, harvest specifications typically will be made annually for specifying the OFL, ABC, and TAC. This includes identifying the stocks and stock complexes for which specifications are made. Salmon stocks or stock complexes may be split or combined for purposes of establishing a new harvest specification unit if such action is desirable based on the commercial importance of a stock or stock complex, or if sufficient biological information is available to manage a stock or stock complex as a single unit. Those stocks and stock complexes also will be separated into three tiers based on the level of information available for each stock and stock complex, and the corresponding tier is used to calculating OFL and ABC.

For each stock and stock complex, NMFS will establish harvest specifications prior to the commercial salmon fishing season. To inform the harvest specifications, NMFS will prepare the annual SAFE report, based on the best available scientific information at the time it is prepared, for review by the SSC, AP, and the Council. The SAFE report will provide information needed for: (1) determining

annual harvest specifications; (2) documenting significant trends or changes in the stocks, marine ecosystem, and fisheries over time; and (3) assessing the performance of existing State of Alaska and Federal fishery management programs. The SAFE report will provide a summary of the most recent biological condition of the salmon stocks, including all reference points, and the social and economic condition of the fishing and processing industries.

For the 2024 salmon specifications, NMFS prepared the draft SAFE and consulted with the Council consistent with amendment 16 and the implementing regulations. The final TACs are based on the SAFE report, which represents the best scientific information currently available for the stock and stock complexes identified by NMFS. The SSC reviewed the stock structure and associated tiers for each stock and stock complex. In February 2024, NMFS consulted with the Council, but the Council ultimately did not recommend any harvest specifications. However, the SSC recommended OFLs and ABCs. NMFS is publishing the OFLs, ABCs, and TACs as informed by the recommendations of the SSC and the consultation with the Council. The TACs are therefore consistent with the process for determining harvest levels for salmon in the Cook Inlet EEZ Area under amendment 16 and the supporting Analysis.

The OFLs and ABCs are based on recommendations prepared by NMFS in January 2024 and were reviewed by the Council's SSC in February 2024. The 2024 OFLs and ABCs are based on the best available science and revised analyses to calculate stock abundance. The 2024 OFLs, ABCs, and TACs are consistent with the biological condition of the salmon stocks as described in the 2024 SAFE report, which is the most recent SAFE report.

Under this action, the ABCs reflect harvest amounts that are less than the specified OFLs. The TACs set by NMFS do not exceed the biological limits (*i.e.*, the ABCs and OFLs) recommended by the SSC. The TACs are adjusted to account for other social and economic considerations consistent with Salmon FMP goals for the Cook Inlet EEZ Area and implementing regulations that annual TAC determinations would be made based on social and economic considerations, including the need to promote efficiency in the utilization of fishery resources (*e.g.*, minimizing costs; the desire to conserve, protect, and rebuild depleted salmon stocks; the importance of a salmon fishery to

harvesters, processors, local communities, and other salmon users in Cook Inlet; and the need to promote utilization of certain species) (see 50 CFR 679.118(a)(2)(ii)). The TACs are less than the ABCs to more comprehensively address management uncertainty and associated conservation concerns, as well as social, economic, and ecological considerations.

This action is economically beneficial to entities operating in the Cook Inlet EEZ Area salmon fishery, including small entities. The action adopts TACs for commercially-valuable salmon and salmon stocks and would allow for the prosecution of the salmon fishery in the Cook Inlet EEZ Area, thereby creating the opportunity for fishery revenue. The TACs set by NMFS for each commercially-valuable salmon stock or stock complex, except for aggregate coho, are higher than the recent ten-year average catch estimated to have been harvested in the Cook Inlet EEZ Area, which may help to reduce foregone yield and allow for additional harvest opportunity. For each salmon species for which NMFS establishes harvest specifications, NMFS determined the final TACs will provide harvest opportunities for entities operating in the Cook Inlet EEZ Area, including small entities. These TACs cannot be set higher because the biological condition of each species does not support a higher TAC. For these reasons, there are no alternative TACs that would reduce impacts to small entities.

In sum, based upon the best scientific information available and in consideration of the objectives for this final action, it appears that there are no significant alternatives to this final rule for salmon harvest specifications that have the potential to comply with applicable court rulings, accomplish the stated objectives of the Magnuson-Stevens Act or any other statutes, and minimize any significant adverse economic impact of the action on small entities while preventing overfishing. After public process during which the Council and NMFS solicited input from stakeholders and after consultation with the Council, NMFS sets TACs that NMFS has determined would best accomplish the stated objectives articulated in the preamble for this final rule, and in applicable statutes, and would minimize to the extent practicable adverse economic impacts on the universe of directly regulated small entities.

Pursuant to 5 U.S.C. 553(d)(3), the Assistant Administrator for Fisheries, NOAA, finds good cause to waive the 30-day delay in the date of effectiveness for this rule because delaying this rule

is contrary to the public interest. The Assistant Administrator for Fisheries finds that the need to establish final total allowable catch amounts in the Cook Inlet EEZ Area makes it contrary to the public interest to delay the effective date of the final harvest specifications for 30 days. If the final harvest specifications are not effective by the start of the Cook Inlet EEZ Area salmon fishery as required by 50 CFR 679.118(e), the Cook Inlet EEZ Area salmon fishery will not be able to operate under Federal management as required by court order. Immediate effectiveness of the final 2024 harvest specifications will allow the Federal fishery to start on June 20, 2024, thus preventing confusion between management by the State of Alaska and Federal governments. In addition, immediate effectiveness of this action is required to provide consistent management and conservation of fishery resources based on the best available scientific information, and to give the fishing industry the earliest possible opportunity to plan its fishing operations. These final harvest specifications, as well as the earlier proposed harvest specifications, were developed as quickly as possible. The SSC provided peer review of the SAFE report at the February 2024 Council meeting, the earliest meeting at which that scientific information was available. Relying on SSC advice, NMFS revised the SAFE report and drafted proposed harvest specifications, which it published on April 12, 2024. NMFS then offered a 30-day public comment period on the proposed harvest specifications, which closed on May 13, 2024. After the close of the comment period, NMFS developed the final harvest specifications as quickly as possible, responding to all comments, to ensure the specifications could be implemented by the June 20, 2024 opening date for the Cook Inlet EEZ Area commercial fishery.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides." The table contained in this final rule is provided online and serves as the plain language guide to assist small entities in complying with this final rule as required by the Small Business Regulatory Enforcement Fairness Act of

1996. This final rule's primary purpose is to announce the final 2024 harvest specifications for the salmon fishery of the Cook Inlet EEZ Area. This action is necessary to establish harvest limits and associated management measures for salmon during the 2024 fishing year, and to accomplish the goals and objectives of the Salmon FMP. This action affects all fishermen who participate in the Cook Inlet salmon fishery. The specific OFLs, ABCs, and TACs, are provided in table 1 in this final rule to assist the reader. This final rule also contains plain language summaries of the underlying relevant regulations supporting the harvest

specifications and the harvest of salmon in the Cook Inlet area that the reader may find helpful.

Information to assist small entities in complying with this final rule is provided online. The OFL, ABC, and TAC table is individually available online at <https://www.fisheries.noaa.gov/alaska/commercial-fishing/cook-inlet-salmon-harvest-specifications>. Harvest specification changes are also available from the same online source, which includes applicable **Federal Register** notices, information bulletins, and other supporting materials. NMFS will announce other closures or openings of directed fishing in the **Federal Register**

and information bulletins released by the Alaska Region. Affected fishermen should keep themselves informed of such actions.

Authority: 16 U.S.C. 773 *et seq.*; 16 U.S.C. 1540(f); 16 U.S.C. 1801 *et seq.*; 16 U.S.C. 3631 *et seq.*; Pub. L. 105–277; Pub. L. 106–31; Pub. L. 106–554; Pub. L. 108–199; Pub. L. 108–447; Pub. L. 109–241; Pub. L. 109–479.

Dated: June 12, 2024.

Samuel D. Rauch III,

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

[FR Doc. 2024–13357 Filed 6–17–24; 8:45 am]

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Proposed Rules

Federal Register

Vol. 89, No. 118

Tuesday, June 18, 2024

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

DEPARTMENT OF ENERGY

2 CFR Part 910

[DOE–HQ–2024–0029]

RIN 1991–AC18

Financial Assistance Regulations—Conflict of Interest and Conflict of Commitment Policy Requirements

AGENCY: Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Energy (DOE or Department) is proposing to amend its Financial Assistance Regulations to establish conflict of interest and conflict of commitment policies and requirements for non-federal entities applying for or receiving financial assistance awards from the Department, and to implement and standardize certain disclosure requirements applicable to financial assistance applications and awards, including responsibilities, general rules, and procedures for non-federal entities to identify, evaluate, resolve, and report conflicts of interest, conflicts of commitment, and organizational conflicts of interest, in financial assistance applications and awards.

DATES: Written comments on this proposed rule must be received on or before August 19, 2024.

ADDRESSES: You may submit comments, identified by *Financial Assistance Regulations—Conflict of Interest and Conflict of Commitment Policy Requirements* and *RIN 1991–AC18*, by any of the following methods:

Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

Email to: COIrulemaking@hq.doe.gov: Include Financial Assistance Regulations—Conflict of Interest Policy and RIN 1991–AC18 in the subject line of the message.

Postal mail to: U.S. Department of Energy, Office of Acquisition Management, Contract and Financial Assistance Policy Division, MA–611,

1000 Independence Avenue SW, Washington, DC 20585.

Comments by email are encouraged. No telefacsimiles (“faxes”) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section IV of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, public meeting transcripts, and other supporting documents/materials, is available for review at www.regulations.gov and can be located by the docket number provided in the heading of this document. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

FOR FURTHER INFORMATION CONTACT: Ms. Krystal Paige, U.S. Department of Energy, Office of Acquisition Management, at (240) 404–8294 or by email at Krystal.Page@hq.doe.gov.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Section-by-Section Analysis
- III. Regulatory Review and Procedural Requirements
 - A. Review Under Executive Orders 12866, 13563, and 14094
 - B. Review Under Executive Order 12988
 - C. Review Under the Regulatory Flexibility Act
 - D. Review Under the Paperwork Reduction Act
 - E. Review Under the National Environmental Policy Act
 - F. Review Under Executive Order 13132
 - G. Review Under Executive Order 13175
 - H. Review Under the Unfunded Mandates Reform Act of 1995
 - I. Review Under the Treasury and General Government Appropriations Act, 1999
 - J. Review Under Executive Order 13211
 - K. Review Under the Treasury and General Government Appropriations Act, 2001
- IV. Public Participation
- V. Approval by the Office of the Secretary of Energy

I. Background

The purpose of this proposed rulemaking is to amend the Department’s Financial Assistance Regulations at 2 CFR part 910. Specifically, DOE is proposing to amend part 910 to prescribe responsibilities, requirements, and procedures for non-Federal entities to identify, evaluate,

resolve, and report conflicts of interest, conflicts of commitment, and organizational conflicts of interest in Federal financial assistance applications and awards, as those terms are proposed to be defined in this notice of proposed rulemaking.

The proposed provisions would implement Office of Management and Budget (OMB) guidance to Federal agencies regarding the establishment of conflict of interest (COI) policies for Federal awards by codifying existing DOE policy, consistent with National Security Presidential Memorandum 33 (NSPM–33).¹

DOE is required to establish COI policies for Federal awards pursuant to 2 CFR 200.112, which also specifies that the non-Federal entity must disclose in writing any potential COI to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy.

On December 20, 2021, DOE issued an interim COI policy² that addresses COI and organizational conflicts of interest, which will be incorporated in and made enforceable through the Special Terms and Conditions for DOE financial assistance awards. The interim COI policy establishes standards that provide a reasonable expectation that the design, conduct, and reporting of projects wholly or in part funded under DOE financial assistance awards (e.g., a grant, cooperative agreement, or technology investment agreement) will be free from bias resulting from COI or

¹ NSPM–33 established national security policy for U.S. Government-supported research and development (R&D). The purpose of NSPM–33 is to strengthen protections of U.S. Government-supported R&D against foreign government interference and misappropriation, while maintaining an open environment to foster research discoveries and innovation that benefit the United States and the world. NSPM–33 is available at <https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/>. See also, OMB guidance, *Guidance for Implementing National Security Presidential Memorandum (NPM–33) on National Security Strategy for United States Government-Supported Research and Development*, available at <https://www.whitehouse.gov/wp-content/uploads/2022/01/010422-NSPM-33-Implementation-Guidance.pdf>.

² Financial Assistance Letter No. 2022–02, *Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance*. Available at <https://www.energy.gov/sites/default/files/2021-12/Interim%20COI%20Policy%20FAL2022-02%20to%20SPEs.pdf>.

conflict of commitment (COC).³ To minimize the implementation burden on non-Federal entities, the interim COI policy is largely aligned with the long-standing COI regulations established by the Public Health Service at 42 CFR part 50, subpart F, which are applicable to research and development entities that include R&D funded by Public Health Service grants or cooperative agreements. The interim COI policy currently remains in effect.

The disclosure requirements proposed in this notice of proposed rulemaking would be established in proposed subpart C to 2 CFR part 910 (Subpart C). If made final, this proposed rule would apply to Federal financial assistance applications and awards, including applications and awards regarding research, development, demonstration, and deployment.

The proposed requirements regarding COI, COC, and organizational conflicts of interest (OCI)⁴ would generally apply to non-Federal entities applying and receiving financial assistance awards from DOE as described in 2 CFR 910.122. DOE is proposing that Subpart C not be applicable to applicants to or recipients of financial assistance under the programs of the DOE Office of Indian Energy, given that office's statutory mission to maximize the development and deployment of energy solutions for the benefit of American Indians and Alaska Natives; the unique sovereign status of Tribes; the practical limitations such regulations would present Tribes serving their communities, which in certain instances are small and remote; and consideration of traditional Tribal practices. DOE also proposes that the applicable DOE program office may tailor as appropriate the COI, COC, and OCI provisions for individuals applying for or receiving a DOE financial assistance award.

DOE requests comment on the scope of the proposed regulations. DOE notes on April 22, 2024, the Office of Management and Budget (OMB) published a final rule that revises sections of the OMB Guidance for Grants and Agreements, and is effective beginning October 1, 2024. 89 FR 30046.

³ In general, as proposed COC means a situation in which an individual accepts or incurs conflicting obligations, whether foreign or domestic, between or among multiple employers or other entities and may include conflicting commitments of time and effort, including obligations to dedicate time in excess of institutional or DOE policies or commitments.

⁴ An OCI means that because of relationships with a parent company, affiliate, or subsidiary organization, a non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization. 2 CFR 200.318(c)(2).

DOE will consider conforming changes to the regulations proposed in this notice of proposed rulemaking based on the finalized OMB guidance once effective, as appropriate.

II. Section-by-Section Analysis

DOE proposes amending Chapter 9 of Title 2 of the Code of Federal Regulations to add subpart C. Proposed subpart C provides the general requirement for applicants for and recipients of federal financial assistance from DOE to maintain a COI and a COC policy; definitions relevant to the COI and COC policy requirements; and for the disclosure of certain COI, COC, and OCI, by applicants and recipients. New subpart C would consist of §§ 910.200 through 910.270 and appendix A as set forth below:

§ 910.200

Proposed § 910.200 would establish definitions applicable to the proposed new subpart C. DOE is proposing to define *conflict of commitment (COC)*, *conflict of interest (COI)*, *covered individual*, *financial interest*, *other support*, *principal investigator (PI)*, *project*, and *significant financial interest*.

§ 910.210

Proposed § 910.210 would establish the applicability of the COI and COC policy and reporting requirements proposed in new subpart C. In general, DOE is proposing the requirements would be applicable to non-Federal entities that are applicants to or recipients of a DOE Federal financial assistance award.

§ 910.220

Reserved.

§ 910.230

Proposed § 910.230 would require non-Federal entities that are applicants to or recipients of DOE Federal financial assistance to establish and maintain COI and COC policies. DOE further proposes in § 910.230 the criteria that such policies would be required to meet and requirements regarding subrecipients.

§ 910.240

Proposed § 910.240 would establish reporting requirements regarding identified COI and COC, mitigation measures relevant to a COI or COC, and requirements to update reporting.

§ 910.250

Consistent with 2 CFR 200.318, proposed § 910.250 would establish requirements regarding non-Federal entities with a parent, affiliate, or

subsidiary organization that is not a state government, local government, or Indian tribe, the non-Federal entity must maintain written standards of conduct covering organizational conflicts of interest (OCI) as that term is defined in 2 CFR 200.318(c)(2). DOE notes that in the context of the Federal Acquisition Regulations, the head of an agency or their designee may waive the organizational conflicts of interest requirement by determining that its application in a particular situation would not be in the Government's interest. 48 CFR 9.503. Comment is requested on whether a similar provision should be applicable to the financial assistance requirements.

§ 910.260

Proposed § 910.260 would establish reporting requirements relevant to any potential or actual OCI to DOE. Proposed § 910.260 would establish the timing and content requires of such reports.

§ 910.270

Proposed § 910.270 would specify actions DOE may take if a non-Federal entity fails to disclose a COI or COC or fails to sufficiently manage or mitigate such a conflict. Proposed § 910.270 would also specify the remedies for failure to disclose an OCI.

Appendix A

Proposed appendix A would provide the certification statement that would be required for compliance with the requirements in proposed subpart C to 2 CFR part 910.

III. Regulatory Review and Procedural Requirements

A. Review Under Executive Orders 12866, 13563, and 14094

Executive Order (E.O.) 12866, "Regulatory Planning and Review," as supplemented and reaffirmed by E.O. 13563, "Improving Regulation and Regulatory Review," and amended by E.O. 14094, "Modernizing Regulatory Review," 88 FR 21879 (April 11, 2023) requires agencies, to the extent permitted by law to: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including

potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fee or profit or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. DOE has initially determined that this notice of proposed rulemaking (NPR) is consistent with these principles, including the requirement that, to the extent permitted by law, agencies adopt a regulation only upon a reasoned determination that its benefits justify its costs and, in choosing among alternative regulatory approaches, those approaches maximize net benefits.

Section 6(a) of E.O. 12866 also requires agencies to submit “significant regulatory actions” to the Office of Information and Regulatory Affairs (OIRA) for review. OIRA has determined that this proposed regulatory action does not constitute a “significant regulatory action” under section 3(f) of E.O. 12866. Accordingly, this action was not submitted to OIRA for review under E.O. 12866.

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, “Civil Justice Reform,” (61 FR 4729, February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction.

With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the

regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the United States Attorney General.

Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or if it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

C. Review Under the Regulatory Flexibility Act

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

DOE has reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE certifies that the proposed rule, if adopted, would not have significant economic impact on a substantial number of small entities. The factual basis for this certification is set forth below.

The proposed rule would be applicable to non-federal entities that are applicants to or recipients of financial assistance awards from the Department. Non-Federal entities, including small entities, are currently subject to the Department’s interim policies implementing the conflicts provisions at 2 CFR 200.112 and the requirements regarding OCI at 2 CFR

200.318(c). If made final, this rule would codify the existing policies applicable to financial assistance awards from the Department. Additionally, as proposed, the applicable DOE program office may tailor as appropriate the COI, COC, and OCI provisions for individuals that are applicants to or recipients of a DOE financial assistance award.

Accordingly, DOE certifies that this rule would not have a significant economic impact on a substantial number of small entities, and, therefore, no regulatory flexibility analysis is required. DOE will transmit a certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

D. Review Under the Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR 1320, Appendix A.1) (PRA), DOE reviewed this proposed rule and determined that there are no new collections of information contained therein. DOE’s procurement reporting and recordkeeping burdens have been approved under OMB Control No. 1910–4100.

E. Review Under the National Environmental Policy Act

DOE has preliminarily determined that promulgation of this proposed rule falls into a class of actions that would not individually or cumulatively have a significant impact on the human environment, as determined by DOE’s regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) (NEPA). Specifically, DOE has preliminarily determined that this proposed rule is covered under the categorical exclusion found in DOE’s NEPA regulations at paragraph A6 of appendix A to subpart D, 10 CFR part 1021. Categorical exclusion A6 applies to rulemakings that are strictly procedural. Additionally, DOE has preliminarily determined that this proposed rule is covered under the Categorical Exclusion found in DOE’s NEPA regulations at paragraph A5 of appendix A to subpart D, 10 CFR part 1021, which applies to a rulemaking that amends an existing rule or regulation and that does not change the environmental effect of the rule or regulation being amended. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

F. Review Under Executive Order 13132

Executive Order 13132, “Federalism” (64 FR 43255, August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. The Executive order requires agencies to have an accountability process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.

On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations (65 FR 13735). DOE has examined the proposed rule and has determined that it does not preempt State law and 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. No further action is required by Executive Order 13132.

G. Review Under Executive Order 13175

Under Executive Order 13175 (65 FR 67249, November 6, 2000) on “Consultation and Coordination with Indian Tribal Governments,” DOE may not issue a discretionary rule that has “Tribal” implications and imposes substantial direct compliance costs on Indian Tribal governments. DOE has determined that the final rule would not have such effects and concludes that Executive Order 13175 does not apply to this proposed rulemaking.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national

economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a “significant intergovernmental mandate,” and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE’s policy statement is also available at https://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf. This proposed rule does not contain a Federal intergovernmental mandate, nor is it expected to require expenditures of \$100 million or more in any one year by the private sector. As a result, the analytical requirements of UMRA do not apply.

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

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Public Law 105–277), requires Federal agencies to issue a Family Policymaking Assessment for any rulemaking or policy that may affect family well-being. This proposed rulemaking will have no impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 13211

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

should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution and use. This proposed rule is not a significant energy action. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects.

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

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB’s guidelines were published at 67 FR 8452 (February 22, 2002), and DOE’s guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

VI. Public Participation

DOE will accept comments regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this document. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via www.regulations.gov. The www.regulations.gov web page will require you to provide your name and contact information. Your contact information will be viewable to DOE staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment.

Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (“CBI”). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail.

Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments. Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No faxes will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters’ names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked “confidential” including all the information believed to be confidential, and one copy of the document marked “non-confidential” with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE’s policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

V. Approval by the Office of the Secretary of Energy

The Secretary of Energy has approved publication of this notice of proposed rulemaking.

List of Subjects in 2 CFR Part 910

Accounting, Administrative practice and procedure, Grant programs, Reporting and recordkeeping requirements.

Signing Authority

This document of the Department of Energy was signed on May 30, 2024, by Berta Schreiber, Director, Office of Acquisition Management and Senior Procurement Executive and William J. Quigley, Deputy Associate Administrator for Office of Partnership and Acquisition Services and Senior Procurement Executive, National Nuclear Security Administration, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE/NSA. 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 June 13, 2024.

Treena V. Garrett,

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

For reasons set out in the preamble, DOE proposes to amend chapter 9 of Title 2 of the Code of Federal Regulations as set forth below:

PART 910—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS

■ 1. The authority citation for part 910 continues to read as follows:

Authority: 42 U.S.C. 7101, *et seq.*; 31 U.S.C. 6301–6308; 50 U.S.C. 2401 *et seq.*; 2 CFR part 200.

■ 2. Add subpart C to part 910 to read as follows:

Subpart C—Conflicts of Interest, Conflicts of Commitment, Organizational Conflicts of Interest, and Other Matters of Concern

Sec.

- 910.200 Definitions.
 - 910.210 Applicability.
 - 910.220 Reserved.
 - 910.230 Required conflict of interest (COI) and conflict of commitment (COC) policies.
 - 910.240 Reporting conflicts of interest (COI) and conflicts of commitment (COC).
 - 910.250 Organizational conflicts.
 - 910.260 Reporting organizational conflicts of interest (OCI).
 - 910.270 Remedies, penalties, and enforcement.
- Appendix A to Subpart C of Part 910—Disclosure Certification Statement

§ 910.200 Definitions.

For the purposes of this subpart, the following definitions are applicable:

Conflict of commitment (COC) means a situation in which an individual accepts or incurs conflicting obligations, whether foreign or domestic, between or among multiple employers or other entities. This may include conflicting commitments of time and effort, including obligations to dedicate time in excess of institutional or DOE policies or commitments. Other types of conflicting obligations, including but not limited to, obligations to improperly share information with, or to withhold information from, an employer or DOE, can also threaten research, technology or economic security and integrity. Examples of situations that may give rise to conflicts of commitment include, but are not limited to, current or

pending employment; positions, appointments, or affiliations such as titled academic, professional, or institutional appointments, whether remuneration is received and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary positions); and participation in or applications to foreign government-sponsored talent recruitment or similar programs.

Conflict of interest (COI) means a situation in which a covered individual or the spouse or a child of the covered individual has a significant financial interest or financial relationship, whether with a domestic or foreign entity, that could directly and significantly affect the design, conduct, reporting or funding of a project or other Federal financial assistance award-related activities. Examples of situations that may give rise to a COI include, but are not limited to, holding an executive position, director position, or equity over a certain dollar amount in a company that stands to benefit from Federal financial assistance award-related activities, receiving financial compensation in the form of consulting payments or payment for services from a company that stands to benefit from Federal financial assistance award-related activities, or intellectual property rights or royalties from such rights whose value may be affected by the outcome of Federal financial assistance award-related activities.

Covered individual means any individual, regardless of title or position, who:

(1) Contributes in a substantive, meaningful way to the development or execution (e.g., purpose, design, conduct, or reporting) of a project funded by DOE or proposed for funding by DOE; and,

(2) Is designated as a covered individual by DOE. DOE designates as covered individuals any principal investigator (PI), project director (PD), co-principal investigator (Co-PI), co-project director (Co-PD), or project manager; and any individual (including an individual at the masters or baccalaureate level) that contributes in a substantive, meaningful way to the development or execution of a subject project that is listed by the non-Federal entity in the application for Federal financial assistance, approved budget, progress report, or any other report submitted to DOE by the non-Federal entity regarding the subject project.

This list of designated covered individuals may be expanded if specified in the applicable funding opportunity announcement and/or terms and conditions of the Federal

financial assistance award, to include individuals on the project team as covered individuals, including up to any person who *participates* in the purpose, design, conduct, or reporting of a project funded by DOE or proposed for funding by DOE, including, for example, collaborators, consultants, graduate (master's or Ph.D.) students, and postdoctoral associates.

DOE means the U.S. Department of Energy and the National Nuclear Security Administration (NNSA).

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Other support means all resources made available to a covered individual in support of and/or related to all of their professional research (including basic and fundamental research), development, demonstration, and/or deployment efforts, including resources provided directly to the covered individual rather than through the research organization, and regardless of whether or not they have monetary value (e.g., even if the support received is only in-kind, such as office/laboratory space, equipment, supplies, or employees). This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts provided with terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers and visiting scholars supported by other sources of funding.

Principal investigator (PI) means an individual identified to direct a project by an applicant to or recipient of a DOE Federal financial assistance award.

Project means the interdependent activities funded wholly or in part under the DOE Federal financial assistance award. A project has a defined start and end point with objectives described in an application or in an approved scope that, when attained, signify completion and achievement of a specific goal, and creation of a unique product, service, or result. For Federal financial assistance awards that include recipient cost share as part of the approved budget, activities funded with that recipient cost share are included.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the covered individual (and those of the covered individual's spouse and dependent children) that reasonably appears to be related to the covered individual's non-Federal entity responsibilities:

(i) With regard to any foreign or domestic publicly traded entity, a

significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any foreign or domestic non-publicly traded entity, a significant financial interest exists if the value of any remuneration, not otherwise disclosed as current, pending, or other support, received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the covered individual (or the covered individual's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the covered individual and not reimbursed to the covered individual so that the exact monetary value may not be readily available) related to their institutional responsibilities that is not otherwise disclosed in current and pending or other support disclosures, but does not include travel that is reimbursed or sponsored by a Federal, state, or local government agency of the United States; a domestic Institution of Higher Education; or a domestic research institute that is affiliated with a domestic Institution of Higher Education.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the non-Federal entity to the covered individual if the covered individual is currently employed or otherwise appointed by the non-Federal entity, including intellectual property rights assigned to the non-Federal entity and agreements to share in royalties related to such rights; any ownership interest in the non-Federal entity held by the covered individual, if the non-Federal entity is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the

covered individual does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education; or income from service on advisory committees or review panels for a Federal, state, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education.

§ 910.210 Applicability.

(a) This subpart applies to any non-Federal entity that is an applicant to or recipient of a DOE Federal financial assistance award on or after *[Date 30 days after date of publication of final rule]*, including any covered individual who plans to participate in or is participating in the project funded wholly or in part under the DOE Federal financial assistance award, and each non-Federal entity subrecipient under the Federal financial assistance award, subject to the following exceptions:

(1) This subpart does not apply to DOE Office of Indian Energy applications and Federal financial assistance awards.

(2) For an individual that is an applicant to or recipient of a DOE Federal financial assistance award the requirements of this subpart may be tailored to the extent determined appropriate by the applicable DOE program office.

(b) [Reserved].

§ 910.220 Reserved.

§ 910.230 Required conflict of interest (COI) and conflict of commitment (COC) policies.

(a) Any non-Federal entity that is an applicant to or recipient of a DOE Federal financial assistance award must maintain a written and enforced policy addressing actual, apparent, and potential COI and COC, both foreign and domestic. The non-Federal entity must make its written policy available within five business days following any request for the policy.

(b) The policy required under paragraph (a) of this section must:

(1) Designate a non-Federal entity official(s) to solicit and review COI and COC disclosures from each covered individual who is planning to participate in, or is participating in, the project funded under a DOE Federal financial assistance award;

(2) Require review by the designated official(s) of all covered individuals' disclosures to determine whether an actual, apparent, or potential COI or COC exists; and, if so, require the designated official(s) determine the actions that have been and shall be taken to eliminate or, where appropriate, manage or reduce the conflict. Examples of conditions or restrictions that a recipient or subrecipient might impose to manage, reduce, or eliminate a conflict include, but are not limited to:

(i) Public disclosure of the conflict (*e.g.*, when presenting or publishing the project);

(ii) For projects involving human subjects, disclosure of the conflict directly to participants;

(iii) Appointment of an independent monitor or oversight committee capable of taking measures to protect the purpose, design, conduct, and reporting of the project against bias resulting from the conflict;

(iv) Modification of the project plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the project;

(vi) Reduction or elimination of the financial interest (*e.g.*, sale of an equity interest) or commitment; or

(vii) Severance of relationship(s) that create the conflict.

(3) Ensure that covered individuals have provided all required disclosures to the non-Federal entity no later than the time an application is submitted to DOE. In the event a non-Federal entity seeks to add a covered individual after the time of application, the non-Federal entity must require the covered individual make such disclosures prior to participating in a project funded under a DOE Federal financial assistance award.

(4) Require each covered individual who is participating in the DOE Federal financial assistance award update those disclosures on an annual basis and as soon as any new actual, apparent, or potential COI or COC arises.

(5) Require each disclosure be signed and dated by the covered individual and include the certification statement in appendix A of this subpart;

(6) Require each covered individual to complete COI and COC training prior to engaging in projects funded under a DOE Federal financial assistance award and complete refresher training least every two years. The training must cover the non-Federal entity's COI and COC policy and the covered individual's responsibilities regarding disclosures. The non-Federal entity must require covered individual to

complete COI and COC training within 30 days of any of the following circumstances:

(i) The non-Federal entity revises its COI and COC policies or procedures in any manner that affects the responsibilities of a covered individual;

(ii) A covered individual is new to a non-Federal entity; or

(iii) A non-Federal entity finds that a covered individual is not in compliance with the non-Federal entity's COI and COC policy or applicable management plan.

(7) With regard to reimbursed or sponsored travel, the non-Federal entity's COI and COC policy must require, at a minimum, reporting the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the non-Federal entity's policy, the non-Federal entity official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a COI or COC with the project funded under the DOE Federal financial assistance award; and

(8) Include adequate enforcement mechanisms and provide for sanctions where appropriate.

(c) Any non-Federal entity that receives a DOE Federal financial assistance award must ensure that subrecipients, if any, follow the requirements of this subpart by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish either the COI and COC policy of the recipient or that of the subrecipient will apply to the subrecipient's covered individuals.

(2) If the subrecipient's covered individuals must comply with the subrecipient's COI and COC policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient's covered individuals are subject to the COI and COC policy of the recipient;

(3) Additionally, if the subrecipient's covered individuals must comply with the subrecipient's COI and COC policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial COI and COC to the recipient. Such time period(s) shall be sufficient to enable the recipient to provide timely COI/COC reports, as necessary, to DOE, as required by this subpart;

(4) Alternatively, if the subrecipient's covered individuals must comply with the recipient's COI and COC policy, the

agreement referenced above shall specify time period(s) for the subrecipient to submit all covered individual's disclosures to the recipient. Such time period(s) shall be sufficient to enable the recipient to comply timely with its review, management, and reporting obligations under this subpart.

§ 910.240 Reporting conflicts of interest (COI) and conflicts of commitment (COC).

(a) Consistent with title 2 of the Code of Federal Regulation (CFR) 200.112, *Conflict of interest*, a non-Federal entity that is an applicant to or recipient of DOE financial assistance must disclose to DOE in writing any actual, apparent, or potential COI or COC, including any actual, apparent, or potential COI or COC reported to the recipient by a subrecipient, if such conflict cannot be eliminated or appropriately managed or reduced in accordance with the entity's policy. In addition, such entity must disclose to DOE in writing any actual, apparent, or potential COI or COC, including any actual, apparent, or potential COI or COC reported to the recipient by a subrecipient, involving any foreign governments, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign government, as well as any measures the entity has taken to eliminate or, where appropriate, manage or reduce the COI or COC.

(1) For all conflicts that require disclosure to DOE:

(i) A non-Federal entity applying for DOE funding must clearly and explicitly disclose such conflict(s) in the application.

(ii) In the event a non-Federal entity seeks to add a covered individual after the time of application, the non-Federal entity must clearly and explicitly disclose such conflict(s) in writing to DOE prior to the individual participating in the project.

(2) If specified in the applicable funding opportunity announcement and/or terms and conditions of the Federal financial assistance award, a DOE program office may require the non-Federal entity disclose to DOE in writing all covered individuals' COIs and COCs, including those COIs and COCs determined by the non-Federal entity to be appropriately managed or reduced.

(b) DOE may require the non-Federal entity to provide associated disclosures, supporting documentation to demonstrate how the COI or COC was managed or reduced; and sufficient information to enable DOE to understand the nature and extent of the COI or COC, and to assess whether the actions are sufficient to ensure the

integrity of the DOE-supported project and to protect the government's interests.

(c) For any COI or COC previously reported by the non-Federal entity regarding an ongoing project funded under a DOE Federal financial assistance award, the non-Federal entity must provide DOE with an annual COI/COC report that addresses the status of the COI or COC and, if applicable, any changes to the management plan for the duration of the DOE Federal financial assistance award. The annual COI/COC report must specify whether the conflict is still being managed or if it remains unmanaged/unmanageable.

Alternatively, the annual COI/COC report must explain why the conflict no longer exists. The non-Federal entity must provide annual COI/COC reports to DOE for the duration of the project period (including extensions with or without funds) in the time and manner required by term and condition of the Federal financial assistance award.

(d) In addition to the annual COI/COC report, DOE may require a non-Federal entity to routinely, or upon request, submit all or some covered individuals' disclosures. Circumstances when DOE may require a non-Federal entity to submit all or some of such covered individual disclosures include but are not limited to:

(1) As part of monitoring the non-Federal entity's compliance with this subpart;

(2) Bankruptcy of the non-Federal entity;

(3) Other legal winding down of the non-Federal entity;

(4) Acquisition of the non-Federal entity by a foreign entity, where "acquisition" includes a foreign entity obtaining a controlling interest in the non-Federal entity; or

(5) As otherwise set forth in 2 CFR part 200 and this part.

(e) If a non-Federal entity becomes aware that a covered individual failed to comply with the non-Federal entity's COI and COC policy or a management plan, the non-Federal entity must promptly notify DOE in writing of the failure to comply and of the corrective action taken or to be taken. DOE will evaluate the situation and, as necessary, take appropriate action, which may include referring the matter to the non-Federal entity for further corrective action consistent with non-Federal entity's established COI and COC policies, DOE directing the non-Federal entity to take specific mitigation measures, or termination of the Federal financial assistance award.

§ 910.250 Organizational conflicts.

(a) Consistent with title 2 of the Code of Federal Regulation (CFR) 200.318, if a non-Federal entity has a parent, affiliate, or subsidiary organization that is not a state government, local government, or Indian tribe, the non-Federal entity must maintain written standards of conduct covering organizational conflicts of interest (OCI) as that term is defined in 2 CFR 200.318(c)(2).

(b) If the effects of a potential or actual OCI cannot be avoided, eliminated, or mitigated, the procurement or other transaction anticipated by the non-Federal entity must not be made using DOE or cost share funds.

§ 910.260 Reporting organizational conflicts of interest (OCI).

(a) The non-Federal entity must disclose in writing any potential or actual OCI to DOE within five business days of learning of the conflict.

(1) The non-Federal entity must provide the disclosure to DOE in an application for financial assistance and prior to engaging in a procurement or transaction using DOE funds with a parent, affiliate, or subsidiary organization that is not a state government, local government, or Indian tribe.

(2) The disclosure must include, at a minimum, the following:

(i) The name, address, and website (as applicable) of the entity that presents a potential or actual OCI;

(ii) The relationship between the non-Federal entity and the entity at issue;

(iii) The nature of the anticipated procurement or other transaction with the parent, affiliate, or subsidiary organization; the anticipated value of the procurement or other transaction; and the basis for making the procurement or other transaction with the parent, affiliate, or subsidiary organization;

(vi) The basis for the non-Federal entity's determination regarding the existence of an OCI; and

(v) How the non-Federal entity will avoid, eliminate, or mitigate the OCI.

§ 920.270 Remedies, penalties, and enforcement.

(a)(1) If a non-Federal entity fails to disclose a conflict of interest (COI) or conflict of commitment (COC) as required under this subpart, or fails to sufficiently manage or mitigate a COI or COC to ensure the integrity of the DOE-supported project or to protect the government's interests, DOE may:

(i) Require the non-Federal entity take action to eliminate or mitigate the

conflict to a risk level acceptable to DOE. In the event the non-Federal entity does not eliminate or mitigate the conflict to a risk level acceptable to DOE, DOE may determine the Federal financial assistance award no longer effectuates the program goals or agency priorities and terminate the Federal financial assistance award;

- (ii) Determine the circumstances disqualify an entity or individual from participating in all or a portion of a Federal financial assistance award; or
- (iii) Reject an application.

(2) DOE may inquire, at any time before, during, or after a Federal financial assistance award, into any covered individual's disclosures and the non-Federal entity's review (including any retrospective review) of and response to such disclosure, regardless of whether the disclosure resulted in the non-Federal entity's determination of a COI or COC. A non-Federal entity is required to submit or permit on-site review of all records pertinent to compliance with this subpart. To the extent permitted by law, DOE will maintain the confidentiality of all records of financial interests. Based on its review of records or other information that may be available, DOE may determine that a particular COI or COC will bias the objectivity of or adversely impact the project funded under the DOE Federal financial assistance award to such an extent that further corrective action is needed or that the non-Federal entity has not managed the COI or COC in accordance with this subpart. DOE may determine that the imposition of specific award conditions under 2 CFR 200.208 is necessary. DOE may also take one or more the actions specified under 2 CFR 200.339, as appropriate in such circumstances.

(b) If a non-Federal entity fails to disclose an OCI to DOE prior to engaging in a procurement or transaction using DOE funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, the costs of such procurement or transaction may be disallowed. If a non-Federal entity fails to disclose an OCI to DOE that is not avoided, eliminated, or mitigated or fails to avoid, eliminate, or mitigate a disclosed OCI, prior to engaging in a procurement or transaction using DOE funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, DOE may determine that imposition of specific award conditions under 2 CFR 200.208 is necessary. DOE may also take one or more actions specified under 2

CFR 200.339, as appropriate in the circumstances.

(c) Any false, fictitious, or fraudulent information, or the omission of any material fact, on a disclosure, report, or other record required under this subpart may be subject to criminal, civil, or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Sections 287 and 1001; and Title 31, 3729–3733 and 3801–3812).

(d) If fraud, misrepresentation, or related misconduct is suspected in relation to any disclosure submitted to DOE, then the cognizant contracting officer and/or program official should coordinate with appropriate counsel and thereafter, as appropriate, refer the matter to the DOE Office of Inspector General (OIG).

(e) If a covered individual knowingly fails to disclose required information, DOE may take one or more of the following enforcement or other actions:

- (1) Reject an application;
- (2) Suspend or terminate a Federal financial assistance award;
- (3) Temporarily or permanently discontinue or de-obligate any or all funding for the covered individual or non-Federal entity;
- (4) Refer recipients for consideration of suspension or debarment proceedings;
- (5) Refer the failure to disclose to the DOE OIG for further investigation or to Federal law enforcement authorities to determine whether any criminal or civil laws were violated;
- (6) Report the entity in the Federal Awardee Performance and Integrity Information System (FAPIIS) to alert other Federal agencies to the noncompliance;
- (7) Take one or more of the actions described in 2 CFR 200.339, Remedies for noncompliance; or
- (8) Take such other actions against the covered individual or non-Federal entity as authorized under applicable law or regulations.

Appendix A to Subpart C of Part 910—Disclosure Certification Statement

All disclosures required under this subpart must include the following certification statement:

“I understand that this Disclosure is required to obtain funding from the U.S. Government. I, [Full Name and Title], certify to the best of my knowledge and belief that the information contained in this Disclosure Statement is true, complete, and accurate. I understand that any false, fictitious, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims, or otherwise. (18

U.S.C. 287, 1001, and 1031, and 31 U.S.C. 3729–3733 and 3801–3812). I further understand and agree that:

(1) The statements and representations made herein are material to the U.S. Government's funding decision, and

(2) I have a responsibility to update the disclosures during the period of performance of the Federal financial assistance award should circumstances change which impact the responses provided above.”

[FR Doc. 2024–13392 Filed 6–17–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1686; Project Identifier MCAI–2023–00595–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, and SA330J helicopters. This proposed AD was prompted by the installation of unapproved main gearbox (MGB) forward and rear suspension bar attachment plates. This proposed AD would require inspecting or measuring the MGB forward and rear suspension bar attachment plates and, depending on the results, taking corrective action, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 2, 2024.

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 [regulations.gov](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.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2024–1686; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet easa.europa.eu. You may find the EASA material on the EASA website at ad.easa.europa.eu.

- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. The EASA material is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2024–1686.

Other Related Material: For Airbus Helicopters material, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at airbus.com/en/products-services/helicopters/hcare-services/airbusworld.

FOR FURTHER INFORMATION CONTACT: Hye Yoon Jang, Aviation Safety Engineer, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (817) 222–5584; email hye.yoon.jang@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA–2024–1686; Project Identifier MCAI–2023–00595–R” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Hye Yoon Jang, Aviation Safety Engineer, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (817) 222–5584; email hye.yoon.jang@faa.gov. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued a series of ADs, the most recent being EASA AD 2023–0076, dated April 11, 2023 (EASA AD 2023–0076), to correct an unsafe condition on Airbus Helicopters Model SA 330 J, AS 332 C, AS 332 C1, AS 332 L, and AS 332 L1 helicopters.

This proposed AD was prompted by the installation of unapproved MGB forward and left-hand (LH) and right-hand (RH) rear suspension bar attachment plates. The FAA is proposing this AD to ensure installation of approved parts. The unsafe condition, if not addressed, could result in damage to the MGB suspension bar attachment plates and surrounding fuselage structure, and subsequent failure of load carrying structural elements. See EASA AD 2023–0076 for additional background information.

Related Material Under 1 CFR Part 51

EASA AD 2023–0076 requires measuring the thickness of the MGB forward suspension bar attachment plate and inspecting the LH and RH MGB rear suspension bar attachment plates. Depending on the results, EASA AD 2023–0076 requires contacting AH [Airbus Helicopters] for approved corrective action instructions and accomplishing those instructions accordingly.

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

Other Related Material

The FAA reviewed Airbus Helicopters Alert Service Bulletin (ASB) No. AS332–53.02.15, Revision 0, dated March 6, 2023, and ASB No. SA330–53.56, Revision 0, dated April 3, 2023. This material specifies procedures for measuring the thickness of the MGB front suspension bar attachment plate and visually checking the LH and RH MGB rear suspension bar attachment plate versions. Depending on the results, this material specifies procedures for contacting Airbus Helicopter to get an approved repair.

FAA’s Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other helicopters of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2023–0076, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under “Differences Between this Proposed AD and the EASA AD.”

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2023–0076 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0076 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same

as the heading of a particular section in EASA AD 2023–0076 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2023–0076. Material referenced in EASA AD 2023–0076 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–1686 after the FAA final rule is published.

Differences Between This Proposed AD and the EASA AD

If, during the inspection or measurement, any discrepancy is detected, EASA AD 2023–0076 specifies contacting AH [Airbus Helicopters] to obtain approved corrective action instructions and accomplishing those instructions, and the material referenced in EASA AD 2023–0076 specifies contacting Airbus Helicopters to get an approved repair, whereas this proposed AD would require accomplishing the corrective action before further flight in accordance with a method approved by the FAA, EASA, or Airbus Helicopters’ EASA Design Organization Approval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 38 helicopters of U.S. Registry. Labor rates are estimated at \$85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Measuring the thickness of the MGB forward suspension bar attachment plate and inspecting the LH and RH MGB rear suspension bar attachment plates would take approximately 2 work-hours for an estimated cost of \$170 per helicopter and \$6,460 for the U.S. fleet.

The corrective action that may be needed as a result of the inspection or measurement could vary significantly from helicopter to helicopter. The FAA has no data to determine the costs to accomplish the corrective action or the number of helicopters that may require corrective action.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2024–1686; Project Identifier MCAI–2023–00595–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by August 2, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, and SA330J helicopters, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 5311, Fuselage Main, Frame.

(e) Unsafe Condition

This AD was prompted by the installation of unapproved main gearbox (MGB) forward and left-hand and right-hand rear suspension bar attachment plates. The FAA is issuing this AD to ensure installation of approved parts. The unsafe condition, if not addressed, could result in damage to the MGB suspension bar attachment plates and surrounding fuselage structure, and subsequent failure of load carrying structural elements.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with European Union Aviation Safety Agency (EASA) AD 2023–0076, dated April 11, 2023 (EASA AD 2023–0076).

(h) Exceptions to EASA AD 2023–0076

(1) Where EASA AD 2023–0076 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2023–0076 refers to its effective date and March 21, 2023 (the effective date of EASA AD 2023–0049, dated March 7, 2023), this AD requires using the effective date of this AD.

(3) Where paragraph (2) of EASA AD 2023–0076 specifies contacting AH [Airbus Helicopters] for approved corrective action instructions and within the compliance time indicated therein, accomplishing those instructions accordingly and, where the material referenced in paragraph (2) of EASA AD 2023–0076 specifies contacting Airbus Helicopters to get an approved repair, this AD requires, before further flight, corrective action done in accordance with a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus Helicopters’ EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) This AD does not adopt the “Remarks” section of EASA AD 2023–0049.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2023–0076 specifies to submit certain information to the manufacturer, this AD does not require that action.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Additional Information

For more information about this AD, contact Hye Yoon Jang, Aviation Safety Engineer, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (817) 222-5584; email hye.yoon.jang@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023-0076, dated April 11, 2023.

(ii) [Reserved]

(3) For EASA material, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet easa.europa.eu. You may find this EASA material on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on June 11, 2024.

James D. Foltz,

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

[FR Doc. 2024-13222 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2024-1685; Project Identifier MCAI-2024-00076-T]

RIN 2120-AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2023-04-06 and AD 2024-04-07, which apply to certain Airbus SAS Model A318, A319, A320 and A321 series airplanes. AD 2023-04-06 and AD 2024-04-07 require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2023-04-06 and AD 2024-04-07, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require certain actions in AD 2023-04-06 and AD 2024-04-07 and would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 2, 2024.

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 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.

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA-2024-1685; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except

Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; website easa.europa.eu. You may find this material on the EASA website ad.easa.europa.eu.

- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. It is also available at regulations.gov under Docket No. FAA-2024-1685.

FOR FURTHER INFORMATION CONTACT:

Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206-231-3367; email timothy.p.dowling@faa.gov.

SUPPLEMENTARY INFORMATION:**Comments Invited**

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA-2024-1685; Project Identifier MCAI-2024-00076-T” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial

information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206-231-3367; email timothy.p.dowling@faa.gov. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2023-04-06, Amendment 39-22353 (88 FR 13665, March 6, 2023) (AD 2023-04-06), for Airbus SAS Model A318-111, -112, -121, and -122 airplanes; Model A319-111, -112, -113, -114, -115, -131, -132, -133, -151N, -153N, and -171N airplanes; Model A320-211, -212, -214, -216, -231, -232, -233, -251N, -252N, -253N, -271N, -272N, and -273N airplanes; and Model A321-111, -112, -131, -211, -212, -213, -231, -232, -251N, -252N, -253N, -271N, -272N, -251NX, -252NX, -253NX, -271NX, and -272NX airplanes. AD 2023-04-06 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2022-0091, dated May 20, 2022 (EASA AD 2022-0091) (which corresponds to FAA AD 2023-04-06), to correct an unsafe condition. AD 2023-04-06 requires revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations. The FAA issued AD 2023-04-06 to address a safety-significant latent failure (that is not annunciated), which, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition.

The FAA issued AD 2024-04-07, Amendment 39-22686 (89 FR 19234, March 18, 2024) (AD 2024-04-07), for Airbus SAS Model A318-111, -112, -121, and -122 airplanes; Model A319-111, -112, -113, -114, -115, -131, -132, -133, -151N, -153N, and -171N airplanes; Model A320-211, -212, -214, -216, -231, -232, -233, -251N, -252N, -253N, -271N, -272N, and -273N airplanes; and Model A321-111, -112, -131, -211, -212, -213, -231, -232,

-251N, -252N, -253N, -271N, -272N, -251NX, -252NX, -253NX, -271NX, and -272NX airplanes. AD 2024-04-07 was prompted by EASA AD 2023-0138, dated July 13, 2023 (EASA AD 2023-0138) (which corresponds to FAA AD 2024-04-07), to correct an unsafe condition. AD 2024-04-07 requires revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations. The FAA issued AD 2024-04-07 to address a safety-significant latent failure (that is not annunciated), which, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition.

Actions Since AD 2023-04-06 and AD 2024-04-07 Were Issued

Since the FAA issued AD 2023-04-06 and AD 2024-04-07, EASA superseded EASA AD 2022-0091 and EASA AD 2023-0138 and issued EASA AD 2024-0030, dated January 31, 2024 (EASA AD 2024-0030) (referred to after this as the MCAI), for all Airbus A318-111, -112, -121, and -122; A319-111, -112, -113, -114, -115, -131, -132, -133, -151N, -153N, and -171N; A320-211, -212, -214, -215, -216, -231, -232, -233, -251N, -252N, -253N, -271N, -272N, and -273N; and A321-111, -112, -131, -211, -212, -213, -231, -232, -251N, -251NX, -252N, -252NX, -253N, -253NX, -271N, -271NX, -272N, and -272NX airplanes. Model A320-215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability. The MCAI states that new or more restrictive airworthiness limitations have been developed.

Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after December 15, 2023, must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

The FAA is proposing this AD to address a safety-significant latent failure (that is not annunciated), which, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition. You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2024-1685.

Related Service Information Under 14 CFR Part 51

The FAA reviewed EASA AD 2024-0030. This service information specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD would also require EASA AD 2023-0138, dated July 13, 2023, which the Director of the Federal Register approved for incorporation by reference as of April 22, 2024 (89 FR 19234, March 18, 2024).

This proposed AD would also require EASA AD 2022-0091, dated May 20, 2022, which the Director of the Federal Register approved for incorporation by reference as of April 10, 2023 (88 FR 13665, March 6, 2023).

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

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain all requirements of AD 2023-04-06 and AD 2024-04-07. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2024-0030 already described, as proposed for incorporation by reference. Any differences with EASA AD 2024-0030 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (e.g., inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator

must request approval for an alternative method of compliance (AMOC) according to paragraph (p)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to retain the IBR of EASA AD 2022–0091 and EASA AD 2023–0138 and incorporate EASA AD 2024–0030 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0091, EASA AD 2023–0138 and EASA AD 2024–0030 through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0030, EASA AD 2023–0138, or EASA AD 2022–0091 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2024–0030, EASA AD 2023–0138, or EASA AD 2022–0091. Service information required by EASA AD 2024–0030, EASA AD 2023–0138 and EASA AD 2022–0091 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2024–1685 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators

must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.*, inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under “Additional AD Provisions.” This new format includes a “New Provisions for Alternative Actions and Intervals” paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 1,898 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2023–04–06 and AD 2024–04–07 to be \$7,650 (90 work-hours × \$85 per work-hour) per AD.

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new proposed actions to be \$7,650 (90 work-hours × \$85 per work-hour).

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing airworthiness directive (AD) 2023–04–06, Amendment 39–22353 (88 FR 13665, March 6, 2023); and AD 2024–04–07, Amendment 39–22686 (89 FR 19234, March 18, 2024); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2024–1685; Project Identifier MCAI–2024–00076–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by August 2, 2024.

(b) Affected ADs

This AD replaces AD 2023–04–06, Amendment 39–22353 (88 FR 13665, March 6, 2023) (AD 2023–04–06); and AD 2024–04–07, Amendment 39–22686 (89 FR 19234, March 18, 2024) (AD 2024–04–07).

(c) Applicability

This AD applies to the Airbus SAS airplanes specified in paragraphs (c)(1) through (4) of this AD, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before December 15, 2023.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address a safety significant latent failure (that is not annunciated), which, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With AD 2024–04–07, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2024–04–07, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before May 12, 2023. Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with EASA AD 2023–0138, dated July 13, 2023 (EASA AD 2023–0138). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (m) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to 2024–04–07, With No Changes

This paragraph restates the exceptions specified in paragraph (h) of AD 2024–04–07, with no changes.

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2023–0138.

(2) Paragraph (3) of EASA AD 2023–0138 specifies revising “the approved AMP” within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after April 22, 2024 (the effective date of AD 2024–04–07).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA

2023–0138 is at the applicable “associated thresholds” as incorporated by the requirements of paragraph (3) of EASA AD 2023–0138, or within 90 days after April 22, 2024 (the effective date of AD 2024–04–07), whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) of EASA AD 2023–0138.

(5) This AD does not adopt the “Remarks” section of EASA AD 2023–0138.

(i) Retained Restrictions on Alternative Actions and Intervals, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2024–04–07, with no changes. Except as required by paragraph (m) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (e.g., inspections) and intervals are allowed unless they are approved as specified in the provisions of the “Ref. Publications” section of EASA AD 2023–0138.

(j) Retained Revision of the Existing Maintenance or Inspection Program, With AD 2023–04–06, With No Changes

This paragraph restates the requirements of paragraph (o) of AD 2023–04–06, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before February 18, 2022. Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with EASA AD 2022–0091, dated May 20, 2022 (EASA AD 2022–0091). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (m) of this AD terminates the requirements of this paragraph.

(k) Retained Exceptions to AD 2023–04–06, With No Changes

This paragraph restates the exceptions specified in paragraph (p) of AD 2023–04–06, with no changes.

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2022–0091 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2022–0091 specifies revising “the approved AMP” within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after April 10, 2023 (the effective date of AD 2023–04–06).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0091 is at the applicable “associated thresholds” as incorporated by the requirements of paragraph (3) of EASA AD 2022–0091, or within 90 days after April 10, 2023 (the effective date of AD 2023–04–06), whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2022–0091 do not apply to this AD.

(5) This AD does not adopt the “Remarks” section of EASA AD 2022–0091.

(l) Retained Restrictions on Alternative Actions and Intervals, With No Changes

This paragraph restates the requirements of paragraph (q) of AD 2023–04–06, with no changes. Except as required by paragraph (m) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (e.g., inspections) and intervals are allowed unless they are approved as specified in the provisions of the “Ref. Publications” section of EASA AD 2022–0091.

(m) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (n) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0030, dated January 31, 2024 (EASA AD 2024–0030). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraphs (g) and (j) of this AD.

(n) Exceptions to EASA AD 2024–0030

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0030.

(2) Paragraph (3) of EASA AD 2024–0030 specifies revising “the approved AMP,” within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0030 is at the applicable “associated thresholds” as incorporated by the requirements of paragraph (3) of EASA AD 2024–0030, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2024–0030.

(5) This AD does not adopt the “Remarks” section of EASA AD 2024–0030.

(o) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (m) of this AD, no alternative actions (e.g., inspections) and intervals are allowed unless they are approved as specified in the provisions of the “Ref. Publications” section of EASA AD 2024–0030.

(p) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation

Branch, mail it to the address identified in paragraph (q) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(q) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206-231-3367; email timothy.p.dowling@faa.gov.

(r) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) European Union Aviation Safety Agency (EASA) AD 2024-0030, dated January 31, 2024.

(ii) [Reserved]

(4) The following service information was approved for IBR on April 22, 2024 (89 FR 19234, March 18, 2024).

(i) EASA AD 2023-0138, dated July 13, 2023.

(ii) [Reserved]

(5) The following service information was approved for IBR on April 10, 2023 (88 FR 13665, March 6, 2023).

(i) EASA AD 2022-0091, dated May 20, 2022.

(ii) [Reserved]

(6) For EASA AD 2024-0030, EASA AD 2023-0138, and EASA AD 2022-0091, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; website easa.europa.eu. You may find these EASA ADs on the EASA website ad.easa.europa.eu.

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

(8) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations, or email fr.inspection@nara.gov.

Issued on June 11, 2024.

Suzanne Masterson,

Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2024-13150 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-13-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1218

[CPSC Docket No. CPSC-2010-0028]

Safety Standard for Bassinets and Cradles; Notice of Comment Period Extension

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On April 16, 2024, the Consumer Product Safety Commission (CPSC) published in the **Federal Register** a notice of proposed rulemaking (NPR) to amend the existing regulation for bassinets and cradles, to ensure that the rule addresses identified hazards and that these sleep products for young infants provide the highest level of safety feasible. The NPR invited the public to submit written comments during a 60-day comment period, beginning on the NPR publication date, and ending on June 17, 2024. In response to a request for a 90-day extension of the comment period, the Commission is extending the comment period for this NPR by 45 days.

DATES: Submit comments by August 1, 2024.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the NPR should be directed to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or emailed to: oira_submission@omb.eop.gov.

Submit all other comments, identified by Docket No. CPSC-2010-0028, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by email, except through www.regulations.gov. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/Hand Delivery/Courier/

Confidential Written Submissions:

Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504-7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to <https://www.regulations.gov>. Do not submit through this website: Confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/ confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, and insert the docket number, CPSC-2010-0028, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT:

Celestine T. Kish, Project Manager, Division of Human Factors, Directorate for Engineering Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; 301-987-2547; ckish@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Pursuant to section 104(b)(1) of the Consumer Product Safety Improvement Act of 2008 (CPSIA; 15 U.S.C. 2056a(b)(1)), the Commission promulgated the current mandatory standard for bassinets and cradles (bassinets/cradles) in October 2013. 78 FR 63019 (Oct. 23, 2013); *see Safety Standard for Bassinets and Cradles*, codified at 16 CFR part 1218 (part 1218). Part 1218 incorporates by reference the 2013 version of the bassinets/cradles voluntary standard, ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles* (ASTM F2194-13), with modifications to make the standard more stringent, to

further reduce the risk of injury associated with bassinets/cribbs.¹

Section 104(b)(2) of the CPSIA requires that after the Commission issues mandatory safety standards for durable infant or toddler products, the Commission shall periodically review and revise the standards to ensure that such standards provide the highest level of safety for such products that is feasible. 15 U.S.C. 2056a(b)(2). Accordingly, on April 16, 2024, the Commission published an NPR in the **Federal Register** proposing to amend part 1218 to address the hazards identified in the NPR and to ensure that the mandatory bassinet/cribble regulation provides the highest level of safety feasible.² 89 FR 27246. The proposed modifications to part 1218 would remove a product category—compact bassinets—and address five identified hazard patterns associated with young infants. The NPR proposed to incorporate by reference ASTM F2194–22^{e1}, with modifications to further reduce the risk of injury associated with bassinets, and to provide the highest level of safety that is feasible for such products. 89 FR 27246, 27247. The 60-day comment period closes on June 17, 2024.³

B. Request for Comment Period Extension

On May 22, 2024, Lisa Trofe, Executive Director of the Juvenile

¹ After issuing the mandatory standard in 2013, ASTM International (ASTM) published several revisions to ASTM F2194, including ASTM F2194–2013a, –2016, and –2016^{e1}. ASTM did not notify CPSC of these revisions, so the mandatory rule has not been updated since 2013. However, ASTM F2194–2016^{e1} is substantially the same as the existing mandatory rule for bassinets/cribbles codified in part 1218. 86 FR 33022, 33034–35 (June 3, 2021).

² On March 20, 2024, the Commission voted (4–0) to publish the NPR, available at: <https://www.cpsc.gov/s3fs-public/Commission-Meeting-Minutes-NPR-Safety-Standard-for-Bassinets-and-Cribbles.pdf?VersionId=GwpmKZ4S9sRrEiBmDFaEWn1jBre6eZ2r>.

³ Staff provided a February 28, 2024, Memorandum, Staff's Draft Proposed Rule to Revise the Safety Standard for Bassinets and Cribbles in support of the NPR, which is available at: <https://www.cpsc.gov/s3fs-public/Briefing-Package-Draft-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Bassinets-and-Cribbles.pdf?VersionId=l37iJVSjn32WnUTBDV27L6c37uJC4lis>. The NPR contains an overview of staff's assessment and analysis, and the Commission's basis for issuing the NPR, which is based on the 2022 Bassinet Rejection Staff Briefing Package. Based on the information and analysis in the NPR and related staff packages, the Commission preliminarily determined that the proposed requirements are more stringent than the requirements in ASTM F2194–22^{e1}, would further reduce the risk of injury associated with products within the scope of the NPR, and would provide the highest level of safety that is feasible for such products. The Commission specifically sought comment on the feasibility of each proposed requirement, including technical feasibility.

Products Manufacturers Association (JPMA), on behalf of JPMA's members and ten companies that individually co-signed the request, submitted a request for a 90-day extension of the NPR comment period (JPMA request).^{4,5} The JPMA request asserts that the 60-day comment period is insufficient, providing three primary reasons for additional time to provide comments: (1) prototyping and evaluating new product designs to “understand if the proposed requirements are feasible, and what new hazards, if any, such designs could create”; (2) testing to evaluate the proposed side-to-side “zero-degree tilt angle, plus or minus one degree,” including the proper equipment needed for repeatable measurements and considering the tilt angle requirement which they allege “does not consider the stacked tolerances of building construction and laboratory floors or consumer floors” and how this may impact the test results; and (3) evaluating the availability of equipment needed to test the proposed side wall rigidity requirement.

C. Assessment of the JPMA Request

The testing equipment identified in the NPR is the same equipment currently identified in the ASTM standard and CPSC's regulation,^{6,7} and therefore, stakeholders do not require additional time to test and evaluate equipment. Moreover, based on CPSC staff's experience testing sample bassinets/cribbles to the NPR proposals, testing should not require more than 10

⁴ JPMA's request has been placed on the docket for this rulemaking, as well as attached as to Staff's June 5, 2024, Briefing Memorandum: Proposed Rule to Amend the Safety Standard for Bassinets and Cribbles; Request to Extend Comment Period (Staff Briefing Memo), available at: https://www.cpsc.gov/s3fs-public/NPR-Safety-Standard-for-Bassinets-and-Cribbles-Draft-Federal-Notice-Regarding-Extension-of-Comment-Period.pdf?VersionId=dBX_tnUc3LSd5vG6_S0UbuLliqi4wPkx.

⁵ On June 11, 2024, the Commission voted (4–1) to publish this notice. Commissioner Feldman issued a statement with his vote, available at: <https://www.cpsc.gov/s3fs-public/RCA-NPR-Safety-Standard-for-Bassinets-and-Cribbles-Draft-Federal-Notice-Regarding-Extension-of-Comment-Period.pdf?VersionId=SbjP34yYPSuhrXa6p1TG9s9bVhkjVWg>.

⁶ ASTM F2194–22^{e1} specifies in section 4.6 that angle measurements shall be taken using a digital inclinometer with a 0.1° minimum resolution for angle measurements. However, section 7.8 specifies the use of a digital inclinometer with a 0.5° minimum resolution. Users of the standard should use the more precise instrumentation to ensure they are following all applicable sections of the standard.

⁷ It is common and a known test setup for lab floors to be 0 +/- 0.5 degrees. This is already addressed in ASTM F2194–22^{e1}, see section 7.10 Rock/Swing Angle Tests. Additionally, the test requires to ZERO out the inclinometer on that test surface (floor) before starting the test to minimize any influence of the floor on the bassinet angle measurements.

business days to test up to 15 product samples; an *additional* 90 days, totaling 5 months (60 days plus 90 days), is unnecessary to assess products to the NPR requirements and provide feedback. However, we agree with JPMA that prototype design, evaluation, and testing to the zero-degree side-to-side tilt angle, plus or minus one degree, and other proposed requirements may require additional time. Assessing how to modify products to feasibly meet the proposed modifications, identifying any new potential hazards, and providing comments on these assessments may benefit from more than the 60 days provided in the NPR. Providing additional time in the comment period will allow manufacturers to produce prototypes that are closer to the final design specifications and that will more accurately reflect what a manufacturer finds to be achievable.

D. Conclusion

The Commission has considered the JPMA request to extend the comment period and staff's assessment of the request. Currently, the comment period is due to close on June 17, 2024. To provide sufficient time for stakeholders to prototype and evaluate new designs, and to assess and provide comment on the NPR proposals, especially as it relates to specific products, the Commission will grant a 45-day extension of the comment period, until August 1, 2024.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024–13330 Filed 6–17–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–124593–23]

RIN 1545–BR07

Certain Partnership Related-Party Basis Adjustment Transactions as Transactions of Interest

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and public hearing.

SUMMARY: This document contains proposed regulations that would identify certain partnership related-party basis adjustment transactions and substantially similar transactions as transactions of interest, a type of

reportable transaction. Material advisors and certain participants in these transactions would be required to file disclosures with the IRS and would be subject to penalties for failure to disclose. The proposed regulations would affect participants in these transactions as well as material advisors. This document also provides a notice of a public hearing on the proposed regulations.

DATES:

Comments due: Written or electronic comments must be received by August 19, 2024.

Public hearing: A public hearing on this proposed regulation has been scheduled for Tuesday, September 17, 2024, at 10 a.m. ET. Requests to speak and outlines of topics to be discussed at the public hearing must be received by August 19, 2024. If no outlines are received by August 19, 2024, the public hearing will be cancelled. Requests to attend the public hearing must be received by 5 p.m. ET on September 13, 2024. The public hearing will be made accessible to people with disabilities. Requests for special assistance during the public hearing must be received by 5 p.m. ET on September 12, 2024.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at <https://www.regulations.gov> (indicate IRS and REG-124593-23) by following the online instructions for submitting comments. Requests for a public hearing must be submitted as prescribed in the "Comments and Requests for a Public Hearing" section. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to the IRS's public docket. Send paper submissions to: CC:PA:01:PR (REG-124593-23), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, Elizabeth Zanet of the Office of Associate Chief Counsel (Passthroughs and Special Industries), (202) 317-6007; concerning the submission of comments or the hearing, Vivian Hayes at (202) 6901 (not toll-free numbers) or by email at publichearings@irs.gov (preferred).

SUPPLEMENTARY INFORMATION:**Background**

This document contains proposed additions to the Income Tax Regulations (26 CFR part 1) under section 6011 of

the Internal Revenue Code (Code). The proposed additions would add § 1.6011-18 to identify certain partnership related-party basis adjustment transactions as transactions of interest for purposes of section 6011 (proposed regulations).

I. Disclosure of Reportable Transactions by Participants and Penalties for Failure To Disclose

Section 6011(a) generally provides that, if required by regulations prescribed by the Secretary of the Treasury or her delegate (Secretary), any person made liable for any tax imposed by the Code, or with respect to the collection thereof, must make a return or statement according to the forms and regulations prescribed by the Secretary. Every person required to make a return or statement must include therein the information required by such forms or regulations.

Section 1.6011-4(a) provides that every taxpayer that has participated in a reportable transaction within the meaning of § 1.6011-4(b) and who is required to file a tax return must file a disclosure statement within the time prescribed in § 1.6011-4(e). Reportable transactions are identified in § 1.6011-4 and include listed transactions, confidential transactions, transactions with contractual protection, loss transactions, and transactions of interest. See § 1.6011-4(b)(2) through (6). Section 1.6011-4(b)(6) defines a "transaction of interest" as a transaction that is the same as or substantially similar to one of the types of transactions that the IRS has identified by notice, regulation, or other form of published guidance as a transaction of interest.

Section 1.6011-4(c)(4) provides that a transaction is "substantially similar" if it is expected to obtain the same or similar types of tax consequences and is either factually similar or based on the same or similar tax strategy. Receipt of an opinion regarding the tax consequences of the transaction is not relevant to the determination of whether the transaction is the same as or substantially similar to another transaction. Further, the term substantially similar must be broadly construed in favor of disclosure. For example, a transaction may be substantially similar to a transaction of interest even though it may involve different entities or use different Code provisions.

Section 1.6011-4(c)(3)(i)(E) provides that a taxpayer has participated in a transaction of interest if the taxpayer is one of the types or classes of persons identified as participants in the

transaction in the published guidance describing the transaction of interest.

Section 1.6011-4(d) and (e) provide that the disclosure statement, *Form 8886, Reportable Transaction Disclosure Statement* (or successor form), must be attached to the taxpayer's tax return for each taxable year in which a taxpayer participates in a reportable transaction. A copy of the disclosure statement must be sent to the IRS's Office of Tax Shelter Analysis (OTSA) at the same time that any disclosure statement is first filed by the taxpayer pertaining to a particular reportable transaction.

Section 1.6011-4(e)(2)(i) provides that if a transaction becomes a transaction of interest after the filing of a taxpayer's tax return (including an amended return) reflecting the taxpayer's participation in the transaction of interest and before the end of the period of limitations for assessment for any taxable year in which the taxpayer participated in the transaction of interest, then a disclosure statement must be filed with OTSA within 90 calendar days after the date on which the transaction becomes a transaction of interest. This requirement extends to an amended return and exists regardless of whether the taxpayer participated in the transaction in the year the transaction became a transaction of interest. The Commissioner of Internal Revenue (Commissioner) may also determine the time for disclosure of transactions of interest in the published guidance identifying the transaction.

Participants required to disclose these transactions under § 1.6011-4 who fail to do so are subject to penalties under section 6707A of the Code. Section 6707A(b) provides that the amount of the penalty is 75 percent of the decrease in tax shown on the return as a result of the reportable transaction (or which would have resulted from such transaction if such transaction were respected for Federal tax purposes), subject to minimum and maximum penalty amounts. The minimum penalty amount is \$5,000 in the case of a natural person and \$10,000 in any other case. For a transaction of interest, the maximum penalty amount is \$10,000 in the case of a natural person and \$50,000 in any other case.

Additional penalties may also apply. In general, section 6662A of the Code imposes a 20 percent accuracy-related penalty on any understatement (as defined in section 6662A(b)(1)) attributable to an adequately disclosed reportable transaction. If the taxpayer had a requirement to disclose participation in the reportable transaction but did not adequately disclose the transaction in accordance

with the regulations under section 6011, the taxpayer is subject to an increased penalty rate equal to 30 percent of the understatement. See section 6662A(c). Section 6662A(b)(2) provides that section 6662A applies to any item which is attributable to any listed transaction and any reportable transaction (other than a listed transaction) if a significant purpose of such transaction is the avoidance or evasion of Federal income tax.

II. Disclosure of Reportable Transactions by Material Advisors and Penalties for Failure To Disclose

Section 6111(a) provides that each material advisor with respect to any reportable transaction must make a return setting forth: (1) information identifying and describing the transaction, (2) information describing any potential tax benefits expected to result from the transaction, and (3) such other information as the Secretary may prescribe. Such return must be filed not later than the date specified by the Secretary.

Section 301.6111-3(a) of the Procedure and Administration Regulations (26 CFR part 301) provides that each material advisor with respect to any reportable transaction, as defined in § 1.6011-4(b), must file a return as described in § 301.6111-3(d) by the date described in § 301.6111-3(e).

Section 301.6111-3(b)(1) provides that a person is a material advisor with respect to a transaction if the person provides any material aid, assistance, or advice with respect to organizing, managing, promoting, selling, implementing, insuring, or carrying out any reportable transaction, and directly or indirectly derives gross income in excess of the threshold amount as defined in § 301.6111-3(b)(3) for the material aid, assistance, or advice. Under § 301.6111-3(b)(2)(i) and (ii), a person provides material aid, assistance, or advice if the person provides a tax statement, which is any statement (including another person's statement), oral or written, that relates to a tax aspect of a transaction that causes the transaction to be a reportable transaction as defined in § 1.6011-4(b)(2) through (7).

Material advisors must disclose transactions on Form 8918, *Material Advisor Disclosure Statement* (or successor form), as provided in § 301.6111-3(d) and (e). Section 301.6111-3(e) provides that the material advisor's disclosure statement for a reportable transaction must be filed with the OTSA by the last day of the month that follows the end of the calendar quarter in which the advisor

becomes a material advisor with respect to a reportable transaction or in which the circumstances necessitating an amended disclosure statement occur. A person may become a material advisor with respect to a transaction that is later identified as a transaction of interest. See § 301.6111-3(b)(4). The disclosure statement must be sent to the OTSA at the address provided in the instructions for Form 8918 (or successor form).

Section 301.6111-3(d)(2) provides that the IRS will issue to a material advisor a reportable transaction number with respect to the disclosed reportable transaction. Receipt of a reportable transaction number does not indicate that the disclosure statement is complete, nor does it indicate that the transaction has been reviewed, examined, or approved by the IRS. Material advisors must provide the reportable transaction number to all taxpayers for whom the material advisor acts as a material advisor as defined in § 301.6111-3(b). The reportable transaction number must be provided at the time the transaction is entered into, or if the transaction is entered into prior to the material advisor receiving the reportable transaction number, within 60 calendar days from the date the reportable transaction number is mailed to the material advisor.

Section 6707(a) of the Code provides that a material advisor who fails to file a timely disclosure, or files an incomplete or false disclosure statement, is subject to a penalty. Pursuant to section 6707(b)(1), the penalty for reportable transactions other than listed transactions, including transactions of interest, is \$50,000.

Additionally, section 6112(a) of the Code provides that each material advisor with respect to any reportable transaction, whether or not required to file a return under section 6111 with respect to such transaction, must maintain a list (1) identifying each person with respect to whom such advisor acted as a material advisor with respect to such transaction and (2) containing such other information as the Secretary may by regulations require. Material advisors must furnish such lists to the IRS in accordance with § 301.6112-1(e).

A material advisor may be subject to a penalty under section 6708 of the Code for failing to maintain a list under section 6112(a) and failing to make the list available upon written request to the Secretary in accordance with section 6112(b) within 20 business days after the date of request. Section 6708(a) provides that the penalty is \$10,000 per day for each day of the failure after the 20th day. However, no penalty will be

imposed with respect to the failure on any day if such failure is due to reasonable cause.

III. Basis Adjustments Under Subchapter K

A. In General

Under subchapter K of chapter 1 of the Code (subchapter K), a distribution by a partnership of the partnership's property (partnership property) or a transfer of an interest in a partnership (partnership interest) may result in an adjustment to the basis of the distributed property, partnership property, or both.

A distribution of partnership property may result in an adjustment to the basis of the distributed property under section 732(a), (b), or (d) of the Code. In the case of a distribution of partnership property to a partner by a partnership with an election under section 754 of the Code (section 754 election) in effect, or with respect to which there is a substantial basis reduction as described in section 734(d) of the Code, the distribution may also result in an adjustment to the basis of the partnership's remaining property (remaining partnership property) under section 734(b).

If a partnership interest is transferred by sale or exchange or on the death of a partner, and the partnership either has a section 754 election in effect or has a substantial built-in loss with respect to the transfer of the partnership interest as described in section 743(d) of the Code, the transfer may result in an adjustment to the basis of partnership property under section 743(b) with respect to the transferee partner.

Section 754 provides that if a partnership makes an election in accordance with regulations prescribed by the Secretary, the basis of partnership property shall be adjusted, in the case of a distribution of property, in the manner provided by section 734, and in the case of a transfer of a partnership interest, in the manner provided in section 743. Unless the election is revoked in accordance with the regulations under section 754, the section 754 election applies with respect to all distributions of property by the partnership and to all transfers of interests in the partnership during the taxable year with respect to which the election was filed and all subsequent taxable years.

B. Basis Adjustments Under Section 732

Section 732 governs a distributee partner's basis in distributed property other than money. In the case of a current distribution, and except as

provided under section 732(a)(1) and (2) provides that the distributee partner's basis in distributed property (other than money) is equal to the partnership's adjusted basis in the distributed property immediately before the distribution. Under section 732(a)(2), however, a distributee partner's basis in distributed property is limited to the adjusted basis of the distributee partner's partnership interest reduced by any money distributed to such partner in the same transaction.

In the case of a liquidating distribution, section 732(b) provides that the distributee partner's basis in distributed property (other than money) is equal to the adjusted basis of the distributee partner's partnership interest reduced by any money distributed to such partner in the same transaction.

In the case of a distribution of more than one property from a partnership, the basis of the distributed properties to which section 732(a)(2) and (b) apply must be allocated among the distributed properties under the rules of section 732(c) and the regulations thereunder.

C. Basis Adjustments Under Section 734

In the case of a distribution of property by a partnership with a section 754 election in effect, and for which either the distributee partner recognizes gain or loss on the distribution, or for which the basis of the distributed property in the distributee partner's hands, as determined under section 732, differs from the partnership's adjusted basis in the distributed property immediately before the distribution, section 734(b) requires the partnership to increase or decrease (as applicable) the basis of its remaining partnership property. Also, in the case of a distribution of property by a partnership that results in a substantial basis reduction under section 734(d), the basis of remaining partnership property must be adjusted under section 734(b), even if the partnership does not have a section 754 election in effect.

Section 734(b)(1) requires a partnership to increase the basis of its remaining partnership property if a distribution of partnership property by the partnership results in the distributee partner recognizing gain under section 731(a)(1) of the Code, or if property (other than money) to which section 732(a)(2) or (b) applies is distributed to the distributee partner and the property's adjusted basis to the partnership immediately before the distribution is greater than the distributee partner's basis in the distributed property as determined under section 732. Section 731(a)(1) requires a distributee partner to

recognize gain in a current or liquidating distribution to the extent that any money distributed to that partner in the distribution exceeds the adjusted basis of that partner's partnership interest immediately before the distribution. The amount of the basis increase to the partnership's remaining property under section 734(b)(1) following a distribution of partnership property to a partner is equal to the amount of gain recognized by the distributee partner in the distribution under section 731(a)(1) and the excess of the partnership's adjusted basis in the distributed property immediately before the distribution over the distributee partner's basis in the distributed property as determined under section 732.

Section 734(b)(2) requires a partnership to decrease the basis of its remaining property if a distribution of property by the partnership results in the distributee partner recognizing loss under section 731(a)(2), or if property (other than money) is distributed to the distributee partner in a distribution to which section 732(b) applies and the property's adjusted basis to the partnership immediately before the distribution is less than the distributee partner's basis in the distributed property as determined under section 732. Under section 731(a)(2), a distributee partner may recognize a loss in a liquidating distribution of that partner's interest in the partnership to the extent that such partner received only money, unrealized receivables described in section 751(c), or inventory items described in section 751(d) of the Code in the distribution. In such a case, the distributee partner is required to recognize a loss to the extent that such partner's adjusted basis in the partnership interest exceeds the sum of any money distributed to that partner in the distribution and the basis to the distributee partner (determined under section 732) of any unrealized receivables or inventory received by that partner in the distribution. The amount of the basis decrease to the partnership's remaining property under section 734(b)(2) following a distribution of partnership property to a partner is equal to the amount of loss recognized by the distributee partner in the distribution under section 731(a)(2) and the excess of the distributee partner's basis in the distributed property as determined under section 732 over the partnership's adjusted basis in the distributed property immediately before the distribution.

A partnership without a section 754 election in effect is subject to a mandatory basis adjustment under

section 734(b)(2) if there is a substantial basis reduction with respect to a distribution of partnership property. Under section 734(d), a substantial basis reduction with respect to a distribution of partnership property occurs if the sum of the amount of loss recognized to the distributee partner on the distribution, plus any increase in basis in the distributed property to the distributee partner under section 732(b), exceeds \$250,000.

D. Basis Adjustments Under Section 743(b)

Generally, if a partnership interest is transferred in a sale or exchange or on the death of a partner, the transferee partner's basis in the transferred partnership interest is determined under section 742 of the Code and the basis of partnership property is determined under section 743(a). Section 742 provides that the transferee partner's basis in a partnership interest acquired other than by contribution is determined under part II of subchapter O of chapter 1 of the Code, beginning at section 1011 of the Code and following. Thus, for example, a transferee partner's basis in a partnership interest acquired by purchase generally is cost basis under section 1012 of the Code. Section 743(a) provides that, in the case of a transfer of a partnership interest by sale or exchange or on the death of a partner, the basis of partnership property is not adjusted unless either the partnership has a section 754 election in effect or the partnership has a substantial built-in loss with respect to the transfer of the partnership interest.

Under section 743(b), in the case of a transfer of a partnership interest by sale or exchange or on the death of a partner, a partnership with a section 754 election in effect or that has a substantial built-in loss with respect to the transfer of the partnership interest must increase or decrease (as applicable) the adjusted basis of partnership property with respect to the transferee partner.

Section 743(b)(1) provides that the adjusted basis of partnership property is increased by the excess of the transferee partner's basis in the transferred partnership interest over the transferee partner's proportionate share of the adjusted basis of partnership property.

Section 743(b)(2) provides that the adjusted basis of partnership property is decreased by the excess of the transferee partner's proportionate share of the adjusted basis of partnership property over the transferee partner's basis in the transferred partnership interest.

A partnership without a section 754 election is subject to a mandatory basis

adjustment under section 743(b) with respect to a transfer of a partnership interest if the partnership has a substantial built-in loss with respect to the transfer of the partnership interest. Under section 743(d)(1), a partnership has a substantial built-in loss with respect to a transfer of an interest in the partnership if either the partnership's adjusted basis in its property exceeds the fair market value of such property by more than \$250,000, or the transferee partner would be allocated a loss of more than \$250,000 if the partnership assets were sold for cash equal to their fair market value immediately after the transfer.

Under regulations prescribed by the Secretary, a basis adjustment under section 743(b) is an adjustment to the basis of partnership property with respect to the transferee partner only. The transferee partner's proportionate share of the partnership's adjusted basis in its property generally is determined in accordance with the transferee partner's interest in the partnership's previously taxed capital (including the transferee partner's share of partnership liabilities) under regulations prescribed by the Secretary.

In the case of a transferee partner who acquired all or part of its partnership interest by a transfer to which no section 754 election was in effect, and to whom a distribution of property (other than money) is made with respect to the transferred interest within two years, section 732(d) and the regulations thereunder allow the partner to make an election to treat as the adjusted basis of the distributed property the adjusted basis such property would have if the adjustment under section 743(b) were in effect with respect to the partnership property.

Under § 1.732-1(d)(4), the special basis adjustment under section 732(d) is required to apply to a distribution of property to a partner who acquired all or part of its interest by a transfer from a partnership without a section 754 election in effect for the taxable year of such transfer, whether or not the distribution is made within two years of such transfer, if at the time the partnership interest was transferred, (i) the fair market value of all partnership property (other than money) exceeded 110 percent of its adjusted basis to the partnership, (ii) an allocation of basis under section 732(c) upon a liquidation of the transferee partner's interest in the partnership immediately after the transfer of such interest would have resulted in a shift of basis from property not subject to an allowance for depreciation, depletion, or amortization to property subject to such an

allowance, and (iii) a basis adjustment under section 743(b) would change the basis to the transferee partner of the property actually distributed.

E. Allocation of Basis Adjustments Under Sections 734 and 743

Section 734(c) states that a basis adjustment under section 734(b) is allocated among partnership properties under the rules of section 755 of the Code. Section 743(c) states that a basis adjustment under section 743(b) is allocated among partnership properties under the rules of section 755.

Section 755(a) generally requires basis adjustments under section 734(b) or section 743(b) to be allocated in a manner that has the effect of reducing the difference between the fair market value and the adjusted basis of partnership properties or in any other manner permitted by regulations. In addition, section 755(b) requires these basis adjustments to be allocated to partnership property of a like character or to subsequently acquired partnership property of a like character if such property is not available or has insufficient basis at the time of the basis adjustment (because a decrease in the adjusted basis of the property would reduce the basis of such property below zero). Section 755(c) provides a special rule that prohibits allocating a basis decrease under section 734(b) to the stock of a corporation that is a partner of the partnership (or to any related partner in the partnership within the meaning of section 267(b) of the Code or section 707(b)(1) of the Code).

F. Common Terminology for Bases With Respect to a Partnership Interest

A partner's adjusted basis in its partnership interest commonly is referred to as the partner's "outside basis" in its partnership interest. A partnership's adjusted basis in its property commonly is referred to as the "inside basis" of the partnership's property. Each partner has a share of inside basis. For ease of explanation, this terminology is used in part IV of this Background section.

IV. Partnership Related-Party Basis Adjustment Transactions

A. Overview

The Treasury Department and the IRS are aware of related persons using partnerships to engage in transactions that inappropriately exploit the basis adjustment provisions of subchapter K applicable to distributions of partnership property or transfers of partnership interests discussed in part III of this Background section. This

awareness results from the IRS's review of various partnership transactions involving related parties in which basis adjustments were created to artificially generate or regenerate Federal income tax benefits that resulted in significant tax savings without a corresponding economic outlay. These transactions were carefully structured to exploit the mechanical basis adjustment provisions of subchapter K to produce significant tax benefits with little or no economic impact on the related parties, and in a manner that would not be a likely arrangement between partners negotiating at arm's-length.

Four variations of the transactions are referred to in this preamble as "Partnership Related-Party Basis Adjustment Transactions." The manner in which the transactions exploit the basis adjustment provisions of sections 732(b) and (d), 734(b), and 743(b), and the potential for tax abuse presented by the transactions are described in this part IV and part VI of this Background section.

Generally, in a Partnership Related-Party Basis Adjustment Transaction, partnership property is distributed to a partner who is related to one or more other partners, and that distribution results in a person related to the distributee partner, the distributee partner, or both, receiving all or a share of a basis increase in the distributed property or remaining partnership property under section 732 or 734(b) (as applicable); alternatively, a partnership interest is transferred between related persons or to a transferee partner who is related to an existing partner in the partnership, and that transfer results in an increase to the inside basis in partnership property with respect to the transferee partner under section 743(b).

Partnership Related-Party Basis Adjustment Transactions generally are structured so that, under the applicable allocation rules (sections 732(c), 734(c), 743(c), and 755), the basis increase is allocated to property that is eligible for cost recovery allowances (or eligible for a shorter cost recovery period) or that the partnership or the distributee partner disposes of in a taxable sale or exchange. Accordingly, the basis increase results in related partners decreasing their overall taxable income through additional or accelerated cost recovery allowances or decreasing their taxable gain or increasing their taxable loss on the subsequent taxable disposition of the property subject to the basis increase.

The related partners receive these tax benefits directly in the case of a distribution of property in which the basis of the distributed property is

increased in the distributee partner's hands under section 732(b) or (d). They receive these benefits indirectly in the case of a transfer of a partnership interest in which the inside basis of partnership property is increased for the transferee partner under section 743(b) or in the case of a distribution of property that results in an increase to the common basis of partnership property under section 734(b). Whether the tax benefits are received directly or indirectly, the resulting decrease in taxable income or gain (or increase in taxable loss) benefits the related-party group as a whole. Further, because the partners are related, the distributions or transfers may have little or no effect on the overall economic ownership of the property yet produce significant tax benefits shared by the related partners.

A related partner's partnership interest must have certain characteristics to create the opportunity for a Partnership Related-Party Basis Adjustment Transaction. In general, these characteristics are (1) a partner's outside basis in its partnership interest that is low compared to the partnership's basis in property it distributes to such partner, (2) a partner's outside basis in its partnership interest that is high compared to such partner's share of the partnership's basis in the partnership property (that is, the partner's share of inside basis), or (3) a partner's outside basis in its partnership interest that is high compared to the partnership's basis in property it distributes to such partner in liquidation of the partner's interest. Partnerships with related parties can create these characteristics through orchestrated contributions and distributions, as well as allocations under section 704(b) and (c). In most commercial transactions involving unrelated parties, the opportunity for abuse is limited because each party has separate, and often competing, economic and tax interests and the parties transact at arm's length. In contrast, for related parties, basis can be manipulated to provide a material net tax benefit to the related parties, as illustrated in part IV.B, C, D and E of this Background section.

B. Partnership Related-Party Basis Adjustment Transactions Under Section 734(b)

In a Partnership Related-Party Basis Adjustment Transaction under section 734(b), a partnership with a section 754 election in effect and two or more direct or indirect partners that are related to each other makes a current or liquidating distribution of partnership property to one or more of the related

partners. Immediately before the distribution, the partnership's basis in the distributed partnership property exceeds the distributee partner's basis in its partnership interest (that is, the partnership distributes property with a relatively high inside basis to a distributee partner with a relatively low outside basis). Under section 732(a)(2) or (b), the low-outside basis partner takes a basis in the distributed property that is lower than the inside basis of the property immediately before the distribution.

As a result of the basis decrease to the distributed property in the hands of the distributee partner under section 732(a)(2) or (b), the partnership increases the basis of its remaining partnership properties under section 734(b) by an amount equal to the excess of the partnership's basis in the distributed property immediately before the distribution over the basis of the distributed property in the hands of the distributee partner immediately after the distribution.

As a result of the distribution, under sections 734(c) and 755, the partnership allocates the basis increase to its remaining partnership properties; these remaining partnership properties are eligible for cost recovery allowances or are disposed of by the partnership in a taxable sale or exchange. The partnership then claims increased cost recovery allowances or decreased taxable gain (or increased taxable loss) on the disposition of the partnership property with the increased basis.

Because the transaction occurs among related persons, any economic consequences inherent in distributing partnership property to a partner that will have to reduce the basis of the distributed property under section 732(a)(2) or (b) can be minimized. For example, the distributed property might be property that the distributee partner intends to hold indefinitely and that is not eligible for cost recovery allowances. Further, because the transaction occurs among related persons, the overall economic ownership of the property remains substantially the same as before the transaction.

Related parties may choose to structure a distribution of partnership property to a related partner so that gain is recognized, for example, by distributing cash or marketable securities. If the recognized gain is insignificant compared with the increase in basis obtained under section 734(b) or is offset because of a tax attribute of the distributee partner (such as net operating losses), then the transfer may be considered a

Partnership Related-Party Basis Adjustment Transaction under section 734(b).

C. Partnership Related-Party Basis Adjustment Transactions Under Section 743(b)

In a Partnership Related-Party Basis Adjustment Transaction under section 743(b), a partner transfers an interest in a partnership with a section 754 election in effect to a related transferee or a transferee that is related to one or more of the partners in a nonrecognition transaction within the meaning of section 7701(a)(45) of the Code, such as a transfer under section 351(a) or 721(a) of the Code. Because the transfer is accomplished through a nonrecognition transaction, the transferee's basis in the transferred partnership interest generally will be equal to the transferor partner's basis in the transferred partnership interest (that is, the transferred partnership interest will be substituted basis property within the meaning of section 7701(a)(42) of the Code, such as that provided under section 362(a) of the Code in the case of a transfer of property to a corporation in exchange for stock under section 351(a), or under section 722 of the Code in the case of a transfer of property to a partnership in exchange for a partnership interest under section 721(a)).

In order for the transfer to give rise to a basis increase under section 743(b)(1), the transferor partner must have an inside-outside basis disparity with respect to its partnership interest so that the transferor partner's basis in the partnership interest (that is, the transferor partner's outside basis that carries over to the transferee partner) is greater than the transferor partner's share of the partnership's basis in its properties (that is, the transferor partner's share of inside basis immediately prior to the transfer). Because a section 754 election is in effect for the taxable year of the transfer, section 743(b) requires a basis increase to eliminate the inside-outside basis disparity of the transferee partner. The basis increase under section 743(b)(1) is equal to the excess of the transferee partner's outside basis over its proportionate share of the inside basis.

As a result of the transfer, under sections 743(c) and 755, the partnership allocates the basis increase with respect to the transferee partner to its partnership properties; these properties are eligible for cost recovery allowances or are disposed of by the partnership in a taxable sale or exchange. The transferee partner then receives increased allocations of cost recovery

allowances or lower allocations of taxable gain (or higher allocations of taxable loss) on the sale or exchange of the property by the partnership. Further, because the transaction occurs among related persons, the overall economic ownership of the partnership among the related partners remains the same as before the transaction.

Related parties may choose to structure a transfer of a partnership interest between a related transferor partner and related transferee so that gain is recognized. If the recognized gain is insignificant compared with the increase in basis obtained under section 743(b)(1) or is offset because of a tax attribute of the transferor (such as net operating losses), then the transfer may be considered a Partnership Related-Party Basis Adjustment Transaction under section 743(b).

D. Partnership Related-Party Basis Adjustment Transactions Under Section 732(b)

In a Partnership Related-Party Basis Adjustment Transaction under section 732(b), a partnership with two or more direct or indirect partners that are related makes a liquidating distribution of property to a related partner. Immediately before the distribution, the partnership's basis in the distributed property was relatively low and the distributee partner had a relatively high outside basis. Under section 732(b), the distributee partner's basis in the distributed property is equal to the partner's outside basis. As a result, the distributed property's basis is increased by an amount equal to the excess of the distributee partner's outside basis over the partnership's basis in the distributed property. As part of the transaction, under section 732(b) and (c), the distributee partner allocates the basis increase to its distributed property; this property is eligible for cost recovery allowances or is property that the distributee partner disposes of in a taxable sale or exchange. Accordingly, the distributee partner receives increased cost recovery allowances or decreases its taxable gain (or increases taxable loss) on the disposition of the distributed property.

Because the transaction occurs among related parties, any economic consequences inherent in distributing partnership property that may result in tax benefits to the distributee, potentially at the expense of the remaining partners, is minimized. Further, because the transaction occurs among related persons, the overall economic ownership of the property among the related partners remains the same as before the transaction.

As a result of the basis increase to the distributed property, the partnership may be required to decrease the basis of one or more of its remaining properties under the elective or mandatory basis adjustment provisions of section 734(b)(2) or (d). The parties may plan the transaction so that this reduction in basis will not have an adverse tax effect on the related parties because the partnership can allocate the basis reduction to property the partnership intends to hold indefinitely and that is not eligible for cost recovery allowances.

The related parties may achieve similar results through a transaction in which the partnership is liquidated. In a Partnership Related-Party Basis Adjustment Transaction in which a partnership makes liquidating distributions to all partners, a partner with a high outside basis (distributee partner) receives a liquidating distribution of low-inside basis property that is eligible for cost recovery allowances or that the distributee partner disposes of in a taxable sale or exchange. The partnership also distributes property to one or more parties related to the distributee partner (related distributee partner(s)), and such distribution may require a reduction to the basis of property under section 732(b) because the related distributee partner's basis in the partnership interest at the time of liquidation may be low compared to the partnership's basis in the distributed property. Similar to the version of the transaction in which only the distributee partner's partnership interest is liquidated, the property that is subject to reduction in basis as a result of the liquidation may be property that the related distributee partner(s) intend to hold indefinitely and that is not eligible for cost recovery allowances.

E. Partnership Related-Party Basis Adjustment Transactions Under Section 732(d)

In a Partnership Related-Party Basis Adjustment Transaction under section 732(d), a partnership with two or more direct or indirect partners that are related makes a current or liquidating distribution of property to a related partner. Prior to the distribution, the related partner acquired all or part of its partnership interest in a transaction that would have been a Partnership Related-Party Basis Adjustment Transaction under section 743(b) if the partnership had a section 754 election in effect.

The subsequent property distribution to the related transferee partner is made within two years of the transfer (in the case of an elective basis adjustment

under section 732(d)) or at any time after the transfer if at the time of the transfer the fair market value of the partnership's property (other than money) exceeded 110 percent of the property's adjusted basis to the partnership (in the case of a mandatory basis under section 732(d)). In either case, under section 732(d), for purposes of section 732(a), (b), and (c), the adjusted partnership basis of the distributed property is treated as equal to the adjusted basis the property would have had if the basis adjustment under section 743(b) were in effect at the time of the transfer.

As part of the transaction, the related distributee partner receives property with a higher basis than the property had before the transaction and either the property is eligible for cost recovery allowances or the distributee partner recovers the property's basis by disposing of it in a taxable sale or exchange.

Similar to a Partnership Related-Party Basis Adjustment Transaction under section 732(b), because the transaction occurs among related parties, any economic consequences inherent in distributing partnership property to a partner that, as a result of the distribution, will receive tax benefits is lessened or eliminated. Further, because the transaction occurs among related persons, the economic ownership of the property remains essentially the same as before the transaction.

V. Tax-Indifferent Parties Involved in Partnership Basis Adjustment Transactions

The Treasury Department and the IRS are aware that persons using partnerships that include tax-indifferent parties as partners may undertake transactions that accomplish the same results as the Partnership Related-Party Basis Adjustment Transactions. These transactions may take the form of any of the variations of the transactions described in part IV of this Background section and produce the same tax benefits for the taxable partners, except that the partners may not be related and negative tax consequences resulting from the transactions are borne by the tax-indifferent party. For example, a partnership with a section 754 election in effect and unrelated partners, one of which is a tax-indifferent party with a low outside basis, may distribute high-basis nondepreciable property to the tax-indifferent party. Under section 732(a)(2) or (b), the distribution results in the tax-indifferent party taking a basis in the distributed property that is lower than the partnership's basis in the property immediately before the

distribution. Under section 734(b), the partnership must adjust the basis of its remaining property and, as part of the transaction under sections 734(c) and 755, it increases the basis of depreciable property. Since the distributee partner is a tax-indifferent party, it does not experience any negative tax consequences from receiving property subject to a basis decrease as a result of the distribution. At the same time, the partners that are not tax-indifferent receive the tax benefit of increased cost recovery allowances through the partnership.

VI. Potential Tax Avoidance Using Partnership Related-Party Basis Adjustment Transactions

In Partnership Related-Party Basis Adjustment Transactions, related persons use partnerships to engage in transactions that inappropriately apply the basis adjustments under section 732, 734(b), or 743(b). These provisions can be exploited to create inappropriate basis increases to the partnership's properties, including any distributed property, but without meaningful change in the economic ownership of the properties or partnership interests because the parties involved in the transactions are related. The basis increases may be used to increase cost recovery allowances or decrease taxable gain or increase taxable loss on the subsequent taxable disposition of the property by the partnership or distributee partner.

The Treasury Department and the IRS propose to identify the Partnership Related-Party Basis Adjustment Transactions and substantially similar transactions as transactions of interest under proposed regulations described in the Explanation of Provisions section of this preamble. Identifying the transactions as transactions of interest would substantially improve the IRS's ability to detect abusive transactions and gather information about their prevalence and the contexts in which they arise.

Explanation of Provisions

I. Partnership Related-Party Basis Adjustment Transactions of Interest

Proposed § 1.6011-18(a) would identify transactions that are the same as or substantially similar (within the meaning of § 1.6011-4(c)(4)) to transactions described in proposed § 1.6011-18(c) as transactions of interest for the purposes of § 1.6011-4(b)(6). Proposed § 1.6011-18(c) would include a relatedness requirement and a \$5 million minimum threshold requirement. Further, proposed

§ 1.6011-18(a) would identify transactions that are substantially similar (within the meaning of § 1.6011-4(c)(4)) to the transactions described in proposed § 1.6011-18(c) as including the transactions described in proposed § 1.6011-18(d).

The relatedness requirement would be set forth in proposed § 1.6011-18(b)(8) and (9). Proposed § 1.6011-18(b)(8) would define "related" as having a relationship described in section 267(b) (without regard to section 267(c)(3)) or 707(b)(1). Proposed § 1.6011-18(b)(9) would define "related partners" as partners of a partnership that are related in the following manner—(i) in a transaction described in proposed § 1.6011-18(c)(1), the partnership has two or more direct or indirect partners that are related to each other within the meaning of proposed § 1.6011-18(b)(8), or (ii) in a transaction described in proposed § 1.6011-18(c)(2), the transferor of a partnership interest is related to the transferee, or the transferee is related to one or more of the partners in the partnership, within the meaning of proposed § 1.6011-18(b)(8). The relatedness requirement may be met either immediately before or immediately after a basis adjustment transaction described in proposed § 1.6011-18(c)(1) or (2).

Proposed § 1.6011-18(c) would provide that a transaction of interest is a transaction the factual elements of which are described in proposed § 1.6011-18(c)(1)(i) through (iii) or (c)(2). A basis adjustment transaction under proposed § 1.6011-18(c)(1)(i) would occur when a partnership makes a current or liquidating distribution of property to a partner who is related to one or more partners, the partnership increases the basis of one or more of its remaining properties under section 734(b) and (c), and the \$5 million threshold under proposed § 1.6011-18(c)(3) is met.

A basis adjustment transaction under proposed § 1.6011-18(c)(1)(ii) would occur when a partnership distributes property to a partner who is related to one or more partners in liquidation of a partnership interest (or in complete liquidation of the partnership), the basis of one or more distributed properties is increased under section 732(b) and (c), and the \$5 million threshold under proposed § 1.6011-18(c)(3) is met.

A basis adjustment transaction under proposed § 1.6011-18(c)(1)(iii) would occur when a partnership distributes property to a partner who is related to one or more partners, the basis of one or more distributed properties is increased under section 732(d), the related partner acquired all or a part of

its interest in the partnership in a transaction that would have been a transaction described in proposed § 1.6011-18(c)(2) if the partnership had a section 754 election in effect for the year of transfer, and the \$5 million threshold under proposed § 1.6011-18(c)(3) is met.

A basis adjustment transaction under proposed § 1.6011-18(c)(2) would occur when a partner transfers an interest in the partnership to a related transferee or to a person who is related to one or more existing partners in a nonrecognition transaction, the basis of one or more partnership properties is increased under section 743(b)(1) and (c), and the \$5 million threshold under proposed § 1.6011-18(c)(3) is met. Proposed § 1.6011-18(b)(2) would define nonrecognition transaction as defined in section 7701(a)(45) (other than a transfer on the death of a partner).

Proposed § 1.6011-18(c)(3) would provide rules for determining the \$5 million threshold. Under proposed § 1.6011-18(c)(3), a basis adjustment would include basis increases from multiple transactions described in proposed § 1.6011-18(c)(1) or (2) by the same partner or partnership during the taxable year that in the aggregate (without netting for any basis adjustments in the same transaction or another transaction that reduces basis) and after reducing the resulting aggregate amount by the gain recognized, if any, on which tax imposed under subtitle A of the Code (subtitle A) is required to be paid by any of the related parties to the transaction equal or exceed \$5 million.

Accordingly, a transaction of a partner or partnership described in proposed § 1.6011-18(c)(1) or (2) that results in a basis increase of less than \$5 million during the taxable year would be a transaction of interest under proposed § 1.6011-18(a) if, in the same taxable year, the partner or partnership participated in another transaction or transactions described in proposed § 1.6011-18(c)(1) or (2), and in the aggregate, the transactions resulted in a basis increase that equals or exceeds \$5 million, without regard to any basis decrease resulting from the transactions and after reducing the resulting aggregate amount by the gain recognized, if any, on which tax imposed under subtitle A is required to be paid by any of the related parties to the transactions. A threshold of \$5 million of basis increases in a taxable year to which no corresponding tax is paid should be sufficiently large to capture situations that use the provisions of subchapter K to produce

significant tax benefits with little or no economic impact.

If a basis adjustment transaction is described in proposed § 1.6011–18(c)(1)(i) through (iii) or (c)(2), any basis adjustments to recoverable property must be reported in the taxable year of the basis adjustment transaction, in each taxable year there is a cost recovery allowance, and in the taxable year the recoverable property is disposed of in a transaction in which gain or loss is recognized in whole or in part. Any basis adjustments to other property must be reported in the taxable year of the basis adjustment transaction and the taxable year in which the other property is disposed of in a transaction in which gain or loss is recognized in whole or in part. See proposed § 1.6011–18(e) and (f).

Proposed § 1.6011–18(b)(7) would define recoverable property as property of a character subject to an allowance for depreciation, amortization, or depletion under subtitle A of the Code.

II. Examples of Partnership Related-Party Basis Adjustment Transactions of Interest

The following examples illustrate the transactions of interest described in proposed § 1.6011–18(c).

A. Example 1. A Partnership Related-Party Basis Adjustment Transaction Under Proposed § 1.6011–18(c)(1)(i)

XY Partnership is owned by partners X and Y. The partners are related to each other within the meaning of proposed § 1.6011–18(b)(8) and (b)(9)(i). Each partner directly owns 50 percent of the capital and profits interests in XY Partnership and shares losses equally. X has an outside basis of \$10 million, and Y has an outside basis of \$1 million. XY Partnership owns property it uses in its trade or business, including Property 1 and Property 2. For Federal income tax purposes, Property 1 is depreciable property and Property 2 is nondepreciable property. XY Partnership has an adjusted basis in Property 1 of zero, and an adjusted basis in Property 2 of \$10 million.

XY Partnership has a section 754 election in effect for the taxable year and makes a current distribution of Property 2 to Y. Under section 732(a)(2), Y's basis in distributed Property 2 is limited to Y's adjusted basis in its partnership interest of \$1 million. As a result of the distribution to Y, Property 2's adjusted basis is decreased from \$10 million immediately before the distribution to \$1 million in Y's hands. Under section 734(b), XY Partnership must increase the basis of its remaining property. The amount of the basis

increase is equal to the excess of XY Partnership's basis in Property 2 immediately before the distribution of \$10 million over Y's adjusted basis in Property 2 after the distribution of \$1 million, which results in an increase to the basis of XY Partnership's remaining property of \$9 million.

Under sections 734(c) and 755 and the regulations thereunder, XY Partnership allocates the basis increase of \$9 million to Property 1. As a result, XY Partnership claims depreciation deductions based on an increased basis in Property 1.

B. Example 2. A Partnership Related-Party Basis Adjustment Transaction Under Proposed § 1.6011–18(c)(1)(ii)

DEF Partnership is owned by partners D, E and F. The partners are related to each other within the meaning of proposed § 1.6011–18(b)(8) and (b)(9)(i). D's outside basis is \$7 million. E and F each have an outside basis of \$1 million. DEF Partnership owns only two properties, Property 1 and Property 2, both of which it uses in its trade or business. For Federal income tax purposes, Property 1 is depreciable property and Property 2 is nondepreciable property. DEF Partnership has an adjusted basis in Property 1 of zero, and an adjusted basis in Property 2 is \$9 million.

DEF Partnership distributes Property 1 to D in liquidation of D's partnership interest. Under section 732(b), D's basis in distributed Property 1 is equal to \$7 million. As a result, D claims depreciation deductions based on a \$7 million basis in Property 1.

C. Example 3. A Partnership Related-Party Basis Adjustment Transaction Under Proposed § 1.6011–18(c)(1)(iii)

XYZ Partnership is owned by partners X, Y and Z. The partners are related to each other within the meaning of proposed § 1.6011–18(b)(8) and (b)(9)(i). Each partner directly owns one-third of the capital and profits interests in XYZ Partnership and shares losses equally.

XYZ Partnership owns Property 1, Property 2, and Property 3. Property 1 is depreciable property, and XYZ Partnership's adjusted basis in Property 1 is zero. Property 2 and Property 3 are nondepreciable property.

X acquired its interest in XYZ Partnership in a nonrecognition transaction from a person related to X within the meaning of proposed § 1.6011–18(b)(8). At the time of the transfer, XYZ Partnership did not have a section 754 election in effect. Immediately after the transfer, X's outside basis was \$12 million and share of inside basis was \$2 million. If XYZ

Partnership had a section 754 election in effect at the time of the transfer, XYZ Partnership would have adjusted X's share of inside basis under section 743(b). Assume that the adjustment under section 743(b) would have resulted in a basis increase to Property 1 of \$10 million.

In a taxable year that is within two years of the transfer of the partnership interest to X, XYZ Partnership makes a current distribution of Property 1 to X. Under section 732(a)(1), X's adjusted basis in Property 1 is zero. However, X makes an election under section 732(d) to adjust the basis of Property 1 to the adjusted basis it would have if the adjustment under section 743(b) were in effect with respect to the partnership property at the time X acquired its interest. As a result of the election under 732(d), because the adjusted basis of Property 1 under section 743(b) with respect to X would have been increased by \$10 million, X takes a basis in Property 1 equal to \$10 million and claims depreciation deductions based on a \$10 million basis in Property 1.

D. Example 4. A Partnership Related-Party Basis Adjustment Transaction Under Proposed § 1.6011–18(c)(2)

AB Partnership is owned by partners A and B. A owns 95 percent of the capital and profits interests in AB Partnership and is allocated 95 percent of all losses. B owns 5 percent of the capital and profits interests in AB Partnership and is allocated 5 percent of all losses. A's outside basis is \$6 million and share of inside basis is \$1 million. AB Partnership owns depreciable property it uses in a trade or business.

In a taxable year in which AB Partnership has a section 754 election in effect, A transfers its entire partnership interest to C, a person related to A within the meaning of proposed § 1.6011–18(b)(8) and (b)(9)(ii), in a nonrecognition transaction in which no gain was recognized. Because AB Partnership has a section 754 election in effect for the taxable year of the transfer, under section 743(b)(1), AB Partnership increases the basis of the partnership property with respect to C by \$5 million.

Assume that under sections 743(c) and 755 and the regulations thereunder, the basis increase with respect to C of \$5 million is allocated to partnership property that is depreciable. As a result, C may be allocated depreciation deductions over the recovery periods of the partnership properties equal to the amount of the basis increase under section 743(b)(1).

III. Substantially Similar Transactions

Proposed § 1.6011–18(a) would provide that substantially similar transactions include, but are not limited to, the transactions described in proposed § 1.6011–18(d). For purposes of proposed § 1.6011–18, transactions would be “substantially similar” transactions if the transactions are substantially similar within the meaning of § 1.6011–4(c)(4).

Under proposed § 1.6011–18(d)(1), a transaction would be substantially similar to a transaction described in proposed § 1.6011–18(c) if the transaction is a basis adjustment transaction described in proposed § 1.6011–18(c)(1) or (2), except that it does not involve related partners and one or more partners of the partnership is a tax-indifferent party. Under proposed § 1.6011–18(b)(11), a tax-indifferent party would mean a person that is either not liable for Federal income tax because of its tax-exempt or, in certain cases, foreign status or to which gain from a transaction described in proposed § 1.6011–18(c) would not result in Federal income tax liability for the person’s taxable year within which such gain is recognized (for example, because the taxpayer has a net operating loss carryforward or capital loss carryforward).

Under proposed § 1.6011–18(d)(2), a transaction would be substantially similar to a transaction described in proposed § 1.6011–18(c) in situations in which a partner transfers its partnership interest in a recognition transaction to a related transferee or to a person related to one or more existing partners, and the \$5 million threshold under proposed § 1.6011–18(c)(3) is met. Proposed § 1.6011–18(b)(6) would define a recognition transaction as a transaction other than a nonrecognition transaction as defined in proposed § 1.6011–18(b)(2).

IV. Persons Treated as Participants

Whether a taxpayer has participated in a transaction of interest described in proposed § 1.6011–18(c) during a taxable year is determined under proposed § 1.6011–18(e). Participants would include a participating partner within the meaning of proposed § 1.6011–18(b)(3), a participating partnership within the meaning of proposed § 1.6011–18(b)(4), and a related subsequent transferee within the meaning of proposed § 1.6011–18(b)(10). A participant would also include a tax-indifferent party within the meaning of proposed § 1.6011–18(b)(11).

Proposed § 1.6011–18(b)(3) would define “participating partner” as any

partner that directly receives a distribution of property or an interest in a participating partnership, or directly transfers an interest in a participating partnership, in a transaction described in proposed § 1.6011–18(c), including a person that becomes or ceases to be a partner as a result of such transaction. Accordingly, except for in the case of a related subsequent transferee, the proposed regulations would impose the disclosure requirement only on the direct distributee, transferor, or transferee in the transaction of interest identified under proposed § 1.6011–18(a). The person identified as the participating partner must be the owner for Federal income tax purposes of the partnership interest. As a result, in the case of a partnership interest held by a disregarded entity, the participating partner would be the owner of the disregarded entity for Federal income tax purposes. In the case of a partnership interest held by a grantor trust, the participating partner would be the grantor or owner of the grantor trust. Similar principles would be applied in determining the participating partner in circumstances similar to the disregarded entity or grantor trust situations. Under proposed § 1.6011–18(e)(2), a participating partner would participate in a transaction of interest in any taxable year in which the partner directly receives a distribution of property or an interest in a participating partnership, or directly transfers an interest in a participating partnership, in a transaction described in proposed § 1.6011–18(c).

Proposed § 1.6011–18(b)(4) would define “participating partnership” as any partnership that makes a distribution of property to a participating partner in a transaction described in proposed § 1.6011–18(c)(1), or a partnership interest of which was transferred in a transaction described in proposed § 1.6011–18(c)(2). Under proposed § 1.6011–18(e)(3), a participating partnership would participate in a transaction of interest in any taxable year in which (i) the partnership makes a distribution of property to a participating partner in a transaction described proposed § 1.6011–18(c)(1) or (ii) a participating partnership interest is transferred in a transaction described proposed § 1.6011–18(c)(2).

Proposed § 1.6011–18(b)(10) would define “related subsequent transferee” as any person related within the meaning of proposed § 1.6011–18(b)(8) to a participating partner that directly received in a nonrecognition transaction a transfer (including a distribution) of property that was subject to an increase

in basis as a result of a transaction described in proposed § 1.6011–18(c). Under proposed § 1.6011–18(e)(4), any direct transfer, in a nonrecognition transaction, to a related person of property subject to a basis increase resulting from a transaction described in proposed § 1.6011–18(c) would result in the related subsequent transferee becoming a participant in the transaction of interest identified under proposed § 1.6011–18(a). However, any subsequent transfer (including a distribution) by the related subsequent transferee to a transferee would not cause that transferee to become a participant.

Proposed § 1.6011–18(e)(5) would provide that a participating partnership, participating partner, or related subsequent transferee also participates in a transaction described in proposed § 1.6011–18(c) in any taxable year in which its tax return reflects the Federal income tax consequences of the basis increase from such transaction.

V. Information Disclosure Requirements

Proposed § 1.6011–18(f) would require participants to provide the information required under § 1.6011–4(d) and the Instructions to Form 8886 (or successor form). For all participants, describing the transaction in sufficient detail would include (but would not be limited to) describing on Form 8886 (or successor form) an increase in basis resulting from a transaction described in proposed § 1.6011–18(c) by providing the information required in proposed § 1.6011–18(f)(1)(i), through (iii).

Proposed § 1.6011–18(f)(1)(i) would require reporting of the names and identifying numbers (for example, social security number, employer identification number) of all participants.

Proposed § 1.6011–18(f)(1)(ii) would require participants to provide all basis adjustments resulting from a transaction described in § 1.6011–18(c), and basis information, including the participating partnership’s adjusted basis in the distributed property immediately before the distribution, any adjustments to basis under sections 732(a)(2), (b), (d) or 734(b), any adjustments to basis under section 743(b) with respect to a participating partner that is transferred an interest in a participating partnership, and with respect to a participating partner that transfers an interest in a participating partnership, that participating partner’s adjusted basis in the participating partnership interest and share of the participating partnership’s adjusted basis in its

property immediately before the transfer.

Proposed § 1.6011–18(f)(1)(iii) would require participants to provide information on Form 8886 (or successor form) of any Federal income tax consequences realized during the taxable year as a result of a transaction described in proposed § 1.6011–18(c), including cost recovery allowances attributable to an increase in basis described in proposed § 1.6011–18(c) or taxable gain or loss attributable to the disposition of property that was subject to an increase in basis described in proposed § 1.6011–18(c). In the case of Federal income tax consequences realized after the taxable year of a transaction described in proposed § 1.6011–18(c), such as cost recovery allowances or taxable gain or loss on a disposition, a participant must provide information on the Federal income tax consequences on Form 8886 (or successor form) for the taxable year of realization.

Under proposed § 1.6011–18(f)(2), if the property subject to an increase in basis as a result of a transaction described in proposed § 1.6011–18(c) is disposed of in a subsequent taxable year in a transaction in which gain or loss is recognized in whole or in part, a participant must send a copy of Form 8886 to OTSA, for the taxable year of the disposition, in addition to sending a copy to OTSA in the taxable year of the basis adjustment transaction.

Proposed § 1.6011–18(g) would provide examples of the participants' disclosure requirements for the taxable year in which the transaction of interest occurred and the subsequent taxable years in which a participant continued to realize the Federal income tax consequences of the transaction of interest.

VI. Effect of Transaction Becoming a Transaction of Interest

Participants required to disclose these transactions under § 1.6011–4 who fail to do so would be subject to penalties under section 6707A. Material advisors required to disclose these transactions under section 6111 who fail to do so would be subject to penalties under section 6707. Material advisors required to maintain lists of investors under section 6112 who fail to do so (or who fail to provide such lists when requested by the IRS) would be subject to penalties under section 6708(a). In addition, the IRS may impose other penalties on persons involved in these transactions or substantially similar transactions, including accuracy-related penalties under section 6662 or section 6662A, the penalty under section 6700

of the Code for promoting abusive tax shelters, and the penalty under section 6701 of the Code for aiding and abetting understatement of a tax liability.

In addition, material advisors have disclosure requirements with regard to transactions occurring in prior years. However, notwithstanding § 301.6111–3(b)(4)(i) and (iii), material advisors would be required to disclose only if they have made a tax statement on or after six years before the date of the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**.

Proposed Applicability Date

Proposed § 1.6011–18(a) would apply to identify certain partnership related-party basis adjustment transactions described in proposed § 1.6011–18(c) and substantially similar transactions as transactions of interest effective as of the date of publication in the **Federal Register** of a Treasury decision adopting these regulations as final regulations.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) generally requires that a federal agency obtain the approval of the Office of Management and Budget (OMB) before collecting information from the public regardless of whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

The proposed regulations would contain reporting and recordkeeping requirements that are required to identify increases to the basis of partnership property in certain transactions involving adjustments to the basis of partnership property. These collections of information would generally be used by the IRS for tax compliance purposes and by taxpayers to facilitate proper reporting and recordkeeping.

The proposed regulations would identify certain transactions as

reportable transactions and require partners and partnerships that participate in the transactions, and material advisors that provide advice on the transactions, to meet the reporting requirements under Sections 6011 and 6111, and material advisors to meet the list maintenance requirements of Section 6112. The reporting requirements contained in the proposed regulations would be met by completing Forms 8886 and 8918. These forms have been approved by OMB under control numbers 1545–1800 and 1545–0865, respectively. Accordingly, the proposed regulations would not be creating new collection of information requirements or changing the collection of information requirements already contained in the burden associated with the control numbers for Forms 8886 and 8918.

III. Regulatory Flexibility Act

When an agency issues a proposed rulemaking, the Regulatory Flexibility Act (5 U.S.C. chapter 6) (RFA) requires the agency to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of the proposed rule on “small entities.” 5 U.S.C. 603(a). The term “small entities” is defined in 5 U.S.C. 601 to mean “small business,” “small organization,” and “small governmental jurisdiction,” which are also defined in 5 U.S.C. 601. Small business size standards define whether a business is “small” and have been established for types of economic activities, or industry, generally under the North American Industry Classification System (NAICS). See 13 CFR part 121 (Small Business Size Regulations). The size standards look at various factors, including annual receipts, number of employees, and amount of assets, to determine whether the business is small. See 13 CFR part 121.201 for the Small Business Size Standards by NAICS Industry.

Section 605 of the RFA provides an exception to the requirement to prepare an initial regulatory flexibility analysis if the agency certifies that the proposed rulemaking will not have a significant economic impact on a substantial number of small entities. The Treasury Department and the IRS hereby certify that these proposed regulations will not have a significant economic impact on a substantial number of small entities under the RFA.

The IRS's Research, Applied Analytics, and Statistics division (RAAS) estimates that, in the case of a Partnership Related-Party Basis Adjustment Transaction identified as a transaction of interest involving a basis

adjustment under section 743(b), partnerships with gross receipts or sales of \$25 million or less might comprise two-thirds and partnerships with gross receipts or sales of over \$25 million might comprise one-third of all partnerships engaging in the transaction. This data provides an estimate that cannot yet be tested or confirmed without actual reporting of these transactions. Further, although the estimate suggests that the majority (two-thirds) of partnerships subject to reporting might be partnerships with gross receipts or sales of \$25 million or less, the estimate does not indicate that the majority of partnerships subject to reporting will be small entities. The “\$25 million or less” parameter is used as a reference point that does not necessarily correlate with the meaning of small entities under the Small Business Size Regulations. Thus, some or many of the partnerships in the category having gross receipts or sales of \$25 million or less might be too large to meet the size standards for small businesses under the Small Business Size Regulations. In addition, the data does not indicate whether the partnerships with gross receipts or sales of \$25 million or less are part of larger enterprises.

The proposed regulations will not have a significant economic impact on small entities because the proposed regulations would implement sections 6111 and 6112 and § 1.6011–4 by specifying the manner in which and the time at which a Partnership Related-Party Basis Adjustment Transaction identified as a transaction of interest must be reported. Accordingly, because the proposed regulations would be limited in scope to time and manner of information reporting, their economic impact is expected to be minimal.

The Treasury Department and the IRS expect that the reporting burden is low because the information sought is necessary for regular annual return preparation and ordinary recordkeeping. The estimated burden for any taxpayer required to file Form 8886 is approximately 10 hours, 16 minutes for recordkeeping, 4 hours, 50 minutes for learning about the law or the form, and 6 hours, 25 minutes for preparing, copying, assembling, and sending the form to the IRS. RAAS estimates that the appropriate wage rate for complying with the proposed regulations is \$102.00 (2022 dollars) per hour. Thus, it is estimated that persons required to comply with the proposed regulations would incur costs totaling approximately \$2,194.70 per filing. This amount is small in comparison to the \$5 million or more of basis increase in a

Partnership Related-Party Basis Adjustment Transaction identified as a transaction of interest. As a result, the relatively small cost to comply with the proposed regulations will not pose any significant economic impact to any small entities that would be subject to the proposed regulations.

For the reasons stated, a regulatory flexibility analysis under the RFA is not required. The Treasury Department and the IRS invite comments on the impact of the proposed regulations on small entities.

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

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of \$100 million (updated annually for inflation). This proposed rule does not include any Federal mandate that may result in expenditures by State, local, or Tribal governments or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

Comments and Public Hearing

Before these proposed amendments to the regulations are adopted as final regulations, consideration will be given to comments regarding the notice of proposed rulemaking that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All comments will be made available at <https://www.regulations.gov>.

Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn.

A public hearing has been scheduled for September 17, 2024 beginning at 10 a.m. ET, in the Auditorium at the Internal Revenue Building, 1111 Constitution Avenue NW, Washington, DC. 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. Participants may alternatively attend the public hearing by telephone.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the time to be devoted to each topic by August 19, 2024. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing. If no outline of the topics to be discussed at the hearing is received by August 19, 2024, the public hearing will be cancelled. If the public hearing is cancelled, a notice of cancellation of the public hearing will be published in the **Federal Register**.

Individuals who want to testify in person at the public hearing must send an email to publichearings@irs.gov to have your name added to the building access list. The subject line of the email must contain the regulation number REG–124593–23 and the language TESTIFY In Person. For example, the subject line may say: Request to TESTIFY In Person at Hearing for REG–124593–23.

Individuals who want to testify by telephone at the public hearing must send an email to publichearings@irs.gov to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–125593–23 and the language TESTIFY Telephonically. For example, the subject line may say: Request to TESTIFY Telephonically at Hearing for REG–124593–23.

Individuals who want to attend the public hearing in person without testifying must also send an email to publichearings@irs.gov to have your name added to the building access list. The subject line of the email must contain the regulation number REG–

124593–23 and the language ATTEND In Person. For example, the subject line may say: Request to ATTEND Hearing In Person for REG–124593–23. Requests to attend the public hearing must be received by 5 p.m. ET on September 13, 2024.

Individuals who want to attend the public hearing by telephone without testifying must also send an email to publichearings@irs.gov to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–124593–23 and the language ATTEND Hearing Telephonically. For example, the subject line may say: Request to ATTEND Hearing Telephonically for REG–124593–23. Requests to attend the public hearing must be received by 5 p.m. ET on September 13, 2024.

Hearings will be made accessible to people with disabilities. To request special assistance during a hearing please contact the Publications and Regulations Section of the Office of Associate Chief Counsel (Procedure and Administration) by sending an email to publichearings@irs.gov (preferred) or by telephone at (202) 317–6901 (not a toll-free number) at least September 12, 2024.

Drafting Information

The principal author of these proposed regulations is Elizabeth Zanet, Office of Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the Treasury Department and the IRS participated in the development of these regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry for § 1.6011–18 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * *

Section 1.6011–18 also issued under 26 U.S.C. 6001 and 26 U.S.C. 6011.

* * *

■ **Par. 2.** Section 1.6011–18 is added to read as follows:

§ 1.6011–18 Certain partnership related-party basis adjustment transactions as transactions of interest.

(a) *Identification as transaction of interest.* Transactions that are the same as or substantially similar (within the meaning of § 1.6011–4(c)(4)) to the transactions described in paragraph (c) of this section are identified as transactions of interest for purposes of § 1.6011–4(b)(6). Transactions that are substantially similar (within the meaning of § 1.6011–4(c)(4)) to the transactions described in paragraph (c) of this section include, but are not limited to, transactions described in paragraph (d) of this section.

(b) *Definitions.* The following definitions apply for purposes of this section:

(1) *Code* means the Internal Revenue Code.

(2) *Nonrecognition transaction* means a nonrecognition transaction within the meaning of section 7701(a)(45) of the Code (other than a transfer on the death of a partner).

(3) *Participating partner* means any partner that directly receives a distribution of property or an interest in a participating partnership, or directly transfers an interest in a participating partnership, in a transaction described in paragraph (c) of this section, including a person that becomes or ceases to be a partner as a result of such transaction. In the case of a participating partnership interest held by an entity that is disregarded as separate from its owner within the meaning of § 301.7701–2(c)(2)(i) of this chapter, participating partner means the owner of the disregarded entity for Federal income tax purposes. In the case of a participating partnership interest held by a grantor trust within the meaning of section 671 of the Code, participating partner means the grantor or other person designated under sections 671 through 679 of the Code as the owner of that portion of the trust that holds the participating partnership interest.

(4) *Participating partnership* means any partnership—

(i) That makes a distribution of property to a participating partner in a transaction described in paragraph (c)(1) of this section, or

(ii) A partnership interest which is transferred in a transaction described in paragraph (c)(2) of this section.

(5) *Participating partnership interest* means any partnership interest in a participating partnership.

(6) *Recognition transaction* means a transaction other than a nonrecognition transaction within the meaning of paragraph (b)(2) of this section.

(7) *Recoverable property* means property of a character subject to an allowance for depreciation, amortization, or depletion under subtitle A of the Code (subtitle A).

(8) *Related* means having a relationship described in section 267(b) of the Code (without regard to section 267(c)(3)) or section 707(b)(1) of the Code.

(9) *Related partners* mean partners of a partnership that are related in the following manner:

(i) In the case of a transaction described in paragraph (c)(1) of this section, the partnership has two or more direct or indirect partners that are related immediately before or immediately after a transaction described in paragraph (c)(1) of this section.

(ii) In the case of a transaction described in paragraph (c)(2) of this section, the transferor of a partnership interest is related to the transferee, or the transferee is related to one or more of the partners in the partnership, immediately before or immediately after a transaction described in paragraph (c)(2) of this section.

(10) *Related subsequent transferee* means any person who is related to a participating partner and directly received in a nonrecognition transaction, a transfer (including a distribution) of property that was subject to an increase in basis as a result of a transaction described in paragraph (c) of this section.

(11) *Tax-indifferent party* means a person that is either not liable for Federal income tax because of its tax-exempt or, in certain cases, foreign status or to which gain from a transaction described in paragraph (c) of this section would not result in Federal income tax liability for the person's taxable year within which such gain is recognized.

(c) *Transaction description.* A transaction is described in this paragraph (c) if the factual elements of the transaction described in paragraph (c)(1)(i) through (iii) or (c)(2) of this section are met.

(1) *Distributions by partnership.* A partnership engages in any of the transactions described in paragraphs (c)(1)(i) through (iii) of this section with one or more of the related partners:

(i) The partnership distributes property to a person who is a related partner in a current or liquidating distribution, the partnership increases the basis of one or more of its remaining properties under section 734(b) and (c) of the Code, and the \$5 million threshold described in paragraph (c)(3) of this section is met.

(ii) The partnership distributes property to a person who is a related partner in liquidation of the person's partnership interest (or in complete liquidation of the partnership), the basis of one or more distributed properties is increased under section 732(b) and (c) of the Code, and the \$5 million threshold described in paragraph (c)(3) of this section is met.

(iii) The partnership distributes property to a person who is a related partner, the basis of one or more distributed properties is increased under section 732(d) of the Code, the related partner acquired all or a part of its interest in the partnership in a transaction that would have been a transaction described in paragraph (c)(2) of this section if the partnership had a section 754 election in effect for the year of transfer, and the \$5 million threshold described in paragraph (c)(3) of this section is met.

(2) *Transfer of partnership interest.* A partner transfers an interest in a partnership to a related partner in a nonrecognition transaction, the basis of one or more partnership properties is increased under section 743(b)(1) and (c) of the Code, and the \$5 million threshold described in paragraph (c)(3) of this section is met.

(3) *\$5 million threshold.* For the purpose of determining whether a transaction is described in paragraph (c)(1), (c)(2), (d)(1), or (d)(2) of this section, the \$5 million threshold is met for a taxable year if the sum of all basis increases resulting from all such transactions of a partnership or partner during the taxable year (without netting for any basis adjustment in the same transaction or another transaction that reduces basis) exceeds by at least \$5 million the gain recognized from such transactions, if any, on which tax imposed under subtitle A is required to be paid by any of the related partners (or tax-indifferent party, in the case of a transaction described in paragraphs (d)(1) and (2) of this section) to such transactions.

(d) *Substantially similar transaction.* A transaction that is substantially similar (within the meaning of § 1.6011-4(c)(4)) to a transaction described in paragraph (c) of this section includes, but is not limited to:

(1) A transaction that is described in paragraph (c) of this section except that the partners of the partnership are not related and one or more partners of the partnership is a tax-indifferent party that facilitates, by receiving a distribution of property from the partnership or otherwise, an increase in the basis of partnership property or an

increase in the basis of property held by another partner in the partnership; and

(2) A transaction in which a partner transfers an interest in a partnership to a related partner in a recognition transaction, and the \$5 million threshold described in paragraph (c)(3) of this section is met.

(e) *Participation*—(1) *In general.* Whether a taxpayer has participated in a transaction of interest described in paragraph (c) of this section during a taxable year is determined under this paragraph (e).

(2) *Participating partners.* A participating partner participates in a transaction of interest described in paragraph (c) of this section in any taxable year in which the partner directly receives a distribution of property or an interest in a participating partnership, or directly transfers an interest in a participating partnership, in a transaction described in paragraph (c) of this section.

(3) *Participating partnerships.* A participating partnership participates in a transaction of interest described in paragraph (c) of this section in any taxable year in which the partnership makes a distribution of property to a participating partner in a transaction described in paragraph (c)(1) of this section, or a participating partnership interest is transferred in a transaction described in paragraph (c)(2) of this section.

(4) *Related subsequent transferees.* A related subsequent transferee participates in a transaction of interest described in paragraph (c) of this section in any taxable year in which the related subsequent transferee directly receives, in a nonrecognition transaction, a transfer (including a distribution) of property that was subject to an increase in basis as a result of a transaction described in paragraph (c) of this section.

(5) *Subsequent realization of tax benefit.* A participating partnership, participating partner or related subsequent transferee also participates in a transaction of interest described in paragraph (c) of this section in any taxable year in which its tax return reflects the tax consequences of a basis increase resulting from a transaction of interest described in paragraph (c) of this section. For example, if a participating partner sells property the basis of which has been increased as a result of a transaction of interest described in paragraph (c) of this section during a taxable year after the year in which the transaction of interest described in paragraph (c) of this section resulting in the basis increase occurred, the participating partner

participates in a transaction of interest described in paragraph (c) of this section during the taxable year(s) in which the tax consequences of the sale are reported on the participating partner's tax return.

(f) *Disclosure requirements*—(1) *In general.* Participants must provide the information required under § 1.6011-4(d) and the Instructions to Form 8886, *Reportable Transaction Disclosure Statement* (or successor form) for each taxable year in which the participant participated in a transaction described in paragraph (c) of this section as determined under paragraph (e) of this section. For all participants, describing the transaction in sufficient detail includes describing the information described in paragraphs (f)(1)(i) through (iii) of this section, as applicable, on Form 8886 (or successor form) for the taxable year of a transaction described in paragraph (c) of this section.

(i) The names and identifying numbers of all participants, including the participating partnership, participating partners and any related subsequent transferees or tax-indifferent parties.

(ii) All basis adjustments resulting from a transaction described in paragraph (c) of this section, and basis information, including the participating partnership's adjusted basis in the distributed property immediately before the distribution, any adjustments to basis under section 732(a)(2), (b), (d) or 734(b), any adjustments to basis under section 743(b) with respect to a participating partner that is transferred an interest in a participating partnership, and with respect to a participating partner that transfers an interest in a participating partnership, that participating partner's adjusted basis in the participating partnership interest and share of the participating partnership's adjusted basis in its property immediately before the transfer.

(iii) Any Federal income tax consequences realized during the taxable year, as a result of a transaction described in paragraph (c) of this section, including cost recovery allowances attributable to an increase in basis as a result of a transaction described in paragraph (c) of this section, and taxable gain or taxable loss attributable to the disposition of property that was subject to an increase in basis as a result of a transaction described in paragraph (c) of this section. For example, in the case of a distribution of depreciable property that was subject to an increase in basis as a result of a transaction described in paragraph (c) of this section, the Federal

income tax consequences realized during the taxable year include the basis increase and cost recovery allowances attributable to the basis increase during the taxable year.

(2) *Disposition in subsequent taxable years.* If the property subject to an increase in basis as a result of a transaction described in paragraph (c) of this section is disposed of in a transaction in which gain or loss is recognized in whole or in part in a subsequent taxable year, the participant must send a copy of Form 8886 to the Office of Tax Shelter Analysis (OTSA). This requirement is in addition to the requirement that a participant send a copy of Form 8886 to OTSA for the taxable year of the basis increase.

(g) *Examples.* The following examples illustrate the provisions of this section.

(1) *Example 1: Reporting by a participating partner and participating partnership in the taxable year of the transaction, including cost recovery allowances—(i) Facts.* ABC Partnership is owned by partners A, B and C. Partners A, B and C are related within the meaning of paragraphs (b)(8) and (9) of this section. At the beginning of taxable year 1, ABC Partnership distributes a depreciable asset, Property X, to Partner A in liquidation of Partner A's interest in ABC Partnership. The distribution is a transaction described in paragraph (c)(1)(ii) of this section. As a result of the distribution, the basis of Property X is increased by \$5 million. On its tax return for taxable year 1, Partner A reports deductions for depreciation expense attributable to the \$5 million increase in the basis of Property X resulting from the transaction under paragraph (c)(1)(ii) of this section. ABC Partnership and Partner A have the same taxable year.

(ii) *Analysis.* Partner A is a participant during taxable year 1 within the meaning of paragraph (e) of this section because it is a participating partner within the meaning of paragraph (b)(3) of this section since it directly received a distribution of property during taxable year 1 in a transaction described in paragraph (c) of this section. ABC Partnership is a participant during taxable year 1 within the meaning of paragraph (e) of this section because it is a participating partnership within the meaning of paragraph (b)(4) of this section since it made a distribution of property to a participating partner during taxable year 1 in a transaction described in paragraph (c) of this section. As part of its disclosure requirements under paragraph (f) of this section and § 1.6011-4(d) and (e), Partner A must disclose the distribution as a transaction of interest under this

section on Form 8886 (or successor form) and file the form with its tax return for taxable year 1. Partner A must include the information described in paragraph (f) of this section, including the amount of the deductions attributable to the \$5 million increase in the basis of Property X resulting from the transaction described in paragraph (c)(1)(ii) of this section. As part of its disclosure requirements under paragraph (f) of this section and § 1.6011-4(d) and (e), ABC Partnership must disclose the distribution as a transaction of interest under this section on Form 8886 (or successor form) and file the form with its tax return for taxable year 1, including the information described in paragraph (f) of this section. In addition, Partner A and ABC Partnership must send a copy of their respective Form 8886 (or successor form) to OTSA.

(2) *Example 2: Reporting of the Federal income tax consequences (cost recovery allowances) of the transaction in all taxable years—(i) Facts.* Under the same facts as in paragraph (g)(1)(i) of this section (*Example 1*), on its tax returns for taxable years 2 through 5, Partner A reports deductions for depreciation expense attributable to the \$5 million increase in the basis of Property X related to the transaction described in paragraph (c)(1)(ii) of this section, which occurred in taxable year 1.

(ii) *Analysis.* As part of its disclosure requirements under paragraph (f) of this section and § 1.6011-4(d) and (e), Partner A must disclose the deductions on Form 8886 (or successor form) for taxable years 2 through 5 as the Federal income tax consequences of the transaction described in paragraph (c)(1)(ii) of this section. As a result, for each taxable year 2 through 5, Partner A must file the form with its tax return for the taxable year with the information described in paragraph (f) of this section, including the amount of the deductions attributable to the \$5 million increase in the basis of Property X resulting from the transaction described in paragraph (c)(1)(ii) of this section.

(3) *Example 3: Reporting by a participating partner, participating partnership, and related subsequent transferee in the taxable year of the transaction—(i) Facts.* The facts are the same as in paragraph (g)(1)(i) of this section (*Example 1*), except that at the beginning of taxable year 1, ABC Partnership distributes a nondepreciable asset, Land with an adjusted basis of \$1 million, to Partner A in liquidation of Partner A's interest in ABC Partnership. The distribution is a transaction described in paragraph (c)(1)(ii) of this

section. As a result of the distribution, the basis of Land is increased to \$6 million. Subsequently in taxable year 1, Partner A contributes Land to another partnership, AX Partnership, in a transfer that is treated as a contribution of property under section 721(a). Partner A and AX Partnership are related within the meaning of paragraph (b)(8) of this section. ABC Partnership, Partner A and AX Partnership have the same taxable year.

(ii) *Analysis.* Partner A is a participant during taxable year 1 within the meaning of paragraph (e) of this section because it is a participating partner within the meaning of paragraph (b)(3) of this section since it directly received a distribution of property during taxable year 1 in a transaction described in paragraph (c) of this section. ABC Partnership is a participant during taxable year 1 within the meaning of paragraph (e) of this section because it is a participating partnership within the meaning of paragraph (b)(4) of this section since it made a distribution of property to a participating partner during taxable year 1 in a transaction described in paragraph (c) of this section. AX Partnership is a participant during taxable year 1 within the meaning of paragraph (e) of this section because it is a related subsequent transferee within the meaning of paragraph (b)(10) of this section since it directly received in a nonrecognition transaction, a transfer of property during taxable year 1 that was subject to an increase in basis as a result of a transaction described in paragraph (c) of this section. As part of its disclosure requirements under paragraph (f) of this section and § 1.6011-4(d) and (e), Partner A must disclose the distribution as a transaction of interest under this section on Form 8886 (or successor form) and file the form with its tax return for taxable year 1. Partner A must include the information described in paragraph (f) of this section. As part of its disclosure requirements under paragraph (f) of this section and § 1.6011-4(d) and (e), ABC Partnership must disclose the distribution as a transaction of interest under this section on Form 8886 (or successor form) and file the form with its tax return for taxable year 1, including the information described in paragraph (f) of this section. Further, AX Partnership is subject to the disclosure requirements under paragraph (f) of this section and § 1.6011-4(d) and (e). AX Partnership must disclose that it is a related subsequent transferee within the meaning of paragraph (b)(10) of this section that received, in a

nonrecognition transaction, a transfer of property that was distributed in a transaction of interest under this section on Form 8886 (or successor form) and file the form with its tax return for taxable year 1. In addition, Partner A, ABC Partnership and AX Partnership must send a copy of their respective Form 8886 (or successor form) to OTSA.

(4) *Example 4: Reporting of the Federal income tax consequences (reduced taxable gain) of the transaction in the taxable year of disposition of the property*—(i) *Facts*. Under the same facts as in paragraph (g)(3)(i) of this section (*Example 3*), in taxable year 2, AX Partnership disposes of Land in a taxable sale for its fair market value of \$6 million and recognizes gain of zero.

(ii) *Analysis*. As part of its disclosure requirements under paragraph (f) of this section and § 1.6011–4(d) and (e), AX Partnership must disclose the taxable gain (zero) on the disposition of Land on Form 8886 (or successor form) for taxable year 2 as the Federal income tax consequences of the transaction described in paragraph (c)(1)(ii) of this section. AX must file the form with its tax return for taxable year 2 and send a copy of the form to OTSA.

(h) *Applicability date*. This section's identification of transactions that are the same as or substantially similar (within the meaning of § 1.6011–4(c)(4)) to the transactions described in paragraph (c) of this section as transactions of interest for purposes of § 1.6011–4(b)(6) and sections 6111 and 6112 of the Code is effective on the date the regulations are published as final regulations in the **Federal Register**.

Douglas W. O'Donnell,
Deputy Commissioner.

[FR Doc. 2024–13282 Filed 6–17–24; 8:45 am]

BILLING CODE 4830–01–P

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

48 CFR Chapter 99

Application of Cost Accounting Standards to Indefinite Delivery Vehicles

AGENCY: Cost Accounting Standards Board, Office of Federal Procurement Policy, Office of Management and Budget.

ACTION: Notice of availability; request for comments.

SUMMARY: The Office of Federal Procurement Policy (OFPP), Cost Accounting Standards Board (CAS Board or the Board), is announcing the availability a document, from case 2021–01, intended to elicit public views on whether and how to amend the Board's rules to address the application of Cost Accounting Standards (CAS) to indefinite delivery vehicles (IDVs).

DATES: Comments must be in writing and must be received by August 19, 2024.

ADDRESSES: Respondents are strongly encouraged to submit comments electronically to ensure timely receipt. Electronic comments may be submitted to OMBCASB@omb.eop.gov. Be sure to include your name, title, organization, and reference case 2021–01. If you must submit by regular mail, please do so at Office of Federal Procurement Policy, 725 17th Street NW, Washington, DC 20503, ATTN: John L. McClung.

Privacy Act Statement: The CAS Board issues this request to elicit public views pursuant to 41 U.S.C. 1502. Submission of comments is voluntary. The information will be used to inform sound decision-making. Please note that all comments received in response to

this document may be posted or released in their entirety, including any personal and business confidential information provided. Do not include any information you would not like to be made publicly available.

Additionally, the OMB System of Records Notice, OMB Public Input System of Records, OMB/INPUT/01, 88 FR 20913 (available at www.federalregister.gov/documents/2023/04/07/2023-07452/privacy-act-of-1974-system-of-records), includes a list of routine uses associated with the collection of this information.

FOR FURTHER INFORMATION CONTACT: John L. McClung, Manager, Cost Accounting Standards Board (telephone: 202–881–9758; email: john.l.mcclung2@omb.eop.gov).

Availability: The full text of the document is available at: <https://www.whitehouse.gov/omb/management/office-federal-procurement-policy/#cost>.

SUPPLEMENTARY INFORMATION:

Application of Cost Accounting Standards to Indefinite Delivery Vehicles (IDVs). The Board is soliciting public views on whether and how to amend its rules to address the application of CAS to IDVs.

Rules, regulations, and standards issued by the Board are codified at 48 CFR chapter 99. In accordance with 41 U.S.C. 1502, the Board is inviting interested persons to provide input on this document. All comments must be in writing and submitted as instructed in the **ADDRESSES** section.

Christine J. Harada,

Senior Advisor Office of Federal Procurement Policy, and Chair, Cost Accounting Standards Board, performing by delegation the duties of the Administrator for Federal Procurement Policy.

[FR Doc. 2024–12225 Filed 6–17–24; 8:45 am]

BILLING CODE 3110–01–P

Notices

Federal Register

Vol. 89, No. 118

Tuesday, June 18, 2024

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Information Collection Request; 30-Day Notice and Request for Comments, Data Collection Form for the USAID Science Champion Award for International Science and Engineering Fair-Affiliated Fairs

AGENCY: Agency for International Development (USAID).

ACTION: Notice of information collection; request for comment.

SUMMARY: The Research Division within the Innovation, Technology, and Research Hub (ITR), under the Bureau for Inclusive Growth, Partnerships, and Innovation (IPI), manages U.S. Agency for International Development (USAID) involvement in the annual Regeneron International Science and Engineering Fair (ISEF). Serving as a Special Award Organization at ISEF since 2014 has allowed the Agency to recognize and award students with the USAID Science for Development Award. In the lead up to ISEF, students compete in high school science fairs that are members of the global network of the Society for Science. USAID also awards the Science Champion Award at these fairs. Winners of the Science Champion Award are selected by the high school science fairs' judges and awards committees for projects that could potentially impact a global development challenge. In order to provide accurate accounting for these awards, we need to collect information from the public, specifically from Judging Committees of science fairs participating in the program.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open

for Public Comments" or by using the search function

ADDRESSES: To access and review the electronic Google forms survey tool, please use <https://forms.gle/NdYUDPhgAHFrpmqU8>. Comments submitted in response to this notice should be submitted electronically through the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Celia Laskowski, Program Analyst, USAID/IPI/ITR/R at stfellowships@usaid.gov or +1 202-704-5599.

SUPPLEMENTARY INFORMATION:

OMB Number: Not yet known.

Expiration Date: Not yet known.

Celia Laskowski,

Program Analyst, USAID/IPI/ITR/R.

[FR Doc. 2024-13385 Filed 6-17-24; 8:45 am]

BILLING CODE 6116-01-P

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Renew Information Collection

AGENCY: National Arboretum, Agricultural Research Service, USDA.

ACTION: Notice and request for comment.

SUMMARY: The U.S. Department of Agriculture (USDA) seeks comments on the U.S. National Arboretum's (USNA) intent to renew an information collection that expires December 31, 2024. The information collection serves to collect fees for certain uses of the facilities, grounds, programs, and services. This includes fees for educational programs and workshops, and for use of the grounds and facilities for commercial photography and cinematography. Fees will be used to promote the mission and defray expenses of the USNA.

DATES: Comments on this notice must be received by August 31, 2024, to be assured of consideration.

ADDRESSES:

Email: USNA.Comments@usda.gov.

- *Mail:* Director, U.S. National Arboretum, Northeast Area, Agricultural Research Service, 3501 New York Avenue NE, Washington, DC 20002

- *Hand Delivery/Courier:* Director, U.S. National Arboretum, Northeast

Area, Agricultural Research Service, 3501 New York Avenue NE, Washington, DC 20002

SUPPLEMENTARY INFORMATION:

Title: Use of the Grounds and Facilities as Well As Commercial Photography and

Cinematography.

OMB Number: 0518-0024.

Expiration Date: 3 years from date of approval.

Type of Request: Renewal of approved information collection.

Abstract: The mission of the U.S. National Arboretum (USNA) is to serve the public need for scientific research, education, and gardens that conserve and showcase plants to enhance the environment. The USNA is a 451-acre facility open to the public for purposes of education and passive recreation. The USNA is a national center for public education and research that welcomes visitors in a stimulating and aesthetically pleasing environment. The USNA receives more than 700,000 visitors on the grounds each year. Many garden clubs and societies utilize the USNA grounds to showcase their activities.

Section 890(b) of the Federal Agriculture Improvement and Reform Act of 1996, Public Law 104-127 (1996 Act), expanded the authorities of the Secretary of Agriculture to charge reasonable fees for the use of USNA facilities and grounds. These authorities include the ability to charge fees for temporary use by individuals or groups of USNA facilities and grounds in furtherance of the mission of the USNA. Also, authority was provided to charge fees for the use of the USNA for commercial photography and cinematography. All rules and regulations noted in 7 CFR part 500, subpart 2A, will apply to individuals or groups granted approval to use USNA facilities and grounds. In order to administer the use of the USNA facilities and to determine if the requested use are consistent with the mission of the USNA, it is necessary for the USNA to obtain information from the requestor. Each request will require the completion of an application and submission of an application fee. The application is simple and requires only information readily available to the requestor. The requestor is asked to indicate by whom and for what purpose the USNA facilities are to be used.

Applications are available in electronic format (PDF fillable) on the USNA website <https://www.usna.usda.gov/>. Completed permit requests are received in person or electronically.

Paperwork Reduction Act: In accordance with the Office of Management and Budget (OMB) regulations (5 CFR part 1320) implementing the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the information collection and recordkeeping requirements that will be imposed will be submitted to OMB for approval. These requirements will not become effective prior to OMB approval.

Estimate of Burden: 850 hours.

Estimated Number of Responses: The USNA estimates 200 requests for the use of facilities, 150 for photography and cinematography, and 500 for educational programs and workshops on an annual basis.

Estimate of Total Annual Burden on Respondents: The total cost for responding is \$6,445.13 for 212.5 hours of time at \$30.33 per hour.

Obtaining Permit Requests: The PDF fillable application for the use of facilities is available on the USNA website and can be submitted electronically to USNA: https://www.usna.usda.gov/assets/images/as_pdf_image/USNA_Facilities_Use_Form.pdf.

The application for photography and cinematography is available on the USNA website and can be submitted electronically: https://usna.usda.gov/assets/images/as_pdf_image/Photography-Videography_Application_March_2023.pdf.

Completed hard copies of permit requests can be submitted to the Administrative Office, USDA, ARS, U.S. National Arboretum, 3501 New York Avenue NE, Washington, DC 20002.

Comments: Comments are invited on whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technology.

Nora Lapitan,

Acting Associate Administrator, ARS.

[FR Doc. 2024-13347 Filed 6-17-24; 8:45 am]

BILLING CODE 3410-03-P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Urban Agriculture and Innovative Production Advisory Committee Meeting

AGENCY: Natural Resources Conservation Service (NRCS), Department of Agriculture (USDA).

ACTION: Notice of public and virtual meeting.

SUMMARY: The Natural Resources Conservation Service (NRCS) will hold a public meeting of the Urban Agriculture and Innovative Production Advisory Committee (UAIPAC). UAIPAC will convene to discuss proposed recommendations for the Secretary of Agriculture on the development of policies and outreach relating to urban, indoor, and other emerging agriculture production practices. UAIPAC is authorized under the Agriculture Improvement Act of 2018 (2018 Farm Bill) and operates in compliance with the Federal Advisory Committee Act (FACA), as amended.

DATES:

Meeting: The UAIPAC meeting will be held on Thursday, July 11, 2024, from 12 p.m. to 5 p.m. Eastern Daylight Time (EDT).

Written Comments: Written comments will be accepted until Thursday, July 25, 2024 at 11:59 p.m. (EDT).

Oral Comments: Registration to provide oral comments during the meeting will be open until Monday, July 8, 2024 at 11:59 p.m. (EDT).

ADDRESSES:

Meeting Location: The meeting will be held virtually via Zoom webinar. Pre-registration is required to attend the UAIPAC meeting and access information will be provided to registered individuals via email. Registration details can be found at: <https://www.usda.gov/partnerships/federal-advisory-committee-urban-ag>.

Written Comments: We invite you to send comments in response to this notice via email to UrbanAgricultureFederalAdvisoryCommittee@usda.gov.

Oral Comments: Only pre-registered individuals will be permitted to provide oral comments. Instructions to register and participate in the meeting can be found at: <https://www.usda.gov/partnerships/federal-advisory-committee-urban-ag>.

FOR FURTHER INFORMATION CONTACT:

Brian Guse; Designated Federal Officer; telephone: (202) 205-9723; email:

UrbanAgricultureFederalAdvisoryCommittee@usda.gov.

Individuals who require alternative means for communication may contact the USDA TARGET Center at (202) 720-2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

UAIPAC Purpose

The Federal Advisory Committee for Urban Agriculture and Innovative Production is one of several ways that USDA is extending support and building frameworks to support urban agriculture, including issues of equity and food and nutrition access. Section 222 of the Department of Agriculture Reorganization Act of 1994, as amended by section 12302 of the 2018 Farm Bill (7 U.S.C. 6923; Pub. L. 115-334) directed the Secretary to establish an "Urban Agriculture and Innovative Production Advisory Committee" to advise the Secretary of Agriculture on any aspect of section 222, including the development of policies and outreach relating to urban, indoor, and other emerging agricultural production practices as well as identify any barriers to urban agriculture. UAIPAC will host public meetings to deliberate on recommendations for the Secretary of Agriculture. These recommendations provide advice to the Secretary on supporting urban agriculture and innovative production through USDA's programs and services.

Meeting Agenda

The agenda items may include, but are not limited to, welcome and introductions; administrative matters; presentations from the UAIPAC or USDA staff; and deliberations for proposed recommendations and plans. The USDA UAIPAC website (<https://www.usda.gov/partnerships/federal-advisory-committee-urban-ag>) will be updated with the final agenda at least 24 hours prior to the meeting.

Written and Oral Comments

Comments should address specific topics pertaining to urban agriculture and innovative production. Written comments will be accepted via email (UrbanAgricultureFederalAdvisoryCommittee@usda.gov) until 11:59 p.m. EDT on Thursday, July 25, 2024.

Only pre-registered individuals will be permitted to provide oral comments. Instructions to register and participate in the meeting can be found at: <https://www.usda.gov/partnerships/federal-advisory-committee-urban-ag>.

www.usda.gov/partnerships/federal-advisory-committee-urban-ag.

Meeting Materials

All written comments received by the deadline specified above will be compiled for UAIPAC review. Duplicate comments from multiple individuals will appear as one comment, with a notation that multiple copies of the comment were received. Please visit <https://www.usda.gov/partnerships/federal-advisory-committee-urban-ag> to view the agenda and minutes from the meeting.

Meeting Accommodations

If you require reasonable accommodation, please make requests in advance for sign language interpretation, assistive listening devices, or other reasonable accommodation, to the person listed under the **FOR FURTHER INFORMATION CONTACT** section. Determinations for reasonable accommodation will be made on a case-by-case basis.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotope, American Sign Language, etc.) should contact the responsible Agency or the USDA TARGET Center at (202) 720-2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any phone). Additionally, program information may be made available in languages other than English.

Equal opportunity practices in accordance with USDA's policies will be followed in all appointments to the FACA Committee: UAIPAC. To ensure that the recommendations of the Committee have taken into account the

needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent the many communities, identities, races, ethnicities, backgrounds, abilities, cultures, and beliefs of the American people, including underserved communities. USDA is an equal opportunity provider, employer, and lender.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at <https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint> and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; (2) fax: (202) 690-7442; or (3) email: OAC@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

Dated: June 11, 2024.

Cikena Reid,

Committee Management Officer, USDA.

[FR Doc. 2024-13270 Filed 6-17-24; 8:45 am]

BILLING CODE 3410-16-P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket #: RBS-24-BUSINESS-0006]

Notice of Revision of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service or Rural Utilities Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 the Rural Business-Cooperative Service (RBCS or Agency), an agency within the United States Department of Agriculture (USDA), Rural Development (RD), announces its intention to request an extension to a currently approved information collection package for Higher Blends Infrastructure Incentive Program (HBIIP) program. The Agency invites comments on this information collection for which it intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by August 19, 2024 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT:

Susan Woolard, RD Innovation Center—Regulations Management Division, U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250, Telephone: 202-720-9631, email: susan.woolard@usda.gov.

SUPPLEMENTARY INFORMATION: The OMB regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that the Agency is submitting to OMB for extension.

Comments are invited on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be submitted electronically by the Federal eRulemaking Portal, <https://www.regulations.gov/>. In the "Search for dockets and documents on agency actions" box enter RBS-24-Business-0006 and click the "Search" button. From the search results, click on or locate the document title: "HBIIP Notice of Revision of a Currently Approved Information Collection" and select the "Comment" button. Before inputting comments, commenters may review the "Commenter's Checklist" (optional). To submit a comment: Insert comments under the "Comment" title, click "Browse" to attach files (if available), input email address, select box to opt to receive email confirmation of submission and tracking (optional), select the box "I'm not a robot," and then select "Submit Comment." Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "FAQ" link. All comments will be available for public inspection

online at the Federal eRulemaking Portal (<https://www.regulations.gov>).

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. Data furnished by the applicants will be used to determine eligibility for program benefits. Furnishing the data is voluntary; however, failure to provide data could result in program benefits being withheld or denied.

Title: Higher Blends Infrastructure Incentive Program (HBIIIP).

OMB Control Number: 0570-0072.

Type of Request: Extension of a currently approved information collection.

Abstract: HBIIIP is intended to encourage a more comprehensive approach to marketing higher blends biofuels by sharing the costs related to building out biofuel-related infrastructure. To be eligible for this program, a project's sole purpose must be to assist transportation fueling and biodiesel distribution facilities with converting to higher ethanol and biodiesel blend friendly status by sharing the costs related to the installation, and/or retrofitting, and/or otherwise upgrading of fuel storage, dispenser/pumps, related equipment, and infrastructure. An eligible project must conform to all applicable Federal, State, and local regulatory requirements.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 8.03 hours per response.

Respondents: Owners of transportation fueling, and fuel distribution facilities located in the United States.

Estimated Number of Respondents: 641.

Estimated Number of Responses per Respondent: 1.06.

Estimated Number of Responses: 10,477.

Estimated Total Annual Burden on Respondents: 84,177 hours.

Copies of this information collection can be obtained from Susan Woolard, RD Innovation Center—Regulations Management Division, Telephone: 202-720-9631, email: susan.woolard@usda.gov.

All responses to this notice will be summarized and included in the request

for OMB approval. All comments will also become a matter of public record.

Kathryn E. Dirksen Londrigan,
Administrator, Rural Business-Cooperative Service, USDA Rural Development.

[FR Doc. 2024-13326 Filed 6-17-24; 8:45 am]

BILLING CODE 3410-XT-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-32-2024]

Foreign-Trade Zone (FTZ) 22, Notification of Proposed Production Activity; AbbVie, Inc.; (Pharmaceutical Products); North Chicago, Illinois

AbbVie, Inc. submitted a notification of proposed production activity to the FTZ Board (the Board) for its facilities in North Chicago, Illinois within Subzone 22S. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on May 31, 2024.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material/component described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz. The proposed material/component would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed foreign-status material/component is 2-Bromo-5-tosyl-5H-pyrrolo[2,3-b]pyrazine (duty rate is 6.5%). The request indicates the material/component is subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is July 29, 2024.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Juanita Chen at juanita.chen@trade.gov.

Dated: June 12, 2024.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2024-13338 Filed 6-17-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S-70-2024]

Approval of Subzone Status; Sediver USA, Inc.; West Memphis, Arkansas

On April 17, 2024, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the City of West Memphis, Arkansas Public Facilities Board, grantee of FTZ 273, requesting subzone status subject to the existing activation limit of FTZ 273, on behalf of Sediver USA, Inc., in West Memphis, Arkansas.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (89 FR 35058, May 1, 2024). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval.

Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 273B was approved on June 13, 2024, subject to the FTZ Act and the Board's regulations, including section 400.13, and further subject to FTZ 273's 2,000-acre activation limit.

Dated: June 13, 2024.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2024-13374 Filed 6-17-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-831]

Fresh Garlic From the People's Republic of China: Affirmative Final Determination of Circumvention of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that small and large garlic chunks produced in the People's Republic of China (China) and exported to the United States constitute merchandise altered in form or appearance in such minor respects that they should be included

within the scope of the antidumping duty (AD) order on fresh garlic from China. As a result, small and large garlic chunks will be subject to suspension of liquidation effective June 8, 2023.

DATES: Applicable June 18, 2024.

FOR FURTHER INFORMATION CONTACT:

Thomas Cloyd, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1246.

SUPPLEMENTARY INFORMATION:

Background

On November 14, 2023, Commerce published the *Preliminary Determination* of the circumvention inquiry of the AD order on fresh garlic from China, in which Commerce determined that imports of small and large garlic chunks from China are circumventing the *Order*.¹ We invited parties to comment on the *Preliminary Determination* and received timely filed comments and rebuttal comments from interested parties.² On April 2, 2024, Commerce extended the deadline for the final determination until June 7, 2024.³

For a complete description of events that followed the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for consideration in the final determination, *see* the Issues and Decision Memorandum.⁴ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty

Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order

The merchandise covered by the *Order* is fresh garlic from China. The subject garlic is currently classifiable under subheadings 0703.20.0005, 0703.20.0010, 0703.20.0015, 0703.20.0020, 0703.20.0000, 0703.20.0090, 0710.80.7060, 0710.80.97500, 0711.90.6000, 0711.90.6500, 2005.90.9500, 2005.90.9700, and 2005.99.9700 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the *Order* is dispositive. For a complete description of the scope of the *Order*, *see* the Issues and Decision Memorandum.

Merchandise Subject to the Circumvention Inquiry

This circumvention inquiry covers small and large garlic chunks produced in China and exported to the United States. A complete description of the merchandise subject to the circumvention inquiry is contained in the Issues and Decision Memorandum.

Methodology

Commerce is conducting this circumvention inquiry pursuant to section 781(c) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.226(j). For a complete description of the methodology underlying the final determination, *see* the Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice.

Changes Since the Preliminary Determination

All issues raised in the case and rebuttal briefs by parties in these inquiries are addressed in the Issues and Decision Memorandum. Based on our analysis of the comments received from interested parties, we made no change to the *Preliminary Determination*.

Final Circumvention Determination

As detailed in the Issues and Decision Memorandum, we determine that small and large garlic chunks produced in China and exported to the United States constitute merchandise altered in form

or appearance in such minor respects that they should be included within the scope of the *Order*, pursuant to section 781(c) of the Act and 19 CFR 351.226(j). We also determine that this affirmative circumvention finding should be applied on a country-wide basis. For a detailed explanation of our determinations with respect to small and large garlic chunks, *see* the *Preliminary Determination* PDM and the Issues and Decision Memorandum.

Suspension of Liquidation and Cash Deposit Requirements

In accordance with 19 CFR 351.226(l)(3), based on this affirmative final determination, Commerce will direct U.S. Customs and Border Protection (CBP) to continue the suspension of liquidation of previously suspended entries and to suspend liquidation and require a cash deposit of estimated duties on unliquidated entries of small and large garlic chunks produced in and exported from China that are entered, or withdrawn from warehouse, for consumption on or after June 8, 2023 (*i.e.*, the date of the publication of the *Initiation Notice*⁵). Pursuant to 19 CFR 351.226(l)(3), we will also instruct CBP to require AD cash deposit rates in effect for fresh garlic for each unliquidated entry of small and large garlic chunks produced in and exported from China that have been entered, or withdrawn from warehouse, for consumption on or after June 8, 2023 (*i.e.*, the date of the initiation of this inquiry).⁶ The suspension of liquidation instructions and cash deposit requirements will remain in effect until further notice.

Opportunity To Request an Administrative Review

Each year during the anniversary month of the publication of an AD or countervailing duty (CVD) order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Act, may request, in accordance with 19 CFR 351.213, that Commerce conduct an administrative review of that AD or CVD order, finding, or suspended investigation. An interested party who would like Commerce to conduct an administrative review should wait until Commerce announces via the **Federal Register** the next opportunity during the anniversary month of the publication of the *Order* to submit such requests. The anniversary month for this *Order* is November.

⁵ *See Fresh Garlic from the People's Republic of China: Initiation of Circumvention Inquiry on the Antidumping Duty Order*, 88 FR 37510 (June 8, 2023) (*Initiation Notice*).

⁶ *See Order*.

¹ *See Antidumping Duty Order: Fresh Garlic from the People's Republic of China*, 59 FR 59209 (November 16, 1994) (*Order*); *see also Fresh Garlic from the People's Republic of China: Preliminary Affirmative Determination of Circumvention*, 88 FR 77959 (November 14, 2023) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² *See Green Garden Produce, LLC's Letter*, "Green Garden Produce, LLC's Comments on Commerce's Preliminary Affirmative Determination of the Circumvention for Small and Large Garlic Chunks," dated December 5, 2023; *see also the Fresh Garlic Producers Association and its individual members' Letter*, "Petitioners' Rebuttal to Green Garden's Comments on Preliminary Affirmative Determination of Circumvention," dated December 19, 2023; *see also I Love Produce, LLC's Letter*, "Rebuttal Comments to Green Garden's Comments on DOC's Preliminary Affirmative Circumvention Determination," dated December 19, 2023.

³ *See Memorandum*, "Extension of Deadline for Final Results of Circumvention Inquiry," dated April 2, 2024.

⁴ *See Memorandum*, "Issues and Decision Memorandum for the Final Affirmative Circumvention Determination of the Antidumping Duty Order on Fresh Garlic from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Administrative Protective Order

This notice will serve as the only reminder to all parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(c) of the Act and 19 CFR 351.226(g)(2).

Dated: June 7, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Merchandise Subject to the Circumvention Inquiry
- V. Period of the Circumvention Inquiry
- VI. Discussion of the Issues
 - Comment 1: Whether the Inquiry Merchandise Is Excluded from the Order Due to Preservation by the Addition of Other Ingredients
 - Comment 2: Whether the Inquiry Merchandise Is Excluded from the Order by being "Further Processed"
 - Comment 3: Whether the Inquiry Merchandise Has Undergone Minor Alteration
- VII. Recommendation

[FR Doc. 2024–13378 Filed 6–17–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–980]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being

provided to producers/exporters of crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (China) during the period of review (POR) January 1, 2021, through December 31, 2021.

DATES: Applicable June 18, 2024.

FOR FURTHER INFORMATION CONTACT: Jose Rivera or Peter Shaw, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0842 or (202) 482–0697, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 22, 2024, Commerce published the preliminary results of this administrative review.¹ For a description of the events that occurred since the *Preliminary Results*, see the Issues and Decision Memorandum.²

Scope of the Order

The products covered by the order are solar cells from China.³ For a full description of the scope of the Order, see the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the parties' briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed is attached to this notice at Appendix I. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users

¹ See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission, and Rescission, in Part*; 2021, 88 FR 88575 (December 22, 2024) (*Preliminary Results*).

² See Memorandum, "Decision Memorandum for the Final Results of the Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China; 2021," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

³ See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Countervailing Duty Order*, 77 FR 73017 (December 7, 2012). On March 20, 2024, based on a changed circumstances review, Commerce amended the Order. See *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Final Results of Changed Circumstances Reviews, and Revocation of the Antidumping and Countervailing Duty Orders, in Part*, 89 FR 19809 (March 20, 2024) (*Order*).

at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRN NoticesListLayout.aspx>.

Changes Since the Preliminary Results

Based on comments received from interested parties and record information, we made certain changes from the *Preliminary Results* regarding the calculations of Chint Solar (Zhejiang) Co., Ltd. (Chint Solar) and High Hope Zhongtian Corporation's (High Hope Zhongtian) program rates. These changes are explained in the Issues and Decision Memorandum.

Methodology

Commerce conducted this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each subsidy program found countervailable, Commerce finds that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.⁴ For a description of the methodology underlying all of Commerce's conclusions, including any determination that relied upon the use of adverse facts available pursuant to section 776(a) and (b) of the Act, see the Issues and Decision Memorandum.

Companies Not Selected for Individual Review

The Act and Commerce's regulations do not directly address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. Generally, Commerce looks to section 705(c)(5) of the Act, which provides instructions for determining the all-others rate in an investigation, for guidance when calculating the rate for companies that were not selected for individual examination in an administrative review. Section 777A(e)(2) of the Act provides that "the individual countervailable subsidy rates determined under subparagraph (A) shall be used to determine the all-others rate under section 705(c)(5) {of the Act}." Under section 705(c)(5)(A) of the Act, the all-others rate is normally "an amount equal to the weighted average of the countervailable subsidy rates established for exporters and producers individually investigated, excluding any

⁴ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

zero or *de minimis* countervailable subsidy rates, and any rates determined entirely {on the basis of facts available}.”

For these final results, we calculated above *de minimis* rates for Chint Solar and High Hope. Therefore, for the remaining companies under review, we calculated the rate for the non-examined companies using a weighted average of the individual subsidy rates calculated for the two mandatory respondents, which is 9.07 percent *ad valorem*.⁵ See Appendix II for a complete list of these companies.

Final Results of Review

In accordance with 19 CFR 351.221(b)(5), we determine that, for the period January 1, 2021, through December 31, 2021, the following net countervailable subsidy rates exist:

Producer/exporter	Subsidy rate (percent <i>ad valorem</i>)
Chint Solar (Zhejiang) Co., Ltd. ⁶	29.55
High Hope Zhongtian Corporation ⁷	3.27
Non-Selected Companies Under Review ⁸	9.07

Disclosure

Commerce intends to disclose the calculations and analysis performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to sections 751(a)(1) and (a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

⁵ See Memorandum, “Calculation of the Non-Selected Rate for the Final Results: 2021,” dated concurrently and hereby adopted by this notice.

⁶ This rate applies to Chint Solar (Zhejiang) Co., Ltd. and its cross-owned companies: Chint New Energy Technology Co., Ltd.; Haining Chint Solar Energy Technology Co., Ltd.; Chint New Energy Technology (Yancheng) Co., Ltd.; Chint Solar (Yancheng) Co., Ltd.; Jiuquan Chint New Energy Technology Co., Ltd.; Chint Group Co., Ltd.; Zhejiang Chint Electrics Co., Ltd.; Zhejiang Chint New Energy Development Co., Ltd.; Chint Solar (Jiuquan) Co., Ltd.; and Chint Solar (Shanghai) Co., Ltd.

⁷ This rate applies to High Hope Zhongtian Corporation and its cross-owned companies: Jiangsu Highhope International Group Corporation and Jiangsu Suhui Asset Management Co., Ltd.

⁸ See Appendix II of this notice for a list of all companies that remain under review but were not selected for individual examination and to which Commerce has assigned the non-examined company rate.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(1) and (a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for the companies listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, effective upon publication of these final results, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing the final results and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: June 12, 2024.

Ryan Majerus,
Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order

- IV. Rate for Non-Selected Companies Under Review
- V. Use of Facts Available and Application of Adverse Inferences
- VI. Changes Since the Preliminary Results
- VII. Subsidies Valuation Information
- VIII. Analysis of Programs
- IX. Discussion of the Issues
 - Comment 1: Whether Commerce Should Apply Adverse Facts Available to the Export Buyers Credit Program
 - Comment 2: Whether Commerce Should Change the Ocean Freight Benchmark
 - Comment 3: Whether Commerce Should Revise its Benefit Calculation for the Preferential Policy Lending Program
 - Comment 4: Whether the Tax Exemptions Under the Article 26(2) of the Enterprise Income Tax Law Program is Countervailable
 - Comment 5: Whether Commerce Should Revise the Benchmark for Electricity for Less than Adequate Remuneration (LTAR)
 - Comment 6: Whether Commerce Should Change the Inland Freight Values Used for the Benefit Calculation of the Provision of Solar Glass, Aluminum Extrusions, and Silicon Wafers for LTAR Programs
 - Comment 7: Whether Chint Electrics Was Uncreditworthy in Certain Years
 - Comment 8: Whether Commerce Should Revise Chint Solar's Sales Denominators
 - Comment 9: Whether Commerce Should Revise its Attribution Calculation for Anhui Uzon
 - Comment 10: Whether Commerce Made Errors in Chint Solar's Preliminary Calculation
- X. Recommendation

Appendix II

Non-Examined Companies Under Review

- 1. Anji Dasol Solar Energy Science & Technology Co., Ltd.
- 2. Baoding Jiasheng Photovoltaic Technology Co. Ltd.
- 3. BYD (Shangluo) Industrial Co., Ltd.; BYD H.K. CO., Ltd.; Shanghai BYD Co., Ltd.
- 4. Chint Solar (Hong Kong) Company Limited.
- 5. Baotou JA Solar Technology Co., Ltd.; Beijing JA Solar PV Technology Co., Ltd.; Beijing Jinfeng Investment Co., Ltd.; Donghai JA Solar Technology Co., Ltd.; Donghai JingAo Solar Energy Science and Technology Co., Ltd.; Hebei Jingle Optoelectronic Technology Co., Ltd.; Hebei Jinglong New Materials Technology Group Co., Ltd.; Hebei Jinglong Sun Equipment Co. Ltd.; Hebei Ningjin Songgong Semiconductor Co., Ltd.; Hebei Ningtong Electronic Materials Co., Ltd.; Hebei Ningtong Electronic Materials Co., Ltd.; Hebei Yujing Electronic Science and Technology Co., Ltd.; Hefei JA Solar Technology Co., Ltd.; JA (Hefei) Renewable Energy Co., Ltd; JA PV Technology Co., Ltd.; JA Solar (Xingtai) Co., Ltd.; JA Solar Investment China Co., Ltd; JA Solar Technology Co., Ltd.; JA Solar Technology Yangzhou Co., Ltd.; Jing Hai Yang Semiconductor Material (Donghai) Co., Ltd.; JingAo Solar Co., Ltd.; Jinglong Industry and Commerce Group Co., Ltd.;

Jinglong Technology Holdings Co., Ltd.; Jingwei Electronic Materials Co., Ltd.; Ningjin County Jing Tai Fu Technology Co., Ltd.; Ningjin County Jingyuan New Energy Investment Co., Ltd.; Ningjin Guiguang Electronics Investment Co., Ltd.; Ningjin Jinglong PV Industry Investment Co., Ltd.; Ningjin Jingxing Electronic Material Co., Ltd.; Ningjin Longxin Investment Co., Ltd.; Ningjin Saimei Ganglong Electronic Materials Co., Ltd.; Ningjin Songgong Electronic Materials Co., Ltd.; Shanghai JA Solar Technology Co., Ltd.; Solar Silicon Peak Electronic Science and Technology Co., Ltd.; Solar Silicon Valley Electronic Science and Technology Co., Ltd.; Taicang Juren PV Material Co., Ltd.; Xingtai Jinglong Electronic Material Co., Ltd.; Xingtai Jinglong New Energy Co., Ltd.; Xingtai Jinglong PV Materials Co., Ltd.

6. Jinko Solar Co., Ltd.; Jinko Solar Import and Export Co., Ltd.; Jiangxi Jinko Photovoltaic Materials Co., Ltd.; Jinko Solar Technology (Haining) Co., Ltd.; JinkoSolar (Chuzhou) Co., Ltd.; JinkoSolar (Shangrao) Co., Ltd.; JinkoSolar (Sichuan) Co., Ltd.; JinkoSolar (Yiwu) Co., Ltd.; Ruixu Industrial Co., Ltd.; Xinjiang Jinko Solar Co., Ltd.; Yuhuan Jinko Solar Co., Ltd.; Zhejiang Jinko Solar Co., Ltd.; Jinko Solar (Shanghai) Management Co., Ltd.
7. LONGi Solar Technology Co., Ltd.
8. Shanghai Nimble Co., Ltd.
9. Shenzhen Sungold Solar Co., Ltd.
10. Toenergy Technology Hangzhou Co., Ltd.
11. Trina Solar Science & Technology (Thailand) Ltd.; Changzhou Trina PV Ribbon Materials Co., Ltd.; Changzhou Trina Solar Energy Co., Ltd. (a.k.a. Trina Solar Co., Ltd.); Changzhou Trina Solar Yabang Energy Co., Ltd.; Hubei Trina Solar Energy Co., Ltd.; Trina Solar (Changzhou) Science and Technology Co., Ltd.; Trina Solar Co., Ltd.; Turpan Trina Solar Energy Co., Ltd.; Yancheng Trina Solar Energy Technology Co., Ltd.
12. Wuxi Suntech Power Co., Ltd.
13. Yancheng Trina Solar Energy Technology Co., Ltd.
14. Yingli Energy (China) Co., Ltd.

[FR Doc. 2024–13377 Filed 6–17–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–920]

Lightweight Thermal Paper From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain companies subject to the administrative review of the antidumping duty order on

lightweight thermal paper (paper) from the People's Republic of China (China) are part of the China-wide entity because they did not file a separate rate application (SRA). The period of review (POR) is November 1, 2022, through October 31, 2023. We invite interested parties to comment on these preliminary results.

DATES: Applicable June 18, 2024.

FOR FURTHER INFORMATION CONTACT: Alex Cipolla, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4956.

SUPPLEMENTARY INFORMATION:

Background

On November 2, 2023, Commerce published a notice of opportunity to request an administrative review of the antidumping duty order on paper from China.¹ On November 30, 2023, Lollicup USA Incorporated (Lollicup), a U.S. importer of subject merchandise, requested an administrative review of the following producers and/or exporters of subject merchandise: Guangdong Guanhao High-Tech (Guangdong Guanhao), Guangdong Polygon New Materials (Guangdong Polygon), and Henan Jianghe Paper (Henan Jianghe).² On December 29, 2023, Commerce initiated this administrative review of the *Order* for the period of review (POR) November 1, 2022, through October 31, 2023.³

In the *Initiation Notice*, Commerce notified parties that the deadline for interested parties to submit an SRA or separate rate certification (SRC) was January 29, 2024.⁴ No party submitted an SRA or an SRC. On July 20, 2023, we placed on the record U.S. Customs and Border Protection (CBP) data for entries of paper from China and invited interested parties to comment.⁵ No party commented on the CBP Data Memorandum. The deadline for the

¹ See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List*, 88 FR 75270 (November 2, 2023); see also *Antidumping Duty Orders: Lightweight Thermal Paper from Germany and the People's Republic of China*, 73 FR 70959 (November 24, 2008) (*Order*).

² See Lollicup's Letter, "Administrative Review Request," dated November 30, 2023.

³ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 88 FR 90168 (December 23, 2023) (*Initiation Notice*).

⁴ *Id.*, 88 FR at 90169–70, specifying that SRAs and SRCs were due 30 days from the publication of Commerce's *Initiation Notice*. In this administrative review, the deadline was January 29, 2024.

⁵ See Memorandum, "Release of U.S. Customs and Border Protection Data," dated March 11, 2024 (CBP Data Memorandum).

preliminary results of this review is August 1, 2024.

Scope of the Order

The products covered by this *Order* includes certain lightweight thermal paper, which is thermal paper with a basis weight of 70 grams per square meter (g/m²) (with a tolerance of ± 4.0 g/m²) or less; irrespective of dimensions;⁶ with or without a base coat⁷ on one or both sides; with thermal active coating(s)⁸ on one or both sides that is a mixture of the dye and the developer that react and form an image when heat is applied; with or without a top coat;⁹ and without an adhesive backing. Certain lightweight thermal paper is typically (but not exclusively) used in point-of-sale applications such as ATM receipts, credit card receipts, gas pump receipts, and retail store receipts. The merchandise subject to this order may be classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3703.10.60, 4811.59.20, 4811.90.8040, 4811.90.9090, 4811.10.20, 4823.40.00, 4811.90.8030, 4811.90.8050,

4811.90.9030, and 4811.90.9050.^{10 11} Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this *Order* is dispositive.

⁶ LWTP is typically produced in jumbo rolls that are slit to the specifications of the converting equipment and then converted into finished slit rolls. Both jumbo and converted rolls (as well as LWTP in any other form, presentation, or dimension) are covered by the scope of these orders.

⁷ A base coat, when applied, is typically made of clay and/or latex and like materials and is intended to cover the rough surface of the paper substrate and to provide insulating value.

⁸ A thermal active coating is typically made of sensitizer, dye, and co-reactant.

⁹ A top coat, when applied, is typically made of polyvinyl acetone, polyvinyl alcohol, and/or like materials and is intended to provide environmental protection, an improved surface for press printing, and/or wear protection for the thermal print head.

¹⁰ HTSUS subheading 4811.90.8000 was a classification used for LWTP until January 1, 2007. Effective that date, subheading 4811.90.8000 was replaced with 4811.90.8020 (for gift wrap, a non-subject product) and 4811.90.8040 (for "other" including LWTP). HTSUS subheading 4811.90.9000 was a classification for LWTP until July 1, 2005. Effective that date, subheading 4811.90.9000 was replaced with 4811.90.9010 (for tissue paper, a non-subject product) and 4811.90.9090 (for "other," including LWTP).

¹¹ As of January 1, 2009, the ITC deleted HTSUS subheadings 4811.90.8040 and 4811.90.9090 and added HTSUS subheadings 4811.90.8030, 4811.90.8050, 4811.90.9030, and 4811.90.9050 to the HTSUS (2009). See Harmonized Tariff Schedule of the United States (2009), available at www.usitc.gov. These HTSUS subheadings were added to the scope of the order in lightweight thermal paper's LTFV investigation.

Preliminary Results of Review

In the *Initiation Notice*, Commerce notified interested parties that SRCs or SRAs, as applicable, are due to Commerce no later than 30 calendar days after publication of the *Initiation Notice* in the **Federal Register**.¹² No party for which a review was requested submitted the requisite SRC or SRA. As such, Commerce finds that all companies for which a review was requested (Guangdong Guanbao, Guangdong Polygon, and Henan Jianghe) have failed to demonstrate eligibility for a separate rate and are part of the China-wide entity.

Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative review.¹³ Accordingly, the China-wide entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the entity. In this administrative review, no party requested a review of the China-wide entity. Moreover, we have not self-initiated a review of the China-wide entity. Because no review of the China-wide entity is being conducted, the China-wide entity's entries are not subject to the review, and the weighted-average dumping margin for the China-wide entity rate (*i.e.*, 115.29 percent) is not subject to change.¹⁴

Disclosure and Public Comment

Normally, Commerce discloses the calculations used in its analysis to parties performed in preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary results, in accordance with 19 CFR 351.224(b). However, because all parties subject to this review have failed to demonstrate eligibility for a separate rate and are part of the China-wide entity, there are no calculations to disclose.

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.¹⁵ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table

of contents listing each issue; and (2) a table of authorities.¹⁶

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹⁷ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁸

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via Enforcement and Compliance's Antidumping and CVD Centralized Electronic Service System (ACCESS). Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.

Final Results of Review

Unless extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case and rebuttal briefs, within 120 days of publication of these preliminary results in the **Federal Register**.¹⁹

¹⁶ See 19 CFR 351.309(c)(2) and (d)(2).

¹⁷ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹⁸ See *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule*, 88 FR 67069 (September 29, 2023).

¹⁹ See section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act); and 19 CFR 351.213(h).

Assessment

For the three companies subject to this review, upon issuance of the final results of this review, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review.²⁰ If Commerce continues to find that Guangdong Guanbao, Guangdong Polygon, and Henan Jianghe are part of the China-wide entity in the final results, Commerce intends to instruct CBP to liquidate entries containing subject merchandise exported by the companies under review that we determine in the final results to be part of the China-wide entity at the China-wide entity rate of 115.29 percent. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) for previously investigated or reviewed Chinese and non-Chinese exporters for which a review was not requested and that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (2) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity; and (3) for all non-Chinese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping and/

²⁰ See 19 CFR 351.212(b)(1).

¹² See *Initiation Notice*, 88 FR at 90169–70.

¹³ See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963, 65969–70 (November 4, 2013).

¹⁴ See *Order*, 73 FR at 70959.

¹⁵ See 19 CFR 351.309(d).

or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of countervailing duties.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 19 CFR 351.221(b)(4).

Dated: June 11, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–13376 Filed 6–17–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE033]

Pacific Island Fisheries; Western Pacific Stock Assessment Review; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Western Pacific Fishery Management Council (Council) and NMFS will convene a Western Pacific Stock Assessment Review (WPSAR) of the fishery dependent and life history data that will be used in the future benchmark stock assessment for the multispecies bottomfish complex in Guam.

DATES: The WPSAR meeting will be held July 8–12, 2024, Chamorro Standard Time (ChST).

ADDRESSES: The meeting will be held at The Gallery Room at the Guam Hilton Resort and Spa (202 Hilton Road, Tumon Bay, 96913 Guam) and by web conference via WebEx. Audio and visual portions for all of the web conferences can be accessed at: <https://wprfmc.webex.com/wprfmc/j.php?MTID=m1b55573461dbde5ff36edc0bd66f4c>. Web conference access information and instructions for providing public comments will be posted on the Council website at www.wpcouncil.org. For

assistance with the web conference connection, contact the Council office at (808) 552–8220.

FOR FURTHER INFORMATION CONTACT:

Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: The NMFS Pacific Islands Fisheries Science Center (PIFSC) is developing a benchmark stock assessment for the bottomfish management unit species (BMUS) in the U.S. territory of Guam. Consistent with National Standard 2 of the Magnuson-Stevens Fishery Conservation and Management Act, the WPSAR Policy requires a review of the data, on an as-needed basis, that will be used in the benchmark stock assessment. The peer-review of the data will provide the analyst with the guidance on the utility and limitations of the available data for use in the assessment. This review is necessary to determine what modeling framework can be applied to the data moving towards the next benchmark.

Meeting Agenda for WPSAR Review

The meeting schedule and agenda are as follows:

Monday, July 8, 2024 (8:30 a.m.–5 p.m., ChST)

1. Introductions
2. Background on Guam bottomfish data WPSAR
3. WPSAR Terms of Reference
4. Presentation of catch estimation data, and panel discussion

6 p.m.–7 p.m.

5. End of day summary for catch estimation data
6. Public Comment

Tuesday, July 9, 2024 (9 a.m.–5 p.m., ChST)

7. Presentation of catch per unit effort (CPUE) data, and panel discussion

6 p.m.–7 p.m.

8. End of day summary for CPUE data
9. Public comment

Wednesday, July 10, 2024 (9 a.m.–5 p.m., ChST)

10. Presentation of length composition data, and panel discussion

6 p.m.–8 p.m.

11. Summary of catch estimate, CPUE, and length composition
12. Public comment

Thursday, July 11, 2024 (9 a.m.–5 p.m., ChST)

13. Presentation of life history data, and panel discussion

6 p.m.–7 p.m.

14. End of day summary for life history
15. Public comment

Friday, July 12, 2024 (9 a.m.–3 p.m., ChST)

16. Data Review Panel discussions (closed to the public)

3 p.m.–5 p.m.

17. Data review results and recommendations

6 p.m.–7 p.m.

18. End of day summary for results and recommendations
19. Public comment
20. Closing comments and adjourn

Special Accommodations

This meeting is physically accessible to people with disabilities. Please direct requests for sign language interpretation or other auxiliary aids to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: June 12, 2024.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–13346 Filed 6–17–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD978]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Site Characterization Surveys Offshore From Massachusetts to New Jersey for Vineyard Northeast, LLC

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

ACTION: Notice; request for comments on proposed renewal incidental harassment authorization (IHA).

SUMMARY: NMFS received a request from Vineyard Northeast, LLC (Vineyard Northeast) for the renewal of their currently active incidental harassment authorization (IHA) (hereafter, the “Project”) to take marine mammals incidental to marine site characterization surveys offshore from Massachusetts to New Jersey in the Bureau of Ocean Energy Management (BOEM) Commercial Lease of Submerged Lands for Renewable Energy

Development on the Outer Continental Shelf Lease Areas OCS-A 0522 and OCS-A 0544 (Lease Areas) and associated offshore export cable corridor (OECC) routes. The proposed action is a subset of the survey efforts that were previously authorized but were not yet completed under the currently active IHA, which will soon expire. Pursuant to the Marine Mammal Protection Act, prior to issuing the currently active IHA, NMFS requested comments on both the proposed IHA and the potential for renewing the initial authorization if certain requirements were satisfied. The renewal requirements have been satisfied, and NMFS is now providing an additional 15-day public comment period to allow for any additional comments on the proposed renewal not previously provided during the initial 30-day comment period.

DATES: Comments and information must be received no later than July 3, 2024.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to ITP.Taylor@noaa.gov.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

Jessica Taylor, Office of Protected Resources, NMFS, (301) 427-8401. Electronic copies of the original application and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable>. In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The Marine Mammal Protection Act (MMPA) prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, an incidental harassment authorization is issued.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as “mitigation measures”). Monitoring and reporting of such takings are also required. The meaning of key terms such as “take,” “harassment,” and “negligible impact” can be found in section 3 of the MMPA (16 U.S.C. 1362) and the agency’s regulations at 50 CFR 216.103.

NMFS’ regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed 1 year for each reauthorization. In the notice of proposed IHA for the initial IHA, NMFS described the circumstances under which we would consider issuing a renewal for this activity, and requested public comment on a potential renewal under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a 1-time 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical, or nearly identical, activities as described in the Detailed Description of Specified Activities section of the initial IHA issuance notice is planned or (2) the activities as described in the Description of the Specified Activities and Anticipated Impacts section of the initial IHA issuance notice would not be completed by the time the initial IHA

expires and a renewal would allow for completion of the activities beyond that described in the **DATES** section of the notice of issuance of the initial IHA, provided all of the following conditions are met:

1. A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA).

2. The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (e.g., reduced effort) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

- A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed renewal. A description of the renewal process may be found on our website at: www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals. Any comments received on the potential renewal, along with relevant comments on the initial IHA, have been considered in the development of this proposed IHA renewal, and a summary of agency responses to applicable comments is included in this notice. NMFS will consider any additional public comments prior to making any final decision on the issuance of the requested renewal, and agency responses will be summarized in the final notice of our decision.

National Environmental Policy Act

This action is consistent with categories of activities identified in

Categorical Exclusion B4 (incidental take authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS determined that the issuance of the initial IHA qualified to be categorically excluded from further NEPA review. NMFS has preliminarily determined that the application of this categorical exclusion remains appropriate for this renewal IHA.

History of Request

On July 27, 2022, NMFS issued an IHA (hereafter, referred to as the 2022 IHA) to Vineyard Northeast to take marine mammals incidental to marine site characterization surveys offshore from Massachusetts to New Jersey, in the BOEM Lease Areas OCS–A 0522 and OCS–A 0544 (Lease Areas) and potential OECC routes to landfall locations, effective from July 27, 2022 through July 26, 2023 (87 FR 52913, August 30, 2022). On April 23, 2023, NMFS received a request from Vineyard Northeast to issue an IHA to take marine mammals incidental to continued marine site characterization surveys offshore from Massachusetts to New Jersey, in the BOEM Lease Areas and potential OECC routes. Although the IHA renewal requirements were otherwise satisfied, NMFS determined that the availability of updated marine mammal density data (Roberts *et al.*, 2023), upon which the take estimates were based, for all species in the Project Area warranted updated analysis and, therefore, the issuance of a new IHA (hereafter, referred to as the 2023 IHA) instead of a renewal IHA, as described in the **Federal Register** notice for the proposed 2023 IHA (88 FR 40212, June 21, 2023). The 2023 IHA, *i.e.* the initial IHA, which is here proposed for renewal, was issued to Vineyard Northeast with effective dates of July 27, 2023 through July 26, 2024 (88 FR 50117, August 1, 2023). Due to unanticipated delays, Vineyard Northeast will not be able to complete the surveys before the expiration date.

Accordingly, on April 29, 2024, NMFS received a request from Vineyard Northeast for the renewal of the 2023 IHA. The activities for which incidental take is requested consist of a subset of the identical activities covered in the 2023 IHA. As required, Vineyard Northeast also provided a preliminary

monitoring report, which demonstrates that they have implemented the required marine mammal mitigation and monitoring and did not exceed the levels of take authorized under the previously issued IHA (88 FR 50117, August 1, 2023). These monitoring results are available to the public on our website: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable>.

Description of the Proposed Specified Activity and Anticipated Impacts

Vineyard Northeast's 2023 IHA authorized take of marine mammals incidental to marine site characterization surveys, including high-resolution geophysical (HRG) surveys, offshore from Massachusetts to southern New Jersey, specifically within the BOEM Lease Areas OCS–A 0522 and OCS–A 0544, and along potential submarine OECCs. The purpose of these surveys are to obtain an assessment of seabed (geophysical, geotechnical, and geohazard), ecological, and archeological conditions within the footprint of the planned offshore wind facility development area. Surveys are also conducted to inform and support engineering design and to map unexploded ordnance. While actively surveying, the vessel operates at a maximum speed of 4 knots (4.6 miles per hour (mph) or 7.4 km per hour (km/h)). The Vineyard Northeast's 2023 IHA survey plan included 37,360 km of track line over 467 survey days. However, in 2023, Vineyard Northeast completed only 860 km of track line over 11 survey days, representing approximately 2 percent of the total planned survey effort.

Under the requested renewal IHA, Vineyard Northeast is proposing to continue to conduct survey activities over the remaining approximately 36,500 km of track line that was not completed in 2023. These surveys would be conducted over up to approximately 456 survey days using a maximum of 4 vessels operating concurrently within the Lease Areas and OECCs. A “survey day” is defined as a 24-hour (hr) activity period in which active HRG acoustic sources are used. This schedule is inclusive of any inclement weather downtime and crew transfers. The number of survey days is calculated as the number of days needed to reach the overall level of effort required to meet survey objectives assuming any single vessel covers, on average, 80 km (49.7 miles) of survey track line per 24 hours of operations.

The potential impacts of Vineyard Northeast's proposed activities on

marine mammals could involve acoustic stressors and are unchanged from the impacts described in the **Federal Register** notice for the proposed 2023 IHA (88 FR 40212, June 21, 2023), which relies upon information in the notice of the proposed 2022 IHA (87 FR 30872, May 20, 2022). Underwater sound, resulting from Vineyard Northeast's activities, has the potential to result in incidental take of marine mammals, in the form of Level B harassment only, in the specified geographic region.

This proposed renewal IHA is for the remainder of work that will not be completed by the expiration date of the 2023 IHA. The renewal IHA would authorize incidental take, by Level B harassment only of 19 species (comprising 20 stocks) of marine mammals for a subset of marine site characterization survey activities to be completed in 1 year, in the same area, using survey methods identical to those conducted under the 2023 IHA. Neither Vineyard Northeast nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate. Take by Level A harassment (injury) is unlikely, even absent mitigation, based on the characteristics of the signals produced by the acoustic sources planned for use. Therefore, the anticipated effects on marine mammals and the affected stocks also remain the same. All mitigation, monitoring, and reporting measures would remain exactly as described in the **Federal Register** notice for the issued 2023 IHA (88 FR 50117, August 1, 2023) and the notice of the proposed 2022 IHA (87 FR 52913, August 30, 2022).

Detailed Description of the Proposed Action

A summary description of the marine site characterization survey activities for which incidental take is proposed here may be found in the **Federal Register** notice for the proposed 2023 IHA (88 FR 40212, June 21, 2023), which relies upon information in the notice of the proposed 2022 IHA (87 FR 30872, May 20, 2022). The specific geographic region and specified activities, including the types of survey equipment and number of survey vessels planned for use, are identical to those described in the previous notices, with the exception of the reduction in the size of the proposed survey area since a small subset of the survey work authorized under the 2022 IHA was completed. The proposed renewal would be effective for a period not exceeding 1 year from the date of expiration of the 2023 IHA.

Description of Marine Mammals

A description of the marine mammals in the proposed survey area may be found in the **Federal Register** notice for the proposed 2023 IHA (88 FR 40212, June 21, 2023), which relies upon information in the notice of the proposed 2022 IHA (87 FR 30872, May 20, 2022). After the 2023 IHA was issued, NMFS released its draft 2023 stock assessment reports (SARs). NMFS has reviewed the draft 2023 SARs, which included updates to certain stock abundances estimates, information on relevant unusual mortality events (UME), and other scientific literature. The draft 2023 SAR updated the population estimate (N_{best}) of North Atlantic right whales from 338 to 340 and annual mortality and serious injury from 31.2 to 27.2. The updated population estimate in the draft 2023 SAR is based upon sighting history through December 2021 (89 FR 5495, January 29, 2024). Total annual average observed North Atlantic right whale mortality during the period 2017–2021 was 7.1 animals and annual average observed fishery mortality was 4.6 animals, however, estimates of 27.2 total mortality and 17.6 fishery mortality account for undetected mortality and serious injury (89 FR 5495, January 29, 2024). In October 2023, NMFS released a technical report identifying that the North Atlantic right whale population size based on sighting history through 2022 was 356 whales, with a 95 percent credible interval ranging from 346 to 363 (Linden, 2023). NMFS conservatively relies on the lower SAR abundance estimate. NMFS has determined that neither this nor any other new information affects which species or stocks have the potential to be affected or any other pertinent information in the Description of the Marine Mammals in the Area of Specified Activities contained in the

supporting documents for the 2023 and 2022 IHAs.

On August 1, 2022, NMFS announced proposed changes to the existing North Atlantic right whale vessel speed regulations to further reduce the likelihood of mortalities and serious injuries to endangered North Atlantic right whales from vessel collisions, which are a leading cause of the species' decline and a primary factor in an ongoing UME (87 FR 46921, August 1, 2022). Should a final vessel speed rule be issued and become effective during the effective period of this proposed renewal IHA (or any other MMPA incidental take authorization), the authorization holder would be required to comply with any and all applicable requirements contained within the final rule. Specifically, where measures in any final vessel speed rule are more protective or restrictive than those in this or any other MMPA authorization, authorization holders would be required to comply with the requirements of the rule. Alternatively, where measures in this or any other MMPA authorization are more restrictive or protective than those in any final vessel speed rule, the measures in the MMPA authorization would remain in place. These changes would become effective immediately upon the effective date of any final vessel speed rule and would not require any further action on NMFS's part.

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which an authorization of incidental take is proposed here may be found in the notice of the proposed IHA for the 2022 IHA (87 FR 30872, May 20, 2022), which is relied upon in the notice for the proposed 2023 IHA (88 FR 40212, June 21, 2023). NMFS has reviewed the monitoring data from the

2023 IHA, recent draft SARs, information on relevant UMEs, and other scientific literature, and determined that there is no new information that affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods used to estimate take for the specified activity are found in the notices of the proposed and final IHA for the 2022 IHA (87 FR 30872, May 20, 2022; 87 FR 52913, August 30, 2022) and summarized in the Notices of the proposed and final IHA for the 2023 IHA (88 FR 40212, June 21, 2023; 88 FR 50117, August 1, 2023). The methods of estimating take are identical to those used in the 2022 IHA and 2023 IHA (88 FR 40212, June 21, 2023). Specifically, the source levels, stocks taken, methods of take, and types of take remain unchanged from the 2022 IHA and 2023 IHA. In 2023, Vineyard Northeast updated the marine mammal densities based on new information (Roberts *et al.*, 2016; Roberts *et al.*, 2023), available online at: <https://seamap.env.duke.edu/models/Duke/EC/>. We refer the reader to table 8 in Vineyard Northeast's 2023 IHA request for the specific density values used in the analysis. The IHA request is available online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-vineyard-northeast-llcs-marine-site-characterization-survey>. The marine mammal density/occurrence data applicable to this renewal authorization remains unchanged from the 2023 IHA. The number of takes proposed for authorization are a subset of the initial authorized takes that better represent the amount of the remaining activity Vineyard Northeast has left to complete. These estimated takes, which reflect the remaining survey days, are indicated below in table 1.

TABLE 1—PROPOSED NUMBER OF TAKES BY LEVEL B HARASSMENT BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK

Species	Scientific name	Stock	Abundance	2023 IHA authorized take	2024 proposed renewal IHA	
					Take proposed for authorization ¹	Max percent population
Blue whale	<i>Balaenoptera musculus</i>	Western North Atlantic	402	1	1	0.25
North Atlantic right whale	<i>Eubalaena glacialis</i>	Western North Atlantic	340	12	12	3.52
Humpback whale	<i>Megaptera novaeangliae</i>	Gulf of Maine	1,396	12	12	0.86
Fin whale	<i>Balaenoptera physalus</i>	Western North Atlantic	6,802	20	20	0.29
Sei whale	<i>Balaenoptera borealis</i>	Nova Scotia	6,292	5	5	0.08
Minke whale	<i>Balaenoptera acutorostrata</i>	Canadian Eastern Coastal	21,968	46	45	0.21
Sperm whale	<i>Physeter macrocephalus</i>	North Atlantic	5,895	2	2	0.03
Long-finned pilot whale ¹	<i>Globicephala melas</i>	Western North Atlantic	39,215	17	17	0.04
Killer whale ^{2,3}	<i>Orcinus orca</i>	Western North Atlantic	UNK	4	4	⁴ 5.97
False killer whale ²	<i>Pseudorca crassidens</i>	Western North Atlantic	1,298	5	5	0.39
Atlantic spotted dolphin ³	<i>Stenella frontalis</i>	Western North Atlantic	31,506	29	29	0.09
Atlantic white-sided dolphin	<i>Lagenorhynchus acutus</i>	Western North Atlantic	93,233	129	126	0.14

TABLE 1—PROPOSED NUMBER OF TAKES BY LEVEL B HARASSMENT BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK—Continued

Species	Scientific name	Stock	Abundance	2023 IHA authorized take	2024 proposed renewal IHA	
					Take proposed for authorization ¹	Max percent population
Bottlenose dolphin	<i>Tursiops truncatus</i>	Western North Atlantic North-ern Migratory Coastal.	6,639	45	44	0.66
Western North Atlantic Off-shore.	64,587	169	165	0.26		
Common dolphin	<i>Delphinus delphis</i>	Western North Atlantic	93,100	7,472	7,296	7.84
Risso's dolphin	<i>Grampus griseus</i>	Western North Atlantic	44,067	9	9	0.02
White-beaked dolphin ^{2,3}	<i>Lagenorhynchus albirostris</i>	Western North Atlantic	536,016	30	30	0.006
Harbor porpoise	<i>Phocoena phocoena</i>	Gulf of Maine/Bay of Fundy	85,765	347	339	0.40
Harbor seal ⁵	<i>Phoca vitulina</i>	Western North Atlantic	61,336	939	917	1.49
Gray seal ⁵	<i>Halichoerus grypus</i>	Western North Atlantic	⁶ 27,911	418	408	0.09

¹ Roberts *et al.* (2023) only provides density estimates for pilot whales as a guild. Given the project's location, NMFS assumes that all take will be of long-finned pilot whales.

² Rare (or unlikely to occur) species.

³ Adjusted according to average group size (Kraus *et al.*, 2016; Palka *et al.*, 2017).

⁴ Based upon minimum population estimate of 67 individual killer whales identified in the Northwestern Atlantic Ocean (Lawson and Stevens, 2014).

⁵ Roberts *et al.* (2023) only provides a density estimate for seals as a guild. Vineyard Wind used Protected Species Observer (PSO) data collected during site characterization surveys within the survey area (2019, 2022–2024) to scale density-based exposure estimates for the seal guild for harbor and gray seals.

⁶ NMFS' stock abundance estimate (and associated PBR value) applies to U.S. population only. Total stock abundance (including animals in Canada) is approximately 451,600.

Description of Proposed Mitigation, Monitoring and Reporting Measures

The mitigation, monitoring, and reporting measures proposed here are identical to those included in the **Federal Register** notices announcing the issuance of the 2023 IHA (88 FR 50117, August 1, 2023) and the 2022 IHA (87 FR 52913, August 30, 2022). In addition, the discussion of the least practicable adverse impact included in those documents as well as the notice of the proposed IHAs for 2022 (87 FR 30872, May 20, 2022) and 2023 (88 FR 40212, August 1, 2023) remains accurate. NMFS proposes the following measures for this renewal IHA:

Establishment of Shutdown Zones—Marine mammal shutdown zones must be established around the HRG survey equipment and monitored by NMFS-approved PSOs during HRG surveys as follows:

- 500-meter (m) shutdown zone for North Atlantic right whales during use of specified acoustic sources (impulsive: sparkers and boomers; non-impulsive: non-parametric sub-bottom profilers); and
- 100-m shutdown zone for all other marine mammals (excluding North Atlantic right whales) during operation of the sparker and boomer. The only exception for this is for pinnipeds (seals) and small delphinids (*i.e.*, those from the genera *Delphinus*, *Lagenorhynchus*, *Stenella* or *Tursiops*).

If a marine mammal is detected approaching or entering the shutdown zones during the HRG survey, the vessel operator would adhere to the shutdown procedures described below to minimize noise impacts on the animals. During use of acoustic sources with the

potential to result in marine mammal harassment (sparkers, boomers, and non-parametric sub-bottom profilers; *i.e.*, anytime the acoustic source is active, including ramp-up), occurrences of marine mammals outside the shutdown zones must be communicated to the vessel operator to prepare for potential shutdown of the acoustic source.

Visual Monitoring—Monitoring must be conducted by NMFS-approved PSOs with minimum qualifications described in the **Federal Register** notices 2023 Proposed and Final IHAs (88 FR 40212, June 21, 2023; 88 FR 50117, August 1, 2023). Vineyard Northeast must have one PSO on duty during the day and a minimum of two NMFS-approved PSOs must be on duty and conducting visual observations when HRG equipment is in use at night. Visual monitoring must begin no less than 30 minutes prior to ramp-up of HRG equipment and continue until 30 minutes after use of the acoustic source. PSOs must establish and monitor the applicable clearance zones, shutdown zones, and vessel separation distances as described in the 2022 IHA (87 FR 52913, August 30, 2022). PSOs must coordinate to ensure 360-degree visual coverage around the vessel from the most appropriate observation posts, and must conduct observations while free from distractions and in a consistent, systematic, and diligent manner. PSOs are required to estimate distances to observed marine mammals. It is the responsibility of the Lead PSO on duty to communicate the presence of marine mammals as well as to communicate action(s) that are necessary to ensure

mitigation and monitoring requirements are implemented as appropriate.

Pre-Start Clearance—Marine mammal clearance zones must be established around the HRG survey equipment and monitored by NMFS-approved PSOs prior to use of boomers, sparkers, and non-parametric sub-bottom profilers as follows:

- 500-m clearance zone for all Endangered Species Act-listed species; and
- 100-m clearance zone for all other marine mammals.

Prior to initiating HRG survey activities, Vineyard Northeast must implement a 30-minute pre-start clearance period. The operator must notify a designated PSO of the planned start of ramp-up where the notification time should not be less than 60 minutes prior to the planned ramp-up to allow the PSOs to monitor the clearance zones for 30 minutes prior to the initiation of ramp-up. Prior to ramp-up beginning, Vineyard Northeast must receive confirmation from the PSO that the clearance zones are clear prior to preceding. Any PSO on duty has the authority to delay the start of survey operations if a marine mammal is detected within the applicable pre-start clearance zones.

During this 30-minute period, the entire clearance zone must be visible. The exception to this would be in situations where ramp-up must occur during periods of poor visibility (inclusive of nighttime) as long as appropriate visual monitoring has occurred with no detections of marine mammals in 30 minutes prior to the beginning of ramp-up.

If a marine mammal is observed within the relevant clearance zones

during the pre-start clearance period, initiation of HRG survey equipment must not begin until the animal(s) has been observed exiting the respective clearance zone, or, until an additional period has elapsed with no further sighting (*i.e.*, minimum 15 minutes for small odontocetes and seals; 30 minutes for all other species). The pre-start clearance requirement includes small delphinids. PSOs must also continue to monitor the zone for 30 minutes after survey equipment is shut down or survey activity has concluded.

Ramp-Up of Survey Equipment—When technically feasible, a ramp-up procedure must be used for geophysical survey equipment capable of adjusting energy levels at the start or re-start of survey activities. The ramp-up procedure must be used at the beginning of HRG survey activities in order to provide additional protection to marine mammals near the project area by allowing them to detect the presence of the survey and vacate the area prior to the commencement of survey equipment operation at full power. Ramp-up of the survey equipment must not begin until the relevant shutdown zones have been cleared by the PSOs, as described above. HRG equipment operators must ramp up acoustic sources to half power for 5 minutes and then proceed to full power. If any marine mammals are detected within the shutdown zones prior to or during ramp-up, the HRG equipment must be shut down (as described below).

Shutdown Procedures—If an HRG source is active and a marine mammal is observed within or entering a relevant shutdown zone (as described above), an immediate shutdown of the HRG survey equipment is required. When shutdown is called for by a PSO, the acoustic source must be immediately deactivated and any dispute resolved only following deactivation. Any PSO on duty has the authority to delay the start of survey operations or to call for shutdown of the acoustic source if a marine mammal is detected within the applicable shutdown zone. The vessel operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the HRG source(s) to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch. Subsequent restart of the HRG equipment may only occur after the marine mammal has been observed exiting the relevant shutdown zone, or, until an additional period has elapsed with no further sighting of the animal within the relevant shutdown zone.

Upon implementation of shutdown, the HRG source may be reactivated after

the marine mammal that triggered the shutdown has been observed exiting the applicable shutdown zone or, following a clearance period of 15 minutes for small odontocetes (*i.e.*, harbor porpoise) and 30 minutes for all other species with no further observation of the marine mammal(s) within the relevant shutdown zone. If the HRG equipment is shut down for brief periods (*i.e.*, less than 30 minutes) for reasons other than mitigation (*e.g.*, mechanical or electronic failure) the equipment may be reactivated as soon as is practicable at full operational level, without 30 minutes of pre-clearance, only if PSOs have maintained constant visual observation during the shutdown and no visual detections of marine mammals occurred within the applicable shutdown zones during that time. For a shutdown of 30 minutes or longer, or if visual observation was not continued diligently during the pause, pre-clearance observation is required, as described above.

The shutdown requirement is waived for pinnipeds (seals) and certain genera of small delphinids (*i.e.*, *Delphinus*, *Lagenorhynchus*, *Stenella*, or *Tursiops*) under certain circumstances. If a delphinid(s) from these genera is visually detected within the shutdown zone, shutdown would not be required. If there is uncertainty regarding identification of a marine mammal species (*i.e.*, whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived), PSOs must use best professional judgment in making the decision to call for a shutdown.

If a species for which authorization has not been granted, or a species for which authorization has been granted but the authorized number of takes have been met, approaches or is observed within the area encompassing the Level B harassment isopleth (178 m), shutdown must occur.

Vessel Strike Avoidance—Vineyard Northeast must comply with vessel strike avoidance measures as summarized in the **Federal Register** notice for the 2023 IHA (88 FR 50117, August 1, 2023). For a detailed description of vessel strike avoidance measures, please see the **Federal Register** notice for the 2022 IHA (87 FR 52913, August 30, 2022). This includes speed restrictions (10 knots or less) when mother/calf pairs, pods, or large assemblages of cetaceans are spotted near a vessel; species-specific vessel separation distances; appropriate vessel actions when a marine mammal is sighted (*e.g.*, avoid excessive speed, remain parallel to animal's course, *etc.*); and monitoring of the NMFS North

Atlantic Right Whale reporting system and WhaleAlert daily.

Throughout all phases of the survey activities, Vineyard Northeast must monitor NOAA Fisheries North Atlantic right whale reporting systems for the establishment of a dynamic management area (DMA). If NMFS establishes a DMA in the surrounding area, including the project area or export cable routes being surveyed, Vineyard Northeast is required to abide by the 10-knot speed restriction.

Training—Project-specific training is required for all vessel crew prior to the start of survey activities.

Reporting—PSOs must record specific information as described in the **Federal Register** notice of the issuance of the 2023 IHA (88 FR 50117, August 1, 2023). Within 90 days after completion of survey activities, Vineyard Northeast must provide NMFS with a monitoring report, which must include summaries of recorded takes and estimates of the number of marine mammals that may have been harassed.

In the event of a ship strike or discovery of an injured or dead marine mammal, Vineyard Northeast must report the incident to the NMFS Office of Protected Resources (PR.ITP.MonitoringReports@noaa.gov) and to the NMFS Greater Atlantic Stranding Hotline (866-755-6622) as soon as feasible. The incident must also be reported to the NMFS Greater Atlantic Regional Fisheries Office (GARFO) (nmfs.gar.incidental-take@noaa.gov). The report must include the information listed in the **Federal Register** notice of the issuance of the 2022 IHA (87 FR 52913, August 30, 2022).

Comments and Responses

As noted previously, NMFS published a notice of the proposed 2023 IHA (88 FR 40212, June 21, 2023) and solicited public comments on both our proposal to issue the initial IHA for take incidental to marine site characterization surveys and on the potential for a renewal IHA, should certain requirements be met.

All public comments were addressed in the notice announcing the issuance of the 2023 IHA (88 FR 50117, August 1, 2023) and none of the comments specifically pertained to the renewal of the 2023 IHA.

Preliminary Determinations

Vineyard Northeast's HRG survey activities are a subset but otherwise unchanged from those analyzed in support of the 2023 IHA. The effects of the activity, taking into consideration the proposed mitigation and related

monitoring measures, remain unchanged from those evaluated in support of the 2023 IHA. NMFS expects that all potential takes would be short-term Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging, reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.*, Southall *et al.*, 2007). In addition to being temporary, the maximum harassment zone around a survey vessel is 178 m from use of the Applied Acoustics AA251 Boomer. Although this distance is assumed for all survey activity evaluated here and in estimating take numbers proposed for authorization, in reality, much of the survey activity would involve use of acoustic sources with a reduced acoustic harassment zone (4 m for the Edge Tech Chirp 216 or 141 m for the GeoMarine Geo Spark 2000), producing expected effects of particularly low severity. Therefore, the ensonified area surrounding each vessel is relatively small compared to the overall distribution of the animals in the area and the available habitat.

The proposed survey area overlaps or is in close proximity to feeding biologically important areas (BIA) for North Atlantic right whales (Cape Cod Bay and Massachusetts Bay BIA, February-April/Great South Channel and Georges Bank Shelf Break BIA, April-June), humpback whales (March-December), fin whales (year-round/March-October), sei whales (May-November), and minke whales (March-November), as well as overlaps the migratory BIA for North Atlantic right whales (November 1-April 30) (LaBrecque *et al.*, 2015). Most of these feeding BIAs are extensive and sufficiently large (*e.g.*, 3,149 km² and 12,247 km² for North Atlantic right whales; 47,701 km² for humpback whales; 18,015 km² and 2,933 km² for fin whales; 56,609 km² for sei whales; 54,341 for minke whales), and the acoustic footprint of the proposed survey is sufficiently small that feeding opportunities for these species would not be reduced appreciably. In addition, the proposed survey area also overlaps with the area south of Martha's Vineyard and Nantucket, primarily along the western side of Nantucket Shoals, which has been identified as year-round core North Atlantic right whale foraging habitat (Leiter *et al.*, 2017; O'Brien *et al.*, 2022; Quintana-Rizzo *et al.*, 2021; Van Parijs *et al.*, 2023). As prey species are mobile and broadly distributed throughout the survey area, marine mammals that are temporarily displaced during survey

activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise, thus we do not expect biologically significant impacts to feeding behavior. Due to the temporary nature of the disturbance, the availability of similar habitat and resources in the surrounding area, and required mitigation measures, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations. The impacts of these lower severity exposures are not expected to accrue to a degree that the fitness of any individuals would be impacted and, therefore, no impacts on the annual rates of recruitment or survival would result.

As previously discussed in the 2023 IHA (88 FR 50117, August 1, 2023), impacts from the survey are expected to be localized to the specific area of activity and only during periods when Vineyard Northeast's acoustic sources are active. There are no rookeries, mating or calving grounds known to be biologically important to marine mammals within the proposed survey area.

As noted for the 2023 IHA (88 FR 50117, August 1, 2023), the proposed survey area overlaps a migratory corridor BIA and migratory route SMAs (Port of New Jersey/New York and Block Island) for North Atlantic right whales. As the survey activities would be temporary and the spatial acoustic footprint produced by the survey would be very small relative to the spatial extent of the available migratory habitat in the BIA (269,448 km²), NMFS does not expect North Atlantic right whale migration to be impacted by the survey. Required vessel strike avoidance measures would also decrease risk of ship strike during migration; no ship strike is expected to occur during Vineyard Northeast's proposed activities. Vineyard Northeast would be required to comply with seasonal speed restrictions of these SMAs, and in any dynamic management area (DMA), should NMFS establish one (or more) in the proposed survey area. The 2022 IHA included the Cape Cod Bay SMA in the survey area, however, in 2023 the survey area was reduced and no longer overlapped with this SMA. The currently proposed survey also does not include the Cape Cod Bay SMA.

Although take by Level B harassment of North Atlantic right whales has been proposed for authorization by NMFS, we anticipate a very low level of harassment, should it occur, because

Vineyard Northeast is required to maintain a shutdown zone of 500 m if a North Atlantic right whale is observed. The takes proposed for authorization account for any missed animals wherein the survey equipment is not shut down immediately. As shutdown would be called for immediately upon detection (if the whale is within 500 m), it is likely the exposure time would be very limited and received levels would not be much above the harassment threshold. Further, the 500-m shutdown zone for right whales is conservative, considering the distance to the Level B harassment isopleth for the most impactful acoustic source (*i.e.*, Applied Acoustics AA251 Boomer—which may not be used on all survey days) is estimated to be 178 m, and thereby minimizes the potential for behavioral harassment of this species. As noted previously, Level A harassment is not expected due to the small permanent threshold shift zones associated with HRG equipment types proposed for use. NMFS does not anticipate North Atlantic right whale takes that would result from Vineyard Northeast's activities would impact annual rates of recruitment or survival. Thus, any takes that occur would not result in population level impacts.

We also note that our findings for other species with active UMEs that were previously described for the 2023 IHA (88 FR 50117, August 1, 2023) remain applicable to this project. In addition, our analysis of survey effects on species with BIAs that overlap with the proposed survey area remains unchanged. Therefore, in conclusion, there is no new information suggesting that our analysis or findings should change.

NMFS has preliminarily concluded that there is no new information suggesting that our analysis or findings should change from those reached for the 2023 IHA. This includes consideration of the slight increase in estimated abundance of 6 stocks and slight decrease in estimated abundance of 3 stocks. Based on the information contained here and in the referenced documents, NMFS has preliminarily determined the following: (1) the required mitigation measures would effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the proposed authorized takes would have a negligible impact on the affected marine mammal species or stocks; (3) the proposed authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) Vineyard Northeast's activities would not have an

unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and (5) appropriate monitoring and reporting requirements are included.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS OPR consults internally whenever we propose to authorize take for endangered or threatened species.

NMFS is proposing to authorize the incidental take of five species of marine mammals which are listed under the ESA, including the North Atlantic right, fin, sei, blue, and sperm whale, and has determined that this activity falls within the scope of activities analyzed in NMFS GARFO's programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the three Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021).

Proposed Renewal IHA and Request for Public Comment

As a result of these preliminary determinations, NMFS proposes to issue a renewal IHA to Vineyard Northeast for conducting marine site characterization surveys offshore of Massachusetts to southern New Jersey from July 27, 2024 through July 26, 2025, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act>. We request comment on our analyses, the proposed renewal IHA, and any other aspect of this notice. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

Dated: June 12, 2024.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024-13328 Filed 6-17-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Matching Fund Opportunity for Ocean and Coastal Mapping and Request for Partnership Proposals

AGENCY: National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of matching fund opportunity; request for proposals.

SUMMARY: This notice invites non-Federal entities to partner with the ocean and coastal mapping programs of NOAA's National Ocean Service on jointly-funded projects of mutual interest, and establishes selection criteria and submission requirements for such projects under the NOAA Rear Admiral Richard T. Brennan Ocean Mapping Fund program. With this funding opportunity, NOAA will match selected non-Federal partners at a 70:30 NOAA:partner ratio for projects totaling up to \$1,000,000, and proposing to contract for ocean, coastal and/or Great Lakes mapping data. Selected non-Federal partners further benefit from this opportunity by leveraging NOAA's contracting (NOAA has a pool of pre-qualified technical experts in surveying and mapping) and data management expertise. This ocean and coastal mapping funding opportunity is subject to the availability of funds.

DATES: Project proposals, including any optional GIS files of the proposed project areas, must be received via email at the email address listed in the **ADDRESSES** section below by 5 p.m. Eastern Time (ET) on October 11, 2024. If an entity is unable to apply for this particular opportunity, but is interested in participating in similar, future opportunities, NOAA requests a one-page statement of interest, also by October 11, 2024. Please include all required components of the proposal in one email. Incomplete and late submissions will not be considered.

After reviewing the project proposals, NOAA will issue its decision on the proposals, which are subject to the availability of funding, on November 18, 2024. Between December 2024 and January 2025, NOAA will work with the project partners it selects to develop agreements to facilitate the transfer of funds for the projects. By March 2025, these agreements will be finalized. Between June and September 2025, non-Federal partners will transfer their matching funds to NOAA. Between January and September of 2026, NOAA

will issue task orders to its survey contractors for the partner projects.

NOAA will host an informational webinar and office hours to provide more information about the matching fund opportunity and answer any questions:

- August 1, 2024: Informational Webinar at 1 p.m. ET. To participate, please register at <https://register.gotowebinar.com/register/8298435806847389269>.
- September 13, 2024: Virtual office hours between 8:00 a.m. and 5:00 p.m. ET. These office hours will present an opportunity for interested entities to validate their proposals with experts before submitting a project proposal. In advance of September 13, 2024, register for a 30-minute time slot by emailing iwgocm.staff@noaa.gov.

NOAA also welcomes questions at any point before the proposal submission deadline at iwgocm.staff@noaa.gov.

ADDRESSES: Project proposals must be submitted via email to iwgocm.staff@noaa.gov.

The following is a list of documents that applicants may find useful and the websites where they may be found:

- the *National Ocean Mapping, Exploring and Characterizing Strategy* (NOMEC), the *Alaska Coastal Mapping Strategy* (ACMS) *Implementation Plan*, and the *Office of Coast Survey Strategic Plan*: <https://iocm.noaa.gov/about/strategic-plans.html>;
- the *Ocean Climate Action Plan* (OCAP): https://www.noaa.gov/sites/default/files/2023-03/Ocean-Climate-Action-Plan_Final.pdf;
- the U.S. Bathymetry Gap Analysis: <https://iocm.noaa.gov/seabed-2030-bathymetry.html>;
- the U.S. Interagency Elevation Inventory: <https://catalog.data.gov/dataset/united-states-interagency-elevation-inventory-usieii>;
- the U.S. Mapping Coordination site: fedmap.seasketch.org;
- OCS's *Hydrographic Surveys Specifications and Deliverables* publication: <https://nauticalcharts.noaa.gov/publications/standards-and-requirements.html>;
- NGS's *Shoreline Mapping Specifications and Deliverables*: <https://geodesy.noaa.gov/ContractingOpportunities/cmp-sow-v15.pdf>;
- the *International Hydrographic Organization Standards for Hydrographic Surveys*, Special Publication 44: https://iho.int/uploads/user/pubs/standards/s-44/S-44_Edition_6.1.0.pdf; and
- NOAA's *Equitable Climate Services Action Plan*: <https://www.noaa.gov/>

[sites/default/files/2024-04/NOAA-ECSAP-Final.pdf](https://default/files/2024-04/NOAA-ECSAP-Final.pdf).

More information on NOAA's surveying and mapping contracting vehicles is available at <https://iocm.noaa.gov/planning/contracts-grants-agreements.html>, along with background information, questions and answers, and slides on this funding opportunity.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or to register for the September 13, 2024 office hours, contact Ashley Chappell, NOAA Integrated Ocean and Coastal Mapping, at iwgomc.staff@noaa.gov, or (240) 429-0293.

SUPPLEMENTARY INFORMATION:

I. Background

NOAA's Office of Coast Survey (OCS) and National Geodetic Survey (NGS) are responsible for conducting hydrographic surveys and coastal mapping for safe navigation, the conservation and management of coastal and ocean resources, and emergency response. NOAA has considerable hydrographic and shoreline mapping contracting expertise, including a cutting-edge understanding of the science and related acoustic systems as well as data standards to ensure broad usability of that data.

NOAA is committed to meeting its mapping missions as collaboratively as possible, adhering to the Integrated Ocean and Coastal Mapping (IOCM) principle of "Map Once, Use Many Times." However, the resources needed to fully achieve the goal of comprehensively mapping U.S. waters and coasts currently exceed NOAA's capacity. Mapping the full extent of waters subject to U.S. jurisdiction means relying on partners to contribute to the effort.

The establishment of the Rear Admiral Richard T. Brennan Ocean Mapping Fund program is one way that NOAA seeks to expand partnerships and acquisition of U.S. ocean, coastal, and Great Lakes mapping data. NOAA Rear Admiral Richard T. Brennan, one of IOCM's strongest advocates, developed the *Ocean Mapping Plan* for OCS in August 2020 in which IOCM plays a large role. The *Ocean Mapping Plan* responds to a number of national drivers to map the full extent of U.S. waters subject to U.S. jurisdiction to modern standards, including the June 2020 publications of the *National Strategy for Mapping, Exploring, and Characterizing the U.S. Exclusive Economic Zone* (NOMEZ), the *Alaska Coastal Mapping Strategy* (ACMS), and the 2023 *Ocean Climate Action Plan*

(OCAP). The *Ocean Mapping Plan* also describes a number of reasons NOAA is committed to surveying and mapping waters subject to U.S. jurisdiction, including, but not limited to:

- Safe marine transportation;
- Coastal community resilience;
- A need to better understand the influence of the ocean's composition on related physical and ecosystem processes that affect climate, weather, and coastal and marine resources and infrastructure;
- Interest in capitalizing on the Blue Economy in growth areas like seafood production, tourism and recreation, marine transportation, and ocean exploration;
- The national prerogative to exercise U.S. sovereign rights to explore, manage, and conserve natural resources in waters subject to U.S. jurisdiction; and
- International interest in mapping the ocean by 2030.

Sadly, Rear Admiral Richard T. Brennan passed away in May 2021. IOCM continues to implement Rear Admiral Richard T. Brennan's vision and passion for collaborative ocean mapping through this matching fund opportunity named in his honor.

II. Description

This notice invites non-Federal entities to partner with the ocean and coastal mapping programs of NOAA's National Ocean Service on jointly-funded projects of mutual interest that address the drivers noted in section I above. These projects will establish ocean, coastal, and Great Lakes survey and mapping partnerships using NOAA's geospatial contracting vehicles. NOAA will use the selection criteria and submission requirements described below in sections V and VI, respectively, to review project proposals.

The goal of the Rear Admiral Richard T. Brennan Ocean Mapping Fund program is to leverage NOAA and non-Federal partner funds to acquire more ocean and coastal mapping data from qualified contract surveyors during Fiscal Year (FY) 2026. Subject to the availability of appropriations, NOAA will provide up to 70 percent of the total project cost, with the selected entity providing at least 30 percent of the total project cost. For example, for a \$1 million project, the partner must provide at least \$300,000, and NOAA would provide up to \$700,000.

NOAA anticipates funding between two and five projects, with a total cost of up to \$1 million per project. NOAA may consider providing additional funding for a project, thereby exceeding

\$1 million, subject to the availability of funds and NOAA's discretion. All projects are expected to have a FY 2026 project start date, and NOAA must receive all non-Federal partner matching funds before October 1, 2025. NOAA reserves the right to increase or decrease its funding match based on the quality and feasibility of proposals received.

After NOAA selects a non-Federal entity as a partner, NOAA will enter into an agreement with the partner pursuant to the Coast and Geodetic Survey Act of 1947 (33 U.S.C. 883e), which enables NOAA to receive funds for the mapping project.

In addition to providing matching funds, NOAA brings its expertise to manage survey planning, quality-ensure all data and products, provide the data and products to the partners within an agreed-upon timeframe, and handle data submission to the National Centers for Environmental Information for archiving and public accessibility. All ocean and coastal data and related products from the Rear Admiral Richard T. Brennan Ocean Mapping Fund program will be available to the public to the greatest extent allowed by applicable laws.

The specific value-added services NOAA will provide include:

- Assurance that the data are collected by qualified survey contractors to ensure broadest use and accessibility of the data;
 - Project management and GIS-based task order planning, negotiation, and award of necessary procurement contracts that are tailored to meet the interests of matching fund partners and managed on aerial, shipboard, and uncrewed vehicles;
 - Managing survey compliance with applicable laws, such as the National Environmental Policy Act and National Historic Preservation Act;
 - Data processing, quality assessment, and review of all acquired hydrographic data; and
 - Data management and stewardship through data archive at the National Centers for Environmental Information.
- Data acquisition collection methods include, but are not limited to, multibeam echosounder, side scan sonar, lidar (topographic, bathymetric, mobile), subsurface and airborne feature investigations, and sediment sampling. Products acquired may include, but are not limited to:
- Bathymetric data (multibeam, single beam, lidar),
 - Backscatter,
 - Water column (depth dependent),
 - Side scan sonar imagery,
 - Feature detection reports,

- Sensor/data corrections and calibrations (e.g., conductivity, temperature and depth casts, horizontal/vertical position uncertainty),

- Survey and control services, including the installation, operation, and removal of water level and Global Positioning System stations,

- High-resolution topographic/bathymetric product generation, and
- A final project report.

More information on NOAA's surveying and mapping processes and products can be found in the OCS Hydrographic Surveys Specifications and Deliverables and the NGS Shoreline Mapping Specifications and Deliverables publications.

III. Strategic Areas of Focus

For this opportunity, proposals will be considered that align with national priorities for climate and infrastructure and the goals of the NOMECE, ACMS, the OCS *Ocean Mapping Plan*, and OCAP. Those goals include:

1. *Map U.S. Waters*: Mapping U.S. deep waters ($\leq 40\text{m}$) by 2030 and shallower waters by 2040 would give the United States unprecedented and detailed information about the depth, shape, and composition of its seafloor and Great Lakes (NOMECE Goal 2). Based on the January 2023 analysis of data holdings at NOAA's National Centers for Environmental Information, 50 percent of waters subject to U.S. jurisdiction are unmapped (<https://iocm.noaa.gov/seabed-2030-status.html>). Acquiring the best available data in poorly surveyed and gap areas means working with partners to contribute to the effort. By sharing its mapping expertise with others, NOAA can build depth in the ocean and coastal mapping community to increase the quantity and quality of seafloor data acquired overall (*Ocean Mapping Plan* Goal 2).

2. *Expand Alaska Coastal Data Collection to Deliver the Priority Geospatial Products Stakeholders Require*: Mapping the Alaska coast is challenging. However, using targeted and coordinated data collections will potentially reduce overall costs and improve the cost-benefit ratio of expanded mapping activities (ACMS Goal 2).

3. *Expand Coastal Mapping to Inform Science-Based Decision-Making Capabilities*: This priority stems from a broader OCAP action for coastal climate resilience to "expand coastal mapping, monitoring, observational systems, research, and modeling to inform science-based decision-making capabilities and advance use of nature-based solutions." Climate change is

greatly influencing the need to map all of our named oceans and coasts in detail. The data is integral to decision-making on coastal resilience efforts to save lives, implement proper infrastructure planning, and protect sensitive coastal ecosystems in light of ocean-born natural disasters.

IV. Proposal Eligibility

This matching fund opportunity is available to non-Federal entities. Examples of non-Federal entities include State and local governments, tribal entities, universities, researchers and academia, the private sector, non-governmental organizations (NGOs), and philanthropic partners. Qualifying proposals must demonstrate the ability to provide at least 30 percent of the funds needed for the proposed project. A coalition of non-Federal entities may assemble funds for the match and submit a proposal jointly. Use of other Federal agency funds as part of the non-Federal entities' match funds will be considered on a case-by-case basis and only as authorized by applicable laws. In-kind contributions are welcome to strengthen the project proposal but do not count toward the match and are not required.

V. Selection Criteria

Proposals will be evaluated by the Rear Admiral Richard T. Brennan Ocean Mapping Fund Program Management Team. Submissions will be ranked based on the following selection criteria:

1. **Project justification (30 points)**—This criterion ascertains whether there is intrinsic IOCM value in the proposed work and/or relevance to NOAA's missions and priorities (several noted in section III), including downstream partner proposals and uses. Use of, and reference to, national priorities on coastal climate resilience and infrastructure, NOMECE, ACMS, the Coast Survey *Ocean Mapping Plan*, and OCAP; gap assessment tools such as the U.S. Bathymetry Gap Analysis; and the U.S. Interagency Elevation Inventory, among others, are recommended. The U.S. Mapping Coordination site shows current NOAA mapping plans as well as the latest in Federal mapping priorities and select regional mapping priorities.

2. **Statement of need (10 points)**—This criterion assesses clarity of project need, partner project funding alternatives if not selected, anticipated outcomes, and public benefit.

3. **Specified partner match (20 points)**—The proposal identifies a point of contact for the entity submitting the proposal, as well as any partnering entities, a clear statement on partner matching funds provenance (e.g., State

appropriations, NGO funds, or other sources) and timing of funds availability. In-kind contributions are welcome to strengthen the proposal but do not count toward the funding match and are not required.

4. **Project costs (15 points)**—This criterion evaluates whether the proposed budget is realistic and commensurate with the proposed project needs and timeframe..

5. **Project feasibility and flexibility (25 points)**—This criterion assesses the likelihood that the proposal would succeed, using evaluations of survey conditions, project size, location, weather, NOAA analysis of environmental compliance implications, project flexibility and adaptability to existing NOAA plans and schedules, and other factors.

During the proposal review period, the Rear Admiral Richard T. Brennan Ocean Mapping Fund Program Management Team reserves the right to engage with proposal points of contact to ask questions and provide feedback on project costs and feasibility.

VI. Submission Requirements

Project Proposal—To qualify, a proposal shall not exceed six (6) total pages and must include the following three components:

1. A project title; executive summary (3–5 sentences); and the names, affiliations, and roles of the project partners and any co-investigators, as well as the project lead that will serve as primary contact (1 page maximum).

2. A justification and statement of need; description and graphics of the proposed survey area, including relevance to the strategic areas of focus noted in section III and degree of flexibility on timing of survey effort (4 pages maximum).

3. A project budget that lists the source(s) and amount(s) of funding that the partner would provide as its match to NOAA. The budget must confirm that partner funds can be transferred to NOAA before October 1, 2025 (1 page maximum).

Proposals must be sent in a PDF format, and use 12-point, Times New Roman font, single spacing, and 1-inch margins. Failure to adhere to these submission requirements will result in the proposal being returned without review and eliminated from further consideration.

To facilitate review, NOAA welcomes the submission of GIS files of project areas. These ancillary GIS files must be in SHP format.

VII. Management and Oversight

Once the Rear Admiral Richard T. Brennan Ocean Mapping Fund Program Management Team selects project proposals, NOAA will coordinate the development of agreements, funding transfers, project planning, environmental compliance, acquisition awards, and the quality assurance process with the project partners. NOAA may bring in additional partners and/or funding (Federal and/or non-Federal) to expand a project further, if feasible. Projects will be reviewed by NOAA annually to ensure they are responsive to partner interests and NOAA mission requirements, and to identify opportunities for outreach and education on the societal benefits of the work.

Authority: 33 U.S.C. 883e.

Benjamin K. Evans,

*RDML Director, Office of Coast Survey,
National Ocean Service, National Oceanic
and Atmospheric Administration.*

[FR Doc. 2024–13387 Filed 6–17–24; 8:45 am]

BILLING CODE 3510–G1–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE025]

Endangered and Threatened Species; Notice of Initiation of a 5-Year Review for Maui's Dolphin and the South Island Hector's Dolphin

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

ACTION: Notice of initiation; request for information.

SUMMARY: The National Marine Fisheries Service (NMFS) announces the initiation of a 5-year review for the Maui's dolphin (*Cephalorhynchus hectori maui*) and South Island Hector's dolphin (*C. hectori hectori*). NMFS is required by the Endangered Species Act (ESA) to conduct 5-year reviews to ensure that the listing classifications of species are accurate. The 5-year review must be based on the best scientific and commercial data available at the time of the review. We request submission of any such information on Maui's dolphin and the South Island Hector's dolphin, particularly information on the status, threats, and recovery of the species that has become available since their original listings as endangered and threatened species, respectively, in 2017.

DATES: To allow us adequate time to conduct this review, we must receive your information no later than August 19, 2024.

ADDRESSES: You may submit information on this document, identified by NOAA–NMFS–2024–0073, by the following method:

- *Electronic Submission:* Submit electronic information via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA–NMFS–2024–0073 in the Search box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

Instructions: Information sent by any other method, to any other address or individual, or received after the end of the specified period, may not be considered by NMFS. All information received is a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive or protected information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous submissions (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT:

Kristen Koyama (301) 427–8456 or Kristen.Koyama@noaa.gov.

SUPPLEMENTARY INFORMATION: This notice announces our review of Maui's dolphin (*Cephalorhynchus hectori maui*) and the South Island Hector's dolphin (*C. hectori hectori*) listed as endangered and threatened under the ESA, respectively. Section 4(c)(2)(A) of the ESA requires that we conduct a review of listed species at least once every 5 years. This will be the first review of this species since it was listed in 2017 under the ESA. The regulations in 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing species currently under active review. On the basis of such reviews under section 4(c)(2)(B), we determine whether any species should be removed from the list (i.e., delisted) or reclassified from endangered to threatened or from threatened to endangered (16 U.S.C. 1533(c)(2)(B)). As described by the regulations in 50 CFR 424.11(e), the Secretary shall delist a species if the Secretary determines based on consideration of the factors and standards set forth in paragraph (c) of that section, that the best scientific and commercial data available substantiate that: (1) the species is extinct; (2) the species has recovered to

the point at which it no longer meets the definition of an endangered species or a threatened species; (3) new information that has become available since the original listing decisions on how the listed entity does not meet the definition of an endangered species or a threatened species; or (4) new information that has become available since the original listing decision shows the listed entity does not meet the definition of a species. Any change in Federal classification would require a separate rulemaking process.

Background information on both subspecies is available on the NMFS website at: <https://www.fisheries.noaa.gov/species/hectors-dolphin>.

Public Solicitation of New Information

To ensure that the review is complete and based on the best available scientific and commercial information, we are soliciting new information from the public, governmental agencies, Tribes, the scientific community, industry, environmental entities, and any other interested parties concerning the status of *Cephalorhynchus hectori maui* and *Cephalorhynchus hectori hectori*. Categories of requested information include: (1) species biology including, but not limited to, population trends, distribution, abundance, demographics, and genetics; (2) habitat conditions including, but not limited to, amount, distribution, and important features for conservation; (3) status and trends of threats to the species and its habitats; (4) conservation measures that have been implemented that benefit the species, including monitoring data demonstrating effectiveness of such measures; and (5) other new information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes and improved analytical methods for evaluating extinction risk.

If you wish to provide information for the review, you may submit your information and materials electronically (see **ADDRESSES** section). We request that all information be accompanied by supporting documentation such as maps, bibliographic references, or reprints of pertinent publications.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: June 12, 2024.

Angela Somma,

*Chief, Endangered Species Conservation
Division, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2024–13368 Filed 6–17–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. CP24–124–000]

Colorado Interstate Gas Company, LLC; Notice of Schedule for the Preparation of an Environmental Assessment for the Totem Enhanced Deliverability Project

On April 8, 2024, Colorado Interstate Gas Company, LLC (CIG) filed an application in Docket No. CP24–124–000 requesting a (Certificate of Public Convenience and Necessity pursuant to Section 7(c) and Authorization pursuant to Section 7(b) of the Natural Gas Act to modify and enhance the existing Totem natural gas storage field in Adams County, Colorado. The proposed project is known as the Totem Enhanced Deliverability Project (Project).

On April 22, 2024, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.¹

Schedule for Environmental Review

Issuance of EA November 8, 2024
90-day Federal Authorization Decision Deadline² February 6, 2025

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

CIG proposes to modify and enhance the existing Totem natural gas storage field to increase the maximum withdrawal rate by about 50 million standard cubic feet of natural gas per day and increase both the maximum

total inventory and base gas capacity of the field by one billion cubic feet.

The Project would consist of the following facilities and activities:

- Installation of six new injection/withdrawal (I/W) wells, each with a wellhead and meter yard and 0.42 mile of 6-inch-diameter lateral pipeline to connect the new wells to gathering lines;
- Conversion of one existing I/W well to an observation well;
- Along Line 254F–1:
 - Replacement of 0.62 mile of 8-inch-diameter gathering pipeline with approximately 0.72 miles of 12-inch-diameter gathering pipeline to connect the Totem Compressor Station to existing and new I/W wells;
 - Replacement of approximately 0.12 mile of existing 6-inch-diameter pipeline with approximately 0.08 mile of new 4-inch and 6-inch-diameter pipeline to interconnect with the new segment;
 - Installation of 7 new tap valves/lateral tie-ins;
 - Replacement of the launcher/receiver facilities;
- Along Line 254–2:
 - Replacement of approximately 0.28 mile of existing 6-inch and 10-inch-diameter pipeline with approximately 0.26 mile of new 3-inch, 4-inch and 6-inch-diameter pipeline to interconnect;
 - Installation of 7 new tap valves/lateral tie-ins;
- Abandonment in place of approximately 0.4 mile of 3-inch diameter on Line 254F–7;
- Installation of approximately 0.68 miles of new permanent access road that will encircle each of the new I/W wells;
- Piping modifications at the existing Totem Compressor Station; and
- Injection of approximately 1 billion cubic feet of additional base gas.

Background

On May 22, 2024, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Totem Enhanced Deliverability Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. Although there have not been any issues raised for the Project as of the issuance of this notice, all substantive comments received will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, 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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (www.ferc.gov). Using the “eLibrary” link, select “General Search” from the eLibrary menu, enter the selected date range and “Docket Number” excluding the last three digits (*i.e.*, CP24–124), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: June 12, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024–13401 Filed 6–17–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 298–081]

Southern California Edison Company; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office

¹ 40 CFR 1501.10 (2020)

² 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.

of Energy Projects has reviewed the application for a new license to continue to operate and maintain the Kaweah Hydroelectric Project No. 298 (project). The project is located on the Kaweah River and East Fork Kaweah River in Tulare County, California. Commission staff has prepared an Environmental Assessment (EA) for the project.

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission's Home Page (<http://www.ferc.gov/>), using the "eLibrary" link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov, or toll-free at (866) 208-3676, or for TTY, (202) 502-8659.

You may also register online at <https://ferconline.ferc.gov/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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Any comments should be filed within 45 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments 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. In lieu of electronic filing, you may submit a

paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-298-081.

If you have process questions, contact Rebecca Kipp at (202) 502-8846 or by email at rebecca.kipp@ferc.gov.

Dated: June 12, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-13397 Filed 6-17-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP24-661-000]

Stingray Pipeline Company, L.L.C.; Notice of Technical Conference

On May 10, 2024, the Commission issued an order directing Commission staff to convene a technical conference to discuss Stingray Pipeline Company, L.L.C.'s proposed changes to the gas quality specifications of its tariff.¹ The technical conference will be held on Wednesday, July 17, 2024, from 9:00 a.m. to 4:00 p.m. Eastern Standard Time. The conference will be held virtually and in person at a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. All interested persons are permitted to attend.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to accessibility@ferc.gov, call toll-free (866) 208-3372 (voice) or (202) 208-8659 (TTY), or send a fax to (202) 208-2106 with the required accommodations.

All interested parties that are not able to attend in person are invited to participate remotely. Staff will use the WebEx platform to view supporting documents related to this docket using the following link—<https://ferc.webex.com/ferc/j.php?MTID=ma9bba4740d3e3deb1f85f91168ab9f61>. For more information about this technical

¹ *Stingray Pipeline Company, L.L.C.*, 187 FERC ¶ 61,071 (2024).

conference, please contact Will Morris at william.morris@ferc.gov or at (202) 502-6169 by July 16, 2024.

Dated: June 12, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-13393 Filed 6-17-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2490-031]

Green Mountain Power Corporation; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

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.:* P-2490-031.

c. *Date filed:* August 30, 2022.

d. *Applicant:* Green Mountain Power Corporation (GMP).

e. *Name of Project:* Taftsville Hydroelectric Project.

f. *Location:* On the Ottauquechee River, in the Village of Taftsville, Windsor County, Vermont.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Jason Lisai, Green Mountain Power Corporation, 163 Acorn Lane, Colchester, VT 05446; (802) 770-2195; or jason.lisai@greenmountainpower.com.

i. *FERC Contact:* David Gandy at (202) 502-8560; or david.gandy@ferc.gov.

j. *Deadline for filing comments, recommendations, terms and conditions, and prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, recommendations, terms and conditions, and prescriptions 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>. 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: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting 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: Taftsville Hydroelectric Project (P-2490-031).

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is ready for environmental analysis at this time.

l. *Project Description:* The existing Taftsville Project consists of: (1) a 220-foot-long by 16-foot-high concrete gravity dam; (2) a 194-foot-long spillway section with a crest elevation of 637.12 feet National Geodetic Vertical Datum of 1929 (NGVD 29), topped with 18-inch wooden flashboards; (3) a 4,600-foot-long, 20.5-acre reservoir at a normal water surface elevation of 638.6 feet NGVD 29; (4) a powerhouse containing one 0.5-megawatt vertical Kaplan generating unit, with a minimum hydraulic capacity of 95 cubic feet per second (cfs) and maximum hydraulic capacity of 370 cfs; (5) a 200-foot-long tailrace section; (6) a 40-foot-long transmission line connecting the powerhouse to the Distribution Substation; (7) the Distribution Substation and Transmission West Substation; and (8) appurtenant facilities. Approximately 290 feet of the Ottauquechee River, between the dam and tailrace channel, are bypassed during normal operations. The project generates 1,038 megawatt-hours annually.

The current license requires GMP to operate in run-of-river mode such that outflow from the project approximates inflow. GMP meets this requirement by maintaining a stable impoundment elevation at 638.6 feet. The current license also requires GMP to provide a continuous minimum flow of 15 cfs over the spillway to the bypassed reach, or inflow, whichever is less. The project is equipped with 18-inch wooden flashboards which are removed in late

fall and replaced in the spring. After re-installation the impoundment is refilled by reducing downstream flows to no less than 100 cfs, or inflow.

GMP proposes no modifications to the existing project facilities. GMP proposes to continue operating as it has under the existing license with modifications to: (1) use no more than 10% of inflow to refill the impoundment after maintenance drawdowns; (2) consult with resource agencies prior to conducting maintenance and unplanned drawdowns and repair work; (3) restrict the removal of trees greater than or equal to 3 inches in diameter at breast height in the project boundary to the period of November 1 through March 31 for protection of the northern-long-eared bat; and (4) update the historic properties management plan to address and mitigate project effects on historic properties.

m. A copy of the application is available for review at the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov. A copy is also available for inspection and reproduction at the address in item h above.

All filings must (1) bear in all capital letters the title "COMMENTS", "REPLY COMMENTS", "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2010. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available

information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *A license applicant must file no later than 60 days following the date of issuance of this notice:* (1) a copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

o. *Procedural schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Deadline for filing comments, recommendations, agency terms and conditions, and prescriptions.	July 2024.
Deadline for the licensee to file reply comments.	August 2024.

Dated: June 12, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-13396 Filed 6-17-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15333-000]

Gravity Storage, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On November 16, 2023, Gravity Storage, 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 Red Lake Pumped Storage Project (project) to be located in Mojave county, Arizona. The proposed closed-loop pumped storage project would occupy federal land managed by the Bureau of Land Management. 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 new facilities: (1) a 3,740-foot-long, 200-foot-high rockfill concrete (upper dam 1) and a 3,000-foot-long, 60-foot-high rockfill concrete (upper dam 2), both of which would impound a new 275-acre upper reservoir with a total storage capacity of 26,000 acre-feet at a normal maximum operating elevation of 5,700 feet average above mean sea level (msl); (2) a 4,240-foot-long, 160-foot-high rockfill concrete lower dam that would impound a new 273-acre lower reservoir with a total storage capacity of 26,000 acre-feet at a normal maximum operating elevation of 3,400 feet msl; (3) three 15,400-foot-long, 36-foot-diameter reinforced concrete branch penstocks; (4) six 330-foot-long, 25-foot-diameter steel turbine penstocks; (5) a 1,200-foot-long, 150-foot-wide and 160-foot-high reinforced concrete powerhouse containing six turbine-generator units 500 megawatts each with a total rated capacity of 3,000 megawatts; (6) a 3,100-foot-long reinforced concrete tailrace; (7) a new 6-mile-long, 500-kilovolt transmission line connecting the powerhouse to the existing Western Area Power Administration substation; and (8) appurtenant facilities. The estimated annual power generation at the project would be 13,140 gigawatt-hours.

Applicant Contact: Mr. Dave E. Drips, Manager, Gravity Storage, LLC 10958 E Cordova Street Gold Canyon, AZ 85118 Dedrips@msn.com.

FERC Contact: Ousmane Sidibe; ousmane.sidibe@ferc.gov.

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's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to

contact OPP at (202) 502-6595 or OPP@ferc.gov.

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/FERCOOnline.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 FERCOOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-15333-000.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's website at <https://elibrary.ferc.gov/eLibrary/search>. Enter the docket number (P-15333) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: June 12, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-13394 Filed 6-17-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3255-016]

Lyonsdale Associates, 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:* New Major License.

b. *Project No.:* 3255-016.

c. *Date Filed:* May 29, 2024.

d. *Applicant:* Lyonsdale Associates, LLC (Lyonsdale Associates).

e. *Name of Project:* Lyonsdale Hydroelectric Project (Lyonsdale Project or project).

f. *Location:* On the Moose River in Lewis County, New York.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* David H. Fox, Senior Director, Regulatory Affairs, Lyonsdale Associates, LLC, c/o Eagle Creek Renewable Energy, LLC, 7315 Wisconsin Ave., Suite 1100W, Bethesda, MD 20814; telephone at (201) 306-5616; email at david.fox@eaglecreekre.com.

i. *FERC Contact:* Kelly Wolcott, Project Coordinator, Great Lakes Branch, Division of Hydropower Licensing; telephone at (202) 502-6480; email at kelly.wolcott@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:* July 28, 2024.

Pursuant to 18 CFR 385.2007(a)(2), the Commission's Rules of Practice and Procedure provide that if a filing deadline falls on a Saturday, Sunday, holiday, or other day when the Commission is closed for business, the filing deadline does not end until the close of business on the next business day.

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/FERCOOnline.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: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting 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: Lyonsdale Hydroelectric Project (P-3255-016).

m. The application is not ready for environmental analysis at this time.

n. *Project Description:* The Lyonsdale Project includes a dam that consists of: (1) a concrete intake structure with two 10.5-foot-long, 8.5-foot-high sluice gates that are equipped with a trashrack with 2.6-inch clear bar spacing; (2) an approximately 100-foot-long concrete non-overflow section with a 5-foot-long, 5-foot-high aluminum debris sluice gate and a non-operational 4-foot-long, 4-foot-high sluice gate; (3) a 149-foot-long overflow concrete section that includes: (a) a 7-foot-long south abutment; (b) an 85.3-foot-long spillway with 3-foot-high flashboards that have a crest elevation of 1,065.9 feet National Geodetic Vertical Dam of 1929 (NGVD 29); (c) a 4-foot-long pier; (d) a 20.5-foot-long, 6-foot-high Pelican gate; (e) a 3.7-foot-long pier; (f) a 21.5-foot-long spillway with 1.7-foot-high flashboards that have a crest elevation of 1,065.9 feet NGVD 29; and (g) a 7-foot-long north abutment; (4) a 39.5-foot-long overflow concrete section that includes: (a) a 4-foot-long south abutment; (b) a 33.5-foot-long spillway with 3-foot-high flashboards that have a crest elevation of 1,065.9 feet NGVD 29; and (c) a 2-foot-long north abutment; (5) an approximately 185-foot-long earthen embankment; and (6) a 48-foot-long overflow concrete section that includes: (a) a 5-foot-long south abutment; (b) a 38-foot-long spillway section with 3-foot-high flashboards that have a crest elevation of 1,065.9 feet NGVD 29; and (c) a 5-foot-long north abutment.

The dam creates an impoundment that has a surface area of 9 acres at the flashboard crest elevation of 1,065.9 feet NGVD 29. The impoundment includes a 100-foot-long, 35-foot-wide, 24-foot-deep concrete-lined forebay that is formed by: (1) a 100-foot-long retaining wall on the south bank of the impoundment; (2) the intake structure

of the dam; and (3) the 100-foot-long non-overflow section of the dam. From the forebay, water flows through the south sluice gate of the intake structure to a 52-foot-long, 8.7-foot-diameter steel penstock, and through the north sluice gate of the intake structure to a 26-foot-long, 8.7-foot-diameter steel penstock. The penstocks convey water to two 1.5-megawatt (MW) vertical Kaplan turbine-generator units located in a 35-foot-wide, 58-foot-long concrete and masonry powerhouse that has a total installed capacity of 3 MW. Water is discharged from the turbines through draft tubes to an approximately 450-foot-long, 70-foot-wide tailrace channel that discharges to the Moose River.

The project creates the following bypassed reach segments: (1) an approximately 200-foot-long southern segment downstream of the 149-foot-long and 39.5-foot-long overflow sections of the dam; and (2) an approximately 70-foot-long segment downstream of the 48-foot-long overflow section of the dam that bifurcates into: (a) an approximately 350-foot-long middle segment that discharges approximately 100 feet downstream of the powerhouse; and (b) an approximately 580-foot-long northern segment that discharges approximately 450 feet downstream of the powerhouse.

The project generators are connected to the regional electric grid by two 400-foot-long (300 feet underground, 100 feet above ground), 4.16-kilovolt (kV) generator lead lines and a 4.16/115-kV step-up transformer. The minimum and maximum hydraulic capacities of the powerhouse are 260 and 1,240 cubic feet per second (cfs), respectively. The average annual energy production of the project from 2016 through 2023, was 10,745 megawatt-hours.

The current license requires the implementation of a December 1, 1986 recreation plan that includes: (1) a trail on the north shoreline of the impoundment, which is shown as a 1,000-foot-long "North Shore Recreation Trail" in the license application; (2) a trail that extends from the north shoreline of the impoundment to the downstream reach of the Moose River, which according to the license application is 1,000 feet long and serves as a portage route; (3) a trail on the south shoreline of the impoundment, which according to the license application, has not been constructed; (4) a parking area between the 39.5-foot-long and 48-foot-long overflow sections of the dam; and (5) signage associated with the project recreation facilities.

Non-project recreation facilities within the project boundary include: (1)

a hand-carry boat access site on the north shoreline of the impoundment that is associated with the project portage route; (2) a picnic area on the north shoreline of the impoundment that includes a picnic table and trash can; (3) a hand-carry boat access site at the end of the project portage route, approximately 580 feet downstream of the dam; and (4) a parking area, informational signage, and shoreline access for anglers on the south shoreline of the impoundment (referred to in the license application as "South Bank Recreation Area").

The current license requires Lyonsdale Associates to operate the project in a run-of-river mode, such that project outflow approximates inflow. Under normal operating conditions, Lyonsdale Associates maintains the surface elevation of the impoundment at the flashboard crest elevation of 1,065.9 feet NGVD 29.

Lyonsdale Associates proposes to continue to operate the project in a run-of-river mode and maintain the surface elevation of the impoundment at the flashboard crest elevation of 1,065.9 feet NGVD 29. Lyonsdale Associates also proposes to: (1) release a minimum flow of 33 cfs or inflow, whichever is less, from the 48-foot-long overflow section of the dam to the middle and northern segments of the bypassed reach from April 1 through November 30; (2) implement an Invasive Species Management Plan and a Bat and Eagle Management Plan filed in Appendix C of Volume 1 of the license application; (3) consult with the New York State Historic Preservation Office (SHPO) on the need for measures prior to any ground-disturbing activities; and (4) stop work and consult with the New York SHPO on the need for measures if archaeological remains or historical sites are discovered during any future construction activities at the project.

Lyonsdale Associates proposes to operate and maintain the following facilities as project recreation facilities: the North Shore Recreation Trail; the picnic area on the north shoreline of the impoundment; the portage route the parking area between the overflow sections of the dam; and the South Bank Recreation Area. In addition, Lyonsdale Associates proposes to update and maintain project recreation signs, and install barriers to deter all-terrain vehicle (ATV) access to project recreation sites.

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-3255). For assistance, contact FERC at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), 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. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

q. *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 and Request Additional Information—July 2024

Issue Scoping Document 1 for comments—September 2024

Request Additional Information (if necessary)—November 2024

Issue Acceptance Letter—November 2024

Issue Scoping Document 2 (if necessary)—November 2024

Issue Notice of Ready for Environmental Analysis—November 2024

r. 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: June 12, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-13395 Filed 6-17-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24-87-000.

Applicants: TrailStone Energy Marketing, LLC, Trailstone Renewables, LLC, Engelhart CTP (US) LLC.

Description: Joint application for authorization under Section 203 of the Federal Power Act of TrailStone Energy Marketing, LLC, et al.

Filed Date: 6/11/24.

Accession Number: 20240611-5265.

Comment Date: 5 p.m. ET 7/2/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER23-2938-002; ER23-1445-002; ER23-2937-002; ER23-2939-002.

Applicants: Wolfskin Solar, LLC, Bird Dog Solar, LLC, Hobnail Solar, LLC, Blackwater Solar, LLC.

Description: Notice of non-material change in status of Blackwater Solar, LLC, et al.

Filed Date: 6/11/24.

Accession Number: 20240611-5255.

Comment Date: 5 p.m. ET 7/2/24.

Docket Numbers: ER24-839-001.

Applicants: EF Oxnard LLC.

Description: Report Filing;

Supplement to Notice of Non-Material Change in Status to be effective N/A.

Filed Date: 6/10/24.

Accession Number: 20240610-5107.

Comment Date: 5 p.m. ET 7/1/24.

Docket Numbers: ER24-1740-001.

Applicants: Southern California Edison Company.

Description: Tariff Amendment: Amendment to South Georgia Formula Rate Revision to be effective 6/12/2024.

Filed Date: 6/11/24.

Accession Number: 20240611-5217.

Comment Date: 5 p.m. ET 6/21/24.

Docket Numbers: ER24-1760-001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Amendment of Amended ISA, SA No. 6876; AC2-141 in Docket ER24-1760 to be effective 6/17/2024.

Filed Date: 6/12/24.

Accession Number: 20240612-5000.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24-1911-000.

Applicants: MidAmerican Central California Transco, LLC.

Description: Supplement to 04/30/2024, petition for limited waiver of

MidAmerican Central California Transco LLC.

Filed Date: 6/11/24.

Accession Number: 20240611-5264.

Comment Date: 5 p.m. ET 6/18/24.

Docket Numbers: ER24-2252-000.

Applicants: Dogwood Energy LLC.

Description: Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 6/13/2024.

Filed Date: 6/12/24.

Accession Number: 20240612-5027.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24-2253-000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 4268 Blue Valley Grid GIA to be effective 5/23/2024.

Filed Date: 6/12/24.

Accession Number: 20240612-5056.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24-2254-000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 3751R2 NorthWestern Energy NITSA and NOA to be effective 6/1/2024.

Filed Date: 6/12/24.

Accession Number: 20240612-5065.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24-2255-000.

Applicants: NextEra Energy Transmission MidAtlantic, Inc., PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: NextEra Energy Transmission MidAtlantic, Inc. submits tariff filing per 35.13(a)(2)(iii): NEET MidAtlantic submits Revisions to OATT, Att. H-33B to be effective 8/12/2024.

Filed Date: 6/12/24.

Accession Number: 20240612-5074.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24-2256-000.

Applicants: Arizona Public Service Company.

Description: 205(d) Rate Filing: Service Agreement No. 421, LGIA w/ CAWCD & DESA to be effective 5/14/2024.

Filed Date: 6/12/24.

Accession Number: 20240612-5088.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24-2257-000.

Applicants: Lockhart CL ESS I, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 8/12/2024.

Filed Date: 6/12/24.

Accession Number: 20240612-5113.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24-2258-000.

Applicants: Lockhart CL ESS II, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 8/12/2024.

Filed Date: 6/12/24.

Accession Number: 20240612–5114.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24–2259–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Amendment to ISA No. 4348, Queue No. AF1–027 to be effective 8/12/2024.

Filed Date: 6/12/24.

Accession Number: 20240612–5121.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24–2260–000.

Applicants: Bear Swamp Power Company LLC.

Description: Baseline eTariff Filing: IROL–CIP Costs ISO–NE Schedule 17 Cost Recovery Rate Schedule to be effective 6/13/2024.

Filed Date: 6/12/24.

Accession Number: 20240612–5126.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24–2261–000.

Applicants: Duke Energy Carolinas, LLC, Duke Energy Progress, LLC.

Description: 205(d) Rate Filing: Duke Energy Carolinas, LLC submits tariff filing per 35.13(a)(2)(iii): DEC–DEP Revisions to Joint OATT Formula Trans Rates Retail Rate Adj Mechanism to be effective 8/12/2024.

Filed Date: 6/12/24.

Accession Number: 20240612–5137.

Comment Date: 5 p.m. ET 7/3/24.

Docket Numbers: ER24–2262–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Amendment to ISA, SA No. 5463; Queue No. AB2–190 (amend) to be effective 8/12/2024.

Filed Date: 6/12/24.

Accession Number: 20240612–5155.

Comment Date: 5 p.m. ET 7/3/24.

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, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

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Dated: June 12, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–13402 Filed 6–17–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–2251–000]

Aron Energy Prepay 43, 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 Aron Energy Prepay 43, 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 July 2, 2024.

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>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

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Dated: June 12, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–13398 Filed 6–17–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Docket No. ER24–2249–000]****Aron Energy Prepay 41 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 Aron Energy Prepay 41 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 July 2, 2024.

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>). From the Commission's Home Page on the internet, this information is available on eLibrary.

The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

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Dated: June 12, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–13400 Filed 6–17–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Docket No. ER24–2250–000]****Aron Energy Prepay 42, 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 Aron Energy Prepay 42, 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 July 2, 2024.

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>). From the Commission's Home Page on the internet, this information is available on eLibrary.

The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

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The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and

assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: June 12, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-13399 Filed 6-17-24; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2024-0007; FRL-12027-01-OCSPP]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions were granted during the period October 1, 2023, to March 31, 2024, to control unforeseen pest outbreaks.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: RDfRNNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed after **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0007 is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

II. Background

EPA has granted emergency exemptions to the following State and Federal agencies. The emergency exemptions may take the following form: Crisis, public health, quarantine, or specific.

Under FIFRA section 18 (7 U.S.C. 136p), EPA can authorize the use of a pesticide when emergency conditions exist. Authorizations (commonly called emergency exemptions) are granted to State and Federal agencies and are of four types:

1. A “specific exemption” authorizes use of a pesticide against specific pests on a limited acreage in a particular State. Most emergency exemptions are specific exemptions.
2. “Quarantine” and “public health” exemptions are emergency exemptions issued for quarantine or public health purposes. These are rarely requested.
3. A “crisis exemption” is initiated by a State or Federal agency (and is confirmed by EPA) when there is insufficient time to request and obtain EPA permission for use of a pesticide in an emergency.

EPA may deny an emergency exemption: If the State or Federal agency cannot demonstrate that an emergency exists, if the use poses unacceptable risks to the environment, or if EPA cannot reach a conclusion that the proposed pesticide use is likely to result in “a reasonable certainty of no harm” to human health, including exposure of residues of the pesticide to infants and children.

If the emergency use of the pesticide on a food or feed commodity would result in pesticide chemical residues, EPA establishes a time-limited tolerance meeting the “reasonable certainty of no harm standard” of the Federal Food, Drug, and Cosmetic Act (FFDCA).

In this document: EPA identifies the State or Federal agency granted the exemption, the type of exemption, the pesticide authorized and the pests, the crop or use for which authorized, number of acres (if applicable), and the duration of the exemption. EPA also gives the **Federal Register** citation for the time-limited tolerance, if any.

III. Emergency Exemptions

A. U.S. States and Territories

California

Department of Pesticide Regulation

Specific exemption: EPA authorized the use of kasugamycin on a maximum of 102,143 acres of almond trees to control bacterial blast. A time-limited tolerance in connection with a past action has been established in 40 CFR 180.614(b). The authorization was effective February 1, 2024, to April 15, 2024.

Colorado

Department of Agriculture

Specific exemption: EPA authorized the use of metamiton on a maximum of 23,468 acres of sugar beets for pre-emergence control of the invasive *Amaranthus* (pigweed) spp., Palmer amaranth. Because an unregistered pesticide was requested, a Notice of Receipt (NOR), with opportunity for public comment (required by 40 CFR 166.24), published in the **Federal Register** on September 28, 2023 (88 FR 66842) (FRL-11396-01-OCSPP). The public comment period closed on October 13, 2023. Two public comments were received: one in favor and one objecting to the use. EPA posted a document addressing the comments to the docket for the NOR, as well as EPA’s evaluations and risk assessments associated with the use, which may be accessed at <https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0463>. EPA authorized the emergency exemption for this use after determining that the use would not result in any risks of concern to human health or the environment, and concluding that an urgent, nonroutine situation existed with significant economic losses expected without the use. The authorization was effective December 14, 2023 to August 31, 2024.

Massachusetts

Department of Agriculture and Resources

Specific exemption: EPA authorized the use of pronamide on a maximum of 5,000 acres of cranberries to control dodder. A time-limited tolerance in connection with this action has been

established in 40 CFR 180.317(b). The specific exemption was authorized on January 24, 2024, and effective April 15, 2024, to June 30, 2024.

Nebraska

Department of Agriculture

Specific exemption: EPA authorized the use of metatriton on a maximum of 47,128 acres of sugar beets for pre-emergence control of the invasive *Amaranthus* (pigweed) spp., Palmer amaranth. Because an unregistered pesticide was requested, a Notice of Receipt (NOR), with opportunity for public comment (required by 40 CFR 166.24), published in the **Federal Register** on September 28, 2023 (88 FR 66842) (FRL-11396-01-OCSPP). The public comment period closed on October 13, 2023. Two public comments were received: one in favor and one objecting to the use. EPA posted a document addressing the comments to the docket for the NOR, as well as EPA's evaluations and risk assessments associated with the use, which may be accessed at <https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0463>. EPA authorized the emergency exemption for this use after determining that the use would not result in any risks of concern to human health or the environment, and concluding that an urgent, nonroutine situation existed with significant economic losses expected without the use. The authorization was effective December 14, 2023 to August 31, 2024.

B. Federal Departments and Agencies

United States Department of Agriculture
Animal and Plant Health Inspection
Service

Quarantine Exemptions: EPA authorized the use of thymol on hard, nonporous surfaces associated with aircraft and associated loading equipment used to transport livestock, for disinfection from African swine fever and foot-and-mouth disease viruses. The authorization was effective October 3, 2023, to October 3, 2026.

EPA authorized the use of spinosad, incorporated into a wax matrix coating on bait stations for control of non-native tephritidae fruit fly species. The bait stations may be employed in US states and territories where the invasive fruit fly species are detected, and use of widespread pesticide spraying is not suitable (e.g., residential areas). The authorization was effective December 21, 2023 to December 31, 2026.

United States Department of Defense
Armed Forces Pest Management Board

Crisis exemption: EPA concurred upon a crisis exemption declared by the Armed Forces Pest Management Board for the use of permethrin to retreat military uniforms to protect against public health insects. The crisis exemption was effective November 6, 2023.

Public Health Exemption: EPA authorized the use of permethrin as a single retreatment on military uniforms to protect wearers from public health pests. The authorization was effective February 14, 2024, to September 30, 2024.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 5, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2024-13351 Filed 6-17-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2022-0223; FRL-11987-01-OCSPP]

Chlorpyrifos; Amendment to Existing Stocks Provisions in Winfield and Liberty Product Cancellation Orders

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On August 31, 2022, EPA issued a final order cancelling several products, including those voluntarily requested by Liberty Crop Protection, LLC (Liberty) and accepted by the Agency, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On May 4, 2023, EPA issued a final cancellation order including three products voluntarily requested by Winfield Solutions, LLC (Winfield) and accepted by the Agency. The Agency is issuing this notice to amend the existing stocks provisions in the August 31, 2022 and May 4, 2023 orders, for the products listed in this document.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA-HQ-OPP-2022-0223, is available online at <https://www.regulations.gov>. Additional instructions on visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Patricia Biggio, Pesticide Re-Evaluation

Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 566-0700; email address: OPPChlorpyrifosInquiries@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

II. What action is the Agency taking?

In the August 31, 2022 *Cancellation Order for Certain Chlorpyrifos Registrations* (87 FR 53471) (FRL-10138-01-OCSPP), EPA granted Liberty's request to cancel its three chlorpyrifos products. In the May 4, 2023 *Cancellation Order for Certain Chlorpyrifos Registrations and Uses* (88 FR 28541) (FRL-10924-01-OCSPP), EPA granted Winfield's request to cancel three chlorpyrifos products. Both of these orders noted that all chlorpyrifos tolerances had been revoked, and thus all use on food, sale, and distribution of existing stocks for the products identified in that order were inconsistent with the purposes of FIFRA, with some exceptions. The May 4, 2023 order allowed for distribution of existing stocks consistent with return agreements approved by EPA. Both orders permitted existing stocks to be sold and distributed for export and for proper disposal.

Subsequent to the issuance of the May 4, 2023 cancellation order, the U.S. Court of Appeals for the Eighth Circuit vacated EPA's rule revoking all tolerances. See *Red River Valley Sugarbeet Growers Associations, et. al vs Regan*, 85 F.4th 881 (8th Cir. 2023). On February 5, 2024, EPA issued a **Federal Register** notice to amend the Code of Federal Regulations (CFR) to reflect the court's reinstatement of those tolerances (89 FR 7625) (FRL-5993-06-OCSPP). At this time, all chlorpyrifos tolerances in effect prior to the 2021 tolerance rule have been reinstated and are currently in effect. See 40 CFR 180.342. With the tolerances in place, both Winfield and Liberty requested amendments to the terms of the cancellation orders governing

disposition of their existing stocks to allow for sale, distribution, and use.

Because the reinstatement of the chlorpyrifos tolerances means that chlorpyrifos products can be used in accordance with their labeling without concern for adulterated food, EPA is amending the August 31, 2022 cancellation order to update the existing stocks provisions as they apply to the following Liberty products:

- Liberty Chlorpyrifos Bifenthrin (EPA Reg. No. 89168–20).
- Liberty Chlorpyrifos 4E (EPA Reg. No. 89168–24).

The registrant for these listed products is Liberty Crop Protection, LLC, and its address is 1880 Fall River Drive, Suite #100, Loveland, CO 80538.

EPA is also amending the May 4, 2023 cancellation order to update the existing stocks provisions as they relate to the following Winfield products:

- Tundra Supreme (EPA Reg. No. 1381–243).
- CPF 4E (EPA Reg. No. 83222–20).
- CPF 15G (EPA Reg. No. 83222–34).

The registrant for all three of the listed products is Winfield Solutions, LLC, and its address is 1080 County Rd., F West, MS5705, P.O. Box 64589, St. Paul, MN 55164.

III. Provisions for Disposition of Existing Stocks

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be cancelled or amended to terminate one or more registered uses. Since the tolerances for chlorpyrifos residues on food commodities have been reinstated by the Eighth Circuit, food bearing chlorpyrifos residues could be sold in interstate commerce. EPA has noted however, that it intends to issue a new rulemaking revoking several chlorpyrifos tolerances in the near future. In the meantime, the following amendments to the existing stocks provisions for Winfield and Liberty products are consistent with the path forward for disposition of existing stocks for other existing stocks amendment requests and voluntary cancellations for chlorpyrifos requested by registrants.

Existing stocks for the products identified in this order are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to August 31, 2022, for the Liberty products and May 4, 2023, for the Winfield products.

At this time, EPA is amending the existing stocks provisions in the August 31, 2022 cancellation order as they

apply to the Liberty chlorpyrifos products mentioned in this notice. EPA has determined that the following existing stocks provisions are not inconsistent with the purposes of FIFRA, given the limited amount of existing stocks and the limited time allowed for use of the existing stocks outlined below:

- Sale and distribution of existing stocks of Liberty Chlorpyrifos Bifenthrin (EPA Reg. No. 89168–20) and Liberty Chlorpyrifos 4E (EPA Reg. Nos. 89168–24) is permitted until April 30, 2025.
- Use of existing stocks of Liberty Chlorpyrifos Bifenthrin (EPA Reg. No. 89168–20) and Liberty Chlorpyrifos 4E (EPA Reg. Nos. 89168–24) must be consistent with the product labeling. Such use is permitted until June 30, 2025. Use of existing stocks Liberty Chlorpyrifos Bifenthrin (EPA Reg. No. 89168–20) and Liberty Chlorpyrifos 4E (EPA Reg. Nos. 89168–24) for non-food purposes is permitted until existing stocks are exhausted, as long as such use is in accordance with the labeling.

At this time, EPA is amending the existing stocks provisions in the May 4, 2023 cancellation order as they apply to the Winfield products identified in this notice. EPA has determined that the following existing stocks provisions are not inconsistent with the purposes of FIFRA given the limited amount of existing stocks and the limited time allowed for use of the existing stocks outlined below:

- Sale and distribution of existing stocks of Tundra Supreme (EPA Reg. No. 1381–243), CPF 4E (EPA Reg. No. 83222–20), and CPF 15G (EPA Reg. No. 83222–34) is permitted until April 30, 2025.
- Use of existing stocks of Tundra Supreme (EPA Reg. No. 1381–243), CPF 4E (EPA Reg. No. 83222–20), and CPF 15G (EPA Reg. No. 83222–34) must be consistent with the product labeling. Such use is permitted until June 30, 2025. Use of existing stocks Tundra Supreme (EPA Reg. No. 1381–243), CPF 4E (EPA Reg. No. 83222–20), and CPF 15G (EPA Reg. No. 83222–34) for non-food purposes is permitted until existing stocks are exhausted, as long as such use is in accordance with the labeling.

After these dates, all sale, distribution, and use of existing stocks is prohibited, except for sale and distribution for export consistent with FIFRA section 17 (7 U.S.C. 136o) and for proper disposal.

Dated: June 11, 2024.

Anne Overstreet,

*Director, Pesticide Re-Evaluation Division,
Office of Pesticide Programs.*

[FR Doc. 2024–13349 Filed 6–17–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11932–01–R5]

Request for Nominations to the Great Lakes Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of request for nominations.

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations from a diverse range of qualified candidates who desire to serve as members of EPA's Great Lakes Advisory Board (GLAB). The GLAB is chartered to provide advice and recommendations to the EPA Administrator, through the Great Lakes National Program Manager, on matters related to the Great Lakes Restoration Initiative and on domestic matters related to the implementation of the Great Lakes Water Quality Agreement between the U.S. and Canada. For appointment consideration, nominations should be submitted by July 30, 2024. Sources in addition to this **Federal Register** notice may also be utilized in the solicitation of nominees.

FOR FURTHER INFORMATION CONTACT:

Alana Davicino, Designated Federal Officer, Great Lakes National Program Office, U.S. Environmental Protection Agency, 77 West Jackson Boulevard, (G–9J), Chicago, Illinois; telephone number: 312–886–2307, email address: davicino.alana@epa.gov.

SUPPLEMENTARY INFORMATION:

Background: The GLAB was established in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., 10) and 41 CFR 102–3.50(d). The board will provide advice and recommendations on matters related to the Great Lakes Restoration Initiative. The board will also advise on domestic matters related to implementation of the Great Lakes Water Quality Agreement between the U.S. and Canada.

The major objectives will be to provide advice and recommendations on:

- a. Great Lakes protection and restoration activities;
- b. Long term goals, objectives, and priorities for Great Lakes protection and restoration; and

c. Other issues identified by the Great Lakes Interagency Task Force/Regional Working Group.

The GLAB is expected to meet in person or by electronic means (e.g., telephone, videoconference, webcast, etc.) approximately two (2) times per year, or as otherwise needed and approved by the Designated Federal Officer. In-person meetings will be held in the Great Lakes region.

Nominations: The GLAB will be composed of approximately fifteen (15) members who will serve as representative members of non-Federal interests. In selecting members, EPA will consider candidates representing a broad range of Great Lakes stakeholders, including, but not limited to: Environmental groups; agricultural groups; industry and/or business groups; citizen groups; environmental justice groups; foundations; academia; and State, local and Tribal governments. In selecting members, EPA will consider the differing perspectives and breadth of collective experience needed to address the GLAB's charter. Other criteria used to evaluate nominees will include:

- Experience with Great Lakes issues;
- Leadership and consensus-building experience in Great Lakes organizations, businesses, and workgroups;
- Membership in professional societies involved with Great Lakes issues;
- Academic leadership and expertise;
- Community leadership; and
- Representation of multiple constituencies within the Great Lakes basin.

GLAB is a Federal advisory committee chartered under the Federal Advisory Committee Act, Public Law 92-463. Members serve on the committee in a voluntary capacity. Although we are unable to offer compensation or an honorarium, members may receive travel and per diem allowances, according to applicable Federal travel regulations and the agency's budget.

According to the mandates of FACA, committees are required to support diversity across a broad range of constituencies, sectors, and groups. In accordance with Executive Order 14035 (June 25, 2021) and consistent with law, EPA values and welcomes opportunities to increase diversity, equity, inclusion, and accessibility on its Federal advisory committees. EPA's Federal advisory committees strive to have a workforce that reflects the diversity of the American people.

How to Submit Nominations: Any interested person or organization may nominate qualified persons to be considered for appointment to the GLAB. Individuals may self-nominate.

For appointment consideration, interested nominees should submit the application materials electronically via email to davicino.alana@epa.gov with the subject line "GLAB Nominations 2024".

To be considered, nominations should include:

- Current contact information for the nominee, including the nominee's name, organization (and position within that organization), current business address, email address and daytime phone number;
- A brief statement describing the nominee's interest in serving on the GLAB;
- A resume and a short biography (no more than two paragraphs) describing the professional and educational qualifications of the nominee, including a list of relevant activities and any current or previous service on Federal advisory committees; and
- A description of the nominee's EPA grant funding history including current EPA grant activities if applicable. If this does not apply to the nominee, please provide a brief statement indicating so.
- *Optional:* Letter(s) of recommendation from a third party supporting the nomination. Letter(s) should describe how the nominee's experience and knowledge will bring value to the work of the GLAB.

To help the Agency evaluate the effectiveness of its outreach efforts, nominees are requested to use their submission packages to identify how they became aware of this request for nominations.

Dated: May 29, 2024.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2024-13203 Filed 6-17-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2024-0222; FRL-11995-01-OCSPP]

Helicoverpa zea nudivir 2 strain 90DR71; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Colorado Department of Agriculture (CDA) to use the pesticide *Helicoverpa zea nudivir 2* strain 90DR71 to treat up to 1,750 acres of sweet corn in Delta and

Montrose Counties in CO to manage corn earworm. The applicant proposes the use of an active ingredient not included in any currently registered pesticide products. EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before July 3, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2024-0222, by one of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

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

FOR FURTHER INFORMATION CONTACT:

Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What action is the Agency taking?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the EPA Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the EPA Administrator determines that emergency conditions exist which require the exemption. The Colorado Department of Agriculture has requested the EPA Administrator to issue a specific exemption for the use of *Helicoverpa zea* nudivirus 2 strain 90DR71 to control corn earworm in sweet corn. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the applicant states that unprecedented outbreaks in 2023 of corn earworm (*Helicoverpa zea*)

were not adequately controlled, leading to average losses of 52%. Testing suggests widespread insecticide resistance has developed, and the applicant asserts that there is an urgent need for additional methods to manage corn earworm to produce an economically viable sweet corn crop in Colorado. The active ingredient of the requested use is an insect virus transmitted by mating, which infects the reproductive tissues of adult moths, causing them to produce fewer eggs with many developing into sterile adult moths. Similar to successful sterile insect techniques used for other pest species, the use would be part of an area-wide strategy, including insecticides targeting the eggs and larvae. Treatment is via release of sterile moths carrying this virus, and field trials have demonstrated reductions in both larvae and corn ear damage relative to controls.

The Applicant proposes to make no more than two applications per treatment site, releasing up to 100 sterile moths per acre, between June 15 to September 23, 2024, at approximately 21 and 15 days prior to harvest of the crop. Overall, an estimated total of 350,000 sterile moths would be used over approximately 1,750 acres.

This notice does not constitute a decision by EPA on the application itself. The regulations governing FIFRA section 18 require publication of a notice of receipt of an application for a specific exemption proposing use of a new chemical (*i.e.*, an active ingredient) which has not been registered by EPA. The notice provides an opportunity for public comment on the application.

The Agency will review and consider all comments received during the comment period in determining whether to issue the specific exemption requested by the Colorado Department of Agriculture.

Authority: 7 U.S.C. 136 *et seq.*

Dated: May 29, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2024-13352 Filed 6-17-24; 8:45 am]

BILLING CODE 6560-50-P

GENERAL SERVICES ADMINISTRATION

[Notice-IEB-2024-06; Docket No. 2024-0002; Sequence No. 28]

Privacy Act of 1974; System of Records

AGENCY: General Services Administration.

ACTION: Notice of a modified system of records.

SUMMARY: GSA proposes to modify a system of records subject to the Privacy Act of 1974, as amended. This system of records was established to collect and maintain records concerning GSA Office of Inspector General (OIG) investigations, including allegations of misconduct, violations of criminal, civil, and administrative laws and regulations pertaining to GSA programs, operations, employees, contractors, and other individuals or entities associated with GSA. This system of records is intended to support and protect the integrity of GSA OIG's investigations and operations; ensure compliance with applicable laws, regulations, and policies; and ensure the integrity of GSA employees' conduct and the conduct of contractors and other entities which have business with GSA. The previously published notice is being revised to update the categories of records in the system to include video and audio recordings, add two new routine uses, and to update additional information in the system of records notice.

DATES: Submit comments on or before July 18, 2024.

ADDRESSES: Comments may be submitted to the Federal eRulemaking Portal, <http://www.regulations.gov>. Submit comments by searching for GSA/ADM-24, Office of Inspector General Investigation Case Files.

FOR FURTHER INFORMATION CONTACT: Call or email Richard Speidel, Chief Privacy Officer at 202-969-5830 and gsa.privacyact@gsa.gov.

SUPPLEMENTARY INFORMATION: GSA proposes to modify a system of records subject to the Privacy Act of 1974, 5 U.S.C. 552a. GSA intends to add two new routine uses that are consistent with the purpose of this system of records.

The Inspector General Empowerment Act of 2016 (IGEA), 5 U.S.C. 406(j), exempts certain computerized data comparisons performed by or in coordination with Inspectors General from the Computer Matching and Privacy Protection Act of 1988, Public Law 100-503. GSA proposes adding a new routine use (routine use "u") to clarify that the GSA Office of Inspector General (OIG) has authority to compare OIG records contained in the system with the records of other federal agencies and non-federal records.

Additionally, GSA proposes adding a second routine use (routine use "q") and revising routine use "p" to reflect the current Office of Management and Budget (OMB) breach response guidance

in M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information.

GSA also proposes to update the categories of records in the system to include video and audio recordings, which will facilitate the GSA OIG's compliance with Executive Order (E.O.) 14074, Advancing Effective, Accountable Policing and Criminal Justice Practices To Enhance Public Trust and Public Safety, issued May, 25, 2022. Video and audio recordings of individuals may be captured by GSA OIG criminal investigators during investigations and operations, e.g., body worn cameras, surveillance equipment etc. The recordings will be used for gathering and preserving evidence.

GSA proposes updating the system location to include the GSA OIG field offices and secure sites and secure servers maintained by third-party secure providers. This modification is being made in conjunction with the implementation of a solution to support GSA OIG's compliance with E.O. 14074, as well as to support other solutions or processes that may require the support of third-party service providers.

Additionally, GSA is making changes to the system of records notice (SORN) to update the information in the SORN. In addition to making minor technical and administrative corrections and changes to format, GSA proposes: (1) a new description of the purpose of the SORN to better summarize the purpose of this system of records; (2) updating the (a) categories of individuals covered by the system, (b) categories of records in the system, and (c) adding a new section titled records source categories; (3) updating the location of electronic records, record storage and safeguarding procedures to reflect new technology and procedures used to protect government records; and (4) changing the notification, access, and amendment procedures to align with the corresponding GSA Code of Federal Regulations. The proposed revisions are compatible with the purpose of this system of record.

Richard Speidel,

Chief Privacy Officer, Office of the Deputy Chief Information Officer, General Services Administration.

SYSTEM NAME:

Investigation Case Files.

SYSTEM NUMBER:

GSA/ADM-24.

SECURITY CLASSIFICATION:

Some of the material contained in the system has been classified in the interests of national security.

SYSTEM LOCATION:

This system is located at the GSA Office of Inspector General, 1800 F Street NW, Washington, DC 20405. The database for the system is known as the E-Investigative Documentation Electronic Administrative System (E-IDEAS). In addition, records are maintained in GSA OIG field offices. GSA OIG field office locations can be obtained by contacting the GSA OIG at the address above. Original and duplicate systems may exist, in whole or in part, at secure sites and on secure servers maintained by third-party service providers for the GSA OIG. These systems are FedRAMP Moderate compliant and have all applicable Federal Information Security Modernization Act (FISMA), Federal Information Processing Standards (FIPS), security controls as applicable.

SYSTEM MANAGER(S):

Director, Information Technology of the Office of Inspector General (JPM), 1800 F Street NW, Washington, DC 20405.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

General authority to maintain the system is contained in the Inspector General Act of 1978, as amended, 5 U.S.C. 401-424.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect and maintain records concerning GSA OIG investigations, including allegations of misconduct, violations of criminal, civil, and administrative laws and regulations pertaining to GSA programs, operations, employees, contractors, and other individuals or entities associated with GSA. This system of records is intended to support and protect the integrity of GSA OIG's investigations and operations; ensure compliance with applicable laws, regulations, and policies; and ensure the integrity of GSA employees' conduct and the conduct of contractors and other entities which have business with GSA. The system also tracks issuance of GSA OIG equipment and GSA OIG personnel training.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system are present and former GSA and GSA OIG employees, applicants for employment with GSA OIG, as well as individuals associated with commissions, committees and small agencies serviced by GSA. The system also includes historical researchers, employees of government contractors, any person who was the source of a complaint or

an allegation of misconduct, a witness who has information or evidence on any side of an investigation, and any possible or actual suspect in a criminal, administrative (including suspension and/or debarment actions), or civil action, as well as individuals referenced in potential or actual cases and matters being investigated by the Office of Investigations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Investigative files contain personal information, including name, date, and place of birth, contact information, social security number, experience, work history, photographs, video, audio recordings, and other investigative material that is used in GSA OIG investigations and operations. The system also contains GSA OIG inventory records of gear and equipment purchased by the OIG for use by OIG personnel in the performance of their official duties. Additionally, the system stores GSA OIG employees' training records, which document employees' training requirements.

RECORD SOURCE CATEGORIES:

Records are collected from other systems, individuals or their representatives, present and former GSA and OIG employees, informants, law enforcement agencies, other government agencies, state agencies, credit bureaus, data services, government contractors, private companies, employers, references, co-workers, neighbors, educational institutions, public sources, and intelligence sources.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to other disclosures generally permitted under subsection (b) of the Privacy Act of 1974, 5 U.S.C. 552a(b), the GSA OIG may disclose records for the following routine uses:

a. A record of any case in which there is an indication of a violation or potential violation of law, whether civil, criminal, or regulatory in nature, may be disseminated to the appropriate federal, state, local, or foreign agency charged with the responsibility for investigating or prosecuting such a violation or charged with enforcing or implementing the law.

b. A record may be disclosed to a federal, state, local, or foreign agency or to an individual or organization in the course of investigating a potential or actual violation of any law, whether civil, criminal, or regulatory in nature, or during the course of a trial or hearing or the preparation for a trial or hearing for such a violation, if there is reason to

believe that such agency, individual, or organization possesses information relating to the investigation, and disclosing the information is reasonably necessary to elicit such information or to obtain the cooperation of a witness or an informant.

c. A record relating to a case or matter may be disclosed in an appropriate federal, state, local, or foreign court or grand jury proceeding in accordance with established constitutional, substantive, or procedural law or practice, even when the agency is not a party to the litigation.

d. A record relating to a case or matter may be disclosed to an actual or potential party or to his or her attorney for the purpose of negotiation or discussion on matters such as settlement of the case or matter, plea-bargaining, or informal discovery proceedings.

e. A record relating to a case or matter that has been referred by an agency for investigation, prosecution, or enforcement or that involves a case or matter within the jurisdiction of any agency may be disclosed to the agency to notify it of the status of the case or matter or of any decision or determination that has been made, or to make such other inquiries and reports as are necessary during the processing of the case or matter.

f. A record relating to a case or matter may be disclosed to a foreign country pursuant to an international treaty or convention entered into and ratified by the United States, or to an Executive agreement.

g. A record may be disclosed to a federal, state, local, foreign, or international law enforcement agency to assist in crime prevention and detection or to provide leads for investigation.

h. A record may be disclosed to a federal, state, local, foreign, tribal, or other public authority in response to its request in connection with the assignment, hiring or retention of an individual and/or employee, or disciplinary or other administrative action concerning an employee, the issuance or revocation of a security clearance, the reporting of an investigation of an individual and/or employee, or the award of a contract, grant, or other benefit by the requesting agency, to the extent that the information relates to the requesting agency's decision on the matter.

i. A record may be disclosed to the news media and public in order to provide information on events in an investigation or administrative or judicial proceeding when the Inspector General determines there exists a legitimate public interest, unless the

Inspector General determines that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

j. A record may be disclosed to an appeal, grievance, hearing, or complaint examiner; an equal opportunity investigator, arbitrator, or mediator; and/or an exclusive representative or other person authorized to investigate or settle a grievance, complaint, or appeal filed by an individual who is the subject of the record.

k. A record may be disclosed as a routine use to a Member of Congress or to a congressional staff member in response to an inquiry of the congressional office made at the request of the person who is the subject of the record.

l. Information may be disclosed at any stage of the legislative coordination and clearance process to the Office of Management and Budget (OMB) for reviewing of private relief legislation as set forth in OMB Circular No. A-19.

m. A record may be disclosed: (a) to an expert, a consultant, or contractor of GSA or GSA OIG engaged in a duty related to an agency function to the extent necessary to perform the function; and (b) to a physician to conduct a fitness-for-duty examination of a GSA or GSA OIG officer or employee.

n. A record may be disclosed to an official charged with the responsibility to conduct qualitative assessment reviews of internal safeguards and management procedures employed in investigative operations. This disclosure category includes members of the Council of the Inspectors General on Integrity and Efficiency (CIGIE) and officials and administrative staff within their investigative chain of command, as well as authorized officials of the Department of Justice and the Federal Bureau of Investigation.

o. A record relating to a case may be disclosed to the GSA Office of Acquisition Policy for a decision or determination regarding suspension and debarment measures taken by the government to disqualify contractors from participation in government contracting or subcontracting.

p. To appropriate agencies, entities, and persons when (1) GSA and/or GSA OIG suspects or has confirmed that there has been a breach of the system of records, (2) GSA and/or GSA OIG has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, GSA and/or GSA OIG (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 GSA's and/or GSA OIG's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

q. To another federal agency or federal entity, when GSA and/or GSA OIG 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.

r. In any legal proceeding, where pertinent, to which GSA or GSA OIG is a party before a court or administrative body.

s. To the Office of Personnel Management (OPM), the Office of Management and Budget (OMB), and the Government Accountability Office (GAO) in accordance with their responsibilities for evaluating federal programs.

t. To the National Archives and Records Administration (NARA) for records management purposes.

u. A record may be disclosed to compare such record with records in other federal agencies' systems of records or to non-federal records.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic records and backups are stored on secure servers and accessed only by authorized personnel, in accordance with GSA OIG IT Security Policy. Paper files are stored in locked rooms or filing cabinets with access limited to authorized personnel.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

System records are retrievable by searching for information in the case file, including but not limited to, name of an individual, case name, case number, or social security number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

System records are retained and disposed of according to GSA's records maintenance and disposition schedules and the requirements of the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in the system are protected from unauthorized access and misuse

through a combination of administrative, technical, and physical security measures. Administrative measures include but are not limited to policies that limit system access to individuals within an agency with a legitimate business need, and regular review of security procedures and best practices to enhance security. Technical measures include but are not limited to system design that allows authorized system users access only to data for which they are responsible per FISMA requirements; required use of strong passwords that are frequently changed; and use of encryption for certain data transfers using current FIPS compliant protocols. Physical security measures include but are not limited to the use of data centers which meet government requirements for storage of sensitive data. Paper files are stored in locked rooms or filing cabinets and can only be accessed by authorized users.

RECORD ACCESS PROCEDURES:

This system of record is exempt from certain notification, access, and amendment procedures of the Privacy Act, as described below. However, GSA OIG will consider individual requests to determine whether or not information may be released. If an individual wishes to access any record pertaining to him or her in the system, that individual should consult the GSA's Privacy Act implementation rules available at 41 CFR part 105–64.2.

CONTESTING RECORD PROCEDURES:

If an individual wishes to contest the content of any record pertaining to him or her in the system, that individual should consult the GSA's Privacy Act implementation rules available at 41 CFR part 105–64.4.

NOTIFICATION PROCEDURES:

Individuals seeking notification of any records about themselves contained in this system of records should contact the system manager at the address above. Follow the procedures on accessing records in 41 CFR part 105–64, subpart 105–64.2 to request such notification.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

a. In accordance with 5 U.S.C. 552a(j), this system of records is exempt from all provisions of the Privacy Act of 1974 with the exception of subsections (b); (c)(1) and (2); (e)(4)(A) through (F); (e)(6), (7), (9), (10), and (11); and (i) of the Act, to the extent that information in the system pertains to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals;

to the activities of prosecutors, courts, and correctional, probation, pardon, or parole authorities; and to (a) information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (b) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, that is associated with an identifiable individual; or (c) reports of enforcement of the criminal laws, from arrest or indictment through release from supervision. This system is exempted to maintain the efficacy and integrity of the Office of Inspector General's law enforcement function.

In accordance with 5 U.S.C. 552a(k), this system of records is exempt from subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), and (I); and (f) of the Privacy Act of 1974 to the extent that the system consists of investigatory material compiled for law enforcement purposes, other than material within the scope of 5 U.S.C. 552a(j). However, if an individual is denied any right, privilege, or benefit to which the individual would otherwise be eligible as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of the Act, under an implied promise that the identity of the source would be held in confidence; and

b. To the extent the system consists of investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of the Act, under an implied promise that the identity of the source would be held in confidence.

This system has been exempted to maintain the efficacy and integrity of lawful investigations conducted pursuant to the Office of Inspector General's law enforcement responsibilities and responsibilities in the areas of federal employment,

government contracts, and access to security classified information.

HISTORY:

This notice revises the previously published notice (74 FR 6038, February 4, 2009).

[FR Doc. 2024–13262 Filed 6–17–24; 8:45 am]

BILLING CODE 6820–AB–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0293; Docket No. 2024–0001; Sequence No. 5]

Submission for OMB Review; Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements

AGENCY: Office of Technology Strategy/ Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division (MVCB) will be submitting to the Office of Management and Budget (OMB) a request to review and approve a revision and renewal of the currently approved information collection requirement on the reporting and use of information concerning integrity and performance of recipients of grants and cooperative agreements.

DATES: Submit comments on or before July 18, 2024.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Salomeh Ghorbani, Director, IAE Outreach and Stakeholder Engagement Division, at 703–605–3467 or IAE_Admin@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

This information collection requirement, OMB Control No. 3090–0293, currently titled “Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements” is necessary in order to comply with section 872 of the Duncan Hunter National Defense Authorization Act of

2009, Public Law 110–417, as amended by Public Law 111–212, hereafter referred to as “the Act.” The Duncan Hunter National Defense Authorization Act of 2009 (Pub. L. 110–417) was enacted on October 14, 2008. Section 872 of this Act required the development and maintenance of an information system that contains specific information on the integrity and performance of covered Federal agency contractors and grantees.

The Federal Awardee Performance and Integrity Information System (FAPIS) was developed to address these requirements and has been superseded by the System for Award Management (SAM) at [SAM.gov](https://sam.gov). SAM provides users access to integrity information from the FAPIS reporting module in the Contractor Performance Assessment Reporting System (CPARS), proceedings information from the Entity Management section of the SAM database, and suspension/debarment information from the Exclusions section of SAM.

As required by 2 CFR part 200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, effective January 1, 2016, Federal agencies are required to review and consider any information about the applicant that is in SAM before making any award in excess of the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance.

Non-Federal entities (NFEs) are required to disclose any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts), as required by 45 CFR part 75, Appendix XII, of the Uniform Guidance, for any period of time during the period of performance of an award/project.

B. Annual Reporting Burden

Proceedings Screening Question #1

Respondents: 19,152.
Responses per Respondent: 1.
Total Annual Responses: 19,152.
Hours per Response: .1.
Total Response Burden Hours: 1,915.

Proceedings Screening Question #2

Respondents: 141.
Responded per Respondent: 1.
Total Annual Responses: 141.
Hours per Response: .1.
Total Response Burden Hours: 14.

Proceedings Details

Respondents: 141.
Responses per Respondent: 2.
Total Annual Responses: 282.
Hours per Response: .5.
Total Response Burden Hours: 141.

C. Public Comments

A 60-day notice was published in the **Federal Register** at 89 FR 25874 on April 12, 2024. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. OMB Control No. 3090–0293, Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements, in all correspondence.

Lois Mandell,

*Director, Regulatory Secretariat Division,
 General Services Administration.*

[FR Doc. 2024–13364 Filed 6–17–24; 8:45 am]

BILLING CODE 6820-WY-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Legal and Advocacy Services for Unaccompanied Children (Office of Management and Budget #0970–0565)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services is inviting public comment on revisions to an approved information collection. The request consists of several forms that allow the Unaccompanied Children (UC) Program to provide legal and advocacy services to unaccompanied children.

DATES: *Comments due* August 19, 2024. In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all

requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This request is to remove two forms from this collection, add two new forms, move one form from a different information collection into this collection (with revisions), and revise three existing forms in this collection. ORR also proposes retitling this information collection “Legal and Advocacy Services for Unaccompanied Children.”

Discontinued Forms

ORR plans to remove the following forms from this information collection:

- *Motion for Change of Venue (Form L–7):* This instrument was created for the UC Path case management system and was intended to be used for filing a motion for change of venue for children transferring to a different ORR care provider program. However, the UC Path system was never implemented, and this form has never been used. In addition, this function is performed by an entity that is party to the proceedings, typically the child’s legal representative or Immigration and Customs Enforcement, because the decision to file a change of venue may affect the child’s immigration case. A change of venue is filed for cases where a Notice to Appear has been filed. Since neither ORR nor its care provider programs perform this function, the form is not needed.

- *Post Legal Status Plan (Form L–8):* The information collected in this form was incorporated into the Legal Services Plan section of the Category 4 Discharge Plan (Form R–9, currently approved under OMB #0970–0552). Therefore, ORR plans to discontinue this form.

New Forms

ORR plans to add the following new forms to this information collection:

- *Case Status Summary for Executive Office for Immigration Review (Form L–9):* This form is completed by the Federal Field Specialist (FFS) or care provider and sent to the Executive Office for Immigration Review (EOIR) in advance of a child’s immigration hearing. The form provides basic information needed to ensure that EOIR has accurate information on the child’s case status. A copy of the form is also shared with the child’s legal service provider or attorney of record and child advocate (if applicable).

- *Recommended States List (Form L–11):* This form is completed by legal service providers for children without viable sponsorship options or where the child is expected to remain in ORR custody for 3 or more months. The form

provides a recommended list of states where long-term foster care programs are present, taking into account the child's potential immigration case.

Forms Transferred From a Different Information Collection

ORR plans to transfer the *Child Advocate Recommendation and Appointment form* into this information collection (currently approved under OMB #0970-0553). ORR also plans to move Section B: Recommendation and Appointment and Section C: ORR Approval into a separate form to better facilitate the referral, recommendation, and appointment process. The separate form containing the information collected in Sections B and C will be completed by fewer than 10 respondents and is, therefore, not subject to PRA and is not included in this request.

In addition, ORR plans to make the following revisions to the current content:

- Rename the form *Child Advocate Referral* (Form L-12A).
- Replace "UC" with "child" throughout the form.
- Add fields for the Title, Email, and Phone Number of the referrer.
- Split the field to for the name of the child into three separate fields for First Name, Second or Middle Name, and Last Name(s).
- Add the following fields for additional information about the child that will assist the child advocate contractor in making recommendations:
 - Other Language(s) Spoken.
 - Is the child in ORR custody?
 - Was the child at another ORR care provider facility?
 - If yes, provide the care provider name.
 - Child's length of care in ORR custody.
 - Does the child have legal representation?
 - If yes, provide the following information for the legal representative: Name, Phone, Email.
- Revise the list of reasons for referral to better reflect the most common reasons child advocate referrals are made.
- Revise the burden estimate to reflect the number of child advocate referrals made from April 2023 through March 2024. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent increased from 5 to 19.

Revisions to Existing Forms

ORR plans to make the following revisions to existing form in this information collection:

- *Request for Specific Consent to Juvenile Court Jurisdiction (Form L-1)*:
 - Replace "UC" with "child" throughout the form.
 - Revised Section D: Next Steps to align with the UC Program Foundational Rule (45 CFR 410).
 - Revise the burden estimate to reflect the number of requests for specific consent received in FY 2023. The annual number of respondents decreased from 40 to 31.
- *Specific Consent Request Case Summary (Form L-2)*:
 - Remove the instruction to complete an internal clearance form because that is no longer part of the process.
 - Update the email address where the form is submitted.
 - Add text fields for the email addresses of the case manager and FFS to better facilitate communication when UC Program headquarter staff have follow-up questions.
 - Replace "UC" with "child" throughout the form.
 - Revise the available dropdown options for the Level of Care field to align with the UC Program Foundational Rule (45 CFR 410).
 - Revise the burden estimate to reflect the number of case summaries completed in FY 2023 and account for an increase in the number of care provider facilities. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent decreased from 0.2 to 0.1.
- *Acknowledgement of Receipt of Legal Resource Guide (Form LRG-4)*:
 - Change form number from LRG-5 to LRG-4.
 - Retitle form *Acknowledgement of Receipt of Legal Resource Guide* (formerly titled *Legal Service Provider List for UC in ORR Care*).
 - Remove the information provided on the first page and the list of legal service providers and their contact information. ORR plans to incorporate this information into a separate document and children will acknowledge receipt of that document in this form.
 - Revise the list of documents provided to children to reflect forthcoming revisions and consolidation of legal resource guide documents.
 - Remove requirement for children to initial each list item to reduce burden for the child.
 - Add instructions to put an "X" in the signature line in cases where the child is unable to sign the form and add a text field for the care provider to document the reason the child was

unable to sign (e.g., child is 2 years old). This will assist ORR in monitoring compliance with requirements to complete this form.

- Add a field for care provider program name.
- Revise the burden estimate to account for an increase in the number of care provider facilities and in the number of children placed in ORR care, and report the burden for care providers and unaccompanied children separately to improve accuracy of the estimate. The annual number of respondents increased from 216 to 300 for care providers and 121,669 unaccompanied child respondents were added. The annual number of responses per respondent increased from 556 to 817 for care providers and the responses per respondent for children is two (2).
- ORR plans to translate the form into Spanish and other languages commonly spoken by unaccompanied children.

Revisions to Burden Estimates Only for Existing Forms

- *Notice of Attorney Representation (Form L-3)*:
 - Previously, the annual number of respondents was overestimated at 13,000. ORR is changing that estimate to 10,000 (which will still be higher than the number of forms submitted in the previous year) based on the actual number of children who received direct representation through ORR's legal service provider contractor and rounded up to account for an expected increase in direct representation and forms submitted by outside attorneys.
 - *UC Legal Information (Form L-4)*:
 - Revise the burden estimate to account for an increase in the number of care provider facilities and in the number of children placed in ORR care. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent increased from 241 to 406.
 - *Legal Service Provider Record (Form L-6)*:
 - Revise the burden estimate to account for an increase in the number of care provider facilities and in the number of children placed in ORR care. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent increased from 241 to 406.
- Respondents:* ORR grantee and contractor staff, unaccompanied children, parents/legal guardians of unaccompanied children, attorneys of record and legal service providers.
- Annual Burden Estimates:*

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual total burden hours
Request for Specific Consent to Juvenile Court Jurisdiction (Form L-1)	31	1.0	0.25	8
Specific Consent Request Case Summary (Form L-2)	300	0.1	0.33	10
Notice of Attorney Representation (Form L-3)	10,000	1.0	0.25	2,500
UC Legal Information (Form L-4)	300	406.0	1.00	121,800
Legal Service Provider Record (Form L-6)	300	406.0	0.08	9,744
Case Status Summary for Executive Office of Immigration Review (Form L-9)	300	5.0	0.17	255
Recommended States List (Form L-11)	60	10.0	0.33	198
Child Advocate Referral (Form L-12A)-Respondents	300	19.0	0.25	1,425
Child Advocate Referral (Form L-12A)-Recordkeepers	1	5,601.0	0.33	1,848
Acknowledgment of Receipt of Legal Resource Guide (LRG-4)-Unaccompanied Children	121,669	2.0	0.25	60,835
Acknowledgment of Receipt of Legal Resource Guide (LRG-4)-Care Providers	300	817.0	0.25	61,275
Estimated Annual Burden Hours Total:				259,898

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores v. Reno* Settlement Agreement, No. CV85-4544-RJK (C.D. Cal. 1996)

Mary C. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2024-13372 Filed 6-17-24; 8:45 am]

BILLING CODE 4184-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-1981]

Facility Readiness: Goal Date Decisions Under Generic Drug User Fee Amendments; 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 final guidance for industry entitled "Facility

Readiness: Goal Date Decisions Under GDUFA." This guidance provides information to applicants on how FDA will use information related to a facility's readiness for inspection as certified on Form FDA 356h to set a goal date for an original abbreviated new drug application (ANDA). This guidance incorporates a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to reauthorization of the Generic Drug User Fee Amendments (GDUFA) and as described in "GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027" (GDUFA III commitment letter). This guidance finalizes the draft guidance of the same title issued on October 7, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on June 18, 2024.

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-1981 for "Facility Readiness: Goal Date Decisions Under GDUFA." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Karen Takahashi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6686, Silver Spring, MD 20993–0002, 301–796–3191.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Facility Readiness: Goal Date Decisions Under GDUFA.” This guidance provides information to applicants on how FDA intends to assign a goal date based on a facility’s readiness for inspection as

certified on Form FDA 356h submitted as part of an original ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). This guidance explains how FDA incorporates a performance enhancement in the GDUFA III commitment letter as part of its goal date assignments.

Under the commitment letter related to the GDUFA authorization for fiscal years 2018 through 2022 (under the Generic Drug User Fee Amendments of 2017), a goal date was assigned without regard to facility readiness for inspection. In contrast, under the GDUFA III commitment letter, FDA agreed to assign a longer goal date if a facility is not ready for an inspection at the time of application submission. An application containing a facility not ready for inspection is more likely to require more than one assessment cycle, extending the time required for possible approval and potentially delaying patient access to quality generic drugs. This change in goal date assignment will help FDA to focus resources on applications with facilities ready for inspection.

This guidance finalizes the draft guidance of the same title issued on October 7, 2022 (87 FR 61039). No public comments were received on the draft guidance. Only minor editorial changes were made.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on “Facility Readiness: Goal Date Decisions Under GDUFA.” 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 for ANDAs have been approved under OMB control number 0910–0001. The collections of information in Form FDA 356h have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 11 for electronic records and electronic signatures have been approved under OMB control number

0910–0303. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information pertaining to the GDUFA III commitment letter have been approved under OMB control number 0910–0727.

III. Electronic Access

Persons with access to the internet may obtain the 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: June 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13391 Filed 6–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2602]

First Annual Animal Drug User Fee Educational Conference; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following educational conference (public meeting) entitled “First Annual Animal Drug User Fee Educational Conference.” This is the first of five annual educational conferences FDA will host as described in the “Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028.” The purpose of this series of conferences is to provide educational sessions for stakeholders who are interested in the new animal drug approval process.

DATES: The first educational conference will be held on July 17, 2024, from 9 a.m. to 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. You may submit comments at any time for this series of educational conferences. We request that you submit either electronic or written comments by 90 days after each annual educational conference to ensure that the Agency considers your comment on a topic discussed at that conference.

ADDRESSES: The first educational conference will be available in person and virtually. The in-person conference will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Great Room Conference Center, Silver Spring, MD 20993-0002. Entrance for conference participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/about-fda/visitor-information>. Persons interested in attending this educational conference must register at: <https://fda.zoom.gov/join/9jZK6RuGrwPznG9A>.

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-2024-N-2602 for "First Annual Animal Drug User Fee Educational Conference." 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.

FOR FURTHER INFORMATION CONTACT: Walter Ellenberg, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-796-0885, adufa_v_edu_conference@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Drug User Fee Act (Pub. L. 108-130) (ADUFA or the Act) was originally signed into law in 2003 and was subsequently reauthorized by Congress in 2008, 2013, 2018, and 2023. ADUFA authorizes FDA to collect fees for certain new animal drug applications, products, establishments, and sponsors. Resources generated under ADUFA supplement the Agency's funding to enhance the performance of the drug review process, ensuring that new animal drug products are safe and effective for animals, and that food derived from treated animals will be safe for consumption. FDA considers the timely review of the safety and effectiveness of new animal drug applications to be central to the Agency's mission to protect and promote human and animal health.

The Animal Drug User Fee Amendments of 2023 (ADUFA V), the most recent reauthorization of the Act, authorizes FDA to collect user fees through fiscal year 2028. "The Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028" (Performance Goals Letter) sets forth the Agency's performance goals for the period covered by ADUFA V. Among other goals, the document commits the Agency to hosting triannual meetings (three meetings per calendar year) with Animal Health Institute (AHI) members. Each year, during one of these meetings, the Agency will commit up to 8 hours for an educational conference intended for the animal drug industry. This notice announces the first of these annual Animal Drug User Fee Educational Conferences. These conferences are open to the public. The educational conference being announced in this notice is the first annual conference of this series.

II. Topics for Discussion at the Educational Conference

As described in the Performance Goals Letter, FDA will plan a series of topics for the educational conferences during the 5 years of ADUFA V. While the agenda for each educational conference is determined by the Agency with input from AHI, all stakeholders are welcome to submit comments to the docket requesting topics to be included for future educational conferences (see **ADDRESSES**).

This initial conference will provide a high-level overview in the following areas:

- (1) Overview of the Approval Process
- (2) Communication Pathways with the Center for Veterinary Medicine

- (3) Best Practices in the Approval Process
- (4) Target Animal Safety Technical Section Overview
- (5) Effectiveness Technical Section Overview
- (6) Chemistry, Manufacturing, and Controls Technical Section Overview
- (7) Human Food Safety Technical Section Overview
- (8) Environmental Impact Technical Section Overview
- (9) Minor Technical Sections Overview

The conference will also contain Q&A sessions during which FDA will address specific questions from the in-person and virtual audience as time allows. Future educational conferences will take a more in-depth approach to these and other topics based on questions and comments received during this conference, as well as questions and comments submitted to the docket.

III. Participating in the Educational Conference

Registration: This educational conference is open to the public and will be available virtually and in-person. When registering, please provide complete contact information for each attendee, including name, title, affiliation (if any), address, email, and telephone number. Also, please self-identify as a member of one of the stakeholder categories: regulated industry, scientific or academic experts, veterinary professionals, consumer advocacy groups, press/media relations, FDA, other government/congress, or other.

Early registration is recommended for persons who wish to attend the conference. Registrants will receive confirmation when their registration has been received and they will be provided the webcast link. Persons interested in attending this conference virtually may register until the start time of the conference. Persons interested in attending this conference in person are encouraged to register online at https://fda.zoomgov.com/webinar/register/WN_cSFEyfDpQK6RuGrwPznG9A no later than July 10, 2024. Onsite registration will be provided on the day of the conference on a first-come, first-served basis, until the room capacity is reached. Onsite registration will open at the conference site at 8 a.m. on July 17, 2024. If room capacity is reached, individuals will be offered the

opportunity to observe the conference from an overflow room located at the conference site.

If you need special accommodations due to a disability, please contact Walter Ellenberg (see **FOR FURTHER INFORMATION CONTACT**) no later than July 10, 2024.

Transcript: Transcripts of the educational conference will be available on FDA's website at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings> approximately 30 days after the conference. Please be advised that as soon as a transcript of the educational conference is available, it will be accessible at <https://www.regulations.gov>, and may also be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings>.

Recording of Conference: Please be advised that as soon as a recording of this conference is available, it will be accessible at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings>.

Dated: June 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13303 Filed 6–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5656]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the

collection of information by July 18, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

State Enforcement Notifications—21 CFR 100.2(d)

OMB Control Number 0910–0275—Extension

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in their own name and within their own jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the **Federal Register** of January 23, 2024 (89 FR 4315), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d); notification	1	1	1	10	10

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: June 13, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2024–13388 Filed 6–17–24; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0987]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, us, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.
DATES: Submit written comments (including recommendations) on the collection of information by July 18, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0796. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRAStaff@fda.hhs.gov.
SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications
OMB Control Number 0910–0796—Extension

This information collection supports FDA’s programs. Under section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA is authorized to conduct educational and public information programs.
In conducting studies relating to the regulation and communications related to tobacco products, FDA will need to employ formative qualitative research including but not limited to focus groups, usability and/or psychometric testing, in-depth interviews (IDIs), cognitive interviews and asynchronous qualitative discussions (e.g., online journaling or web-based discussion boards), naturalistic observation and ethnographic studies to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve four major purposes. First, foundational research will provide critical knowledge and insights about intended audiences. FDA

must first understand people’s knowledge of, perceptions of, and reactions to tobacco related topics prior to developing survey/research questions as well as stimuli for experimental studies. Second, formative research will provide information about people’s responses, thoughts, and feelings regarding potential creative messaging, or stimuli. Third, by collecting communications usability information, FDA will be able to serve and respond to the ever-changing demands of consumers of tobacco products. Additionally, we will be able to determine the best way to communicate with intended audiences around tobacco prevention and cessation. Fourth, cognitive testing will allow FDA to assess consumer understanding of survey/research questions and study stimuli. Focus groups and/or IDIs with a sample of the intended audience will allow FDA to refine the survey/research questions and study stimuli while they are still in the developmental stage. FDA will collect, and interpret information gathered through this generic clearance to: (1) better understand characteristics of the intended audience—its perceptions, knowledge, attitudes, beliefs, and behaviors—and use these in the development of appropriate survey/research questions, study stimuli, or communications; (2) more efficiently and effectively design survey/research questions and study stimuli; and (3) more efficiently and effectively design experimental studies.
FDA is requesting approval of an extension of this generic clearance for collecting information using qualitative methods (e.g., interviews, focus groups, asynchronous discussion boards, etc.) for studies involving all tobacco products regulated by FDA. This information will be used to explore concepts of interest and assist in the development of quantitative study proposals, complementing other important research efforts in the Agency. This information may also be used to help identify and develop communication messages, which may be used in education campaigns. Qualitative research plays an important role in gathering information because it allows for an in-depth understanding of

individuals' attitudes, beliefs, motivations, and feelings. Qualitative research serves the narrowly defined need for direct and informal public opinion on a specific topic.

The number of respondents to be included in each new study may vary, depending on the nature of the study (e.g., foundational, formative, etc.), approach (synchronous vs. asynchronous, or virtual vs. in person) and the intended audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during the 3-year period. Time to read, view, or listen to the message being tested is built into the "Average Burden per Response" figures.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment on the proposed collection of information in the **Federal Register** of January 9, 2024 (89 FR 1097). FDA received two PRA related comments.

(Comment) The comment expressed that the Paperwork Reduction Act was written to reduce burden on the public, but the overuse of surveys is encouraged generically, making it even easier to collect information with no need based. The comment stated further that "This seems to be counterintuitive to the purpose of the PRA and exactly what the Act was supposed to be protecting us from, another survey we do not have time or resources to complete buy you would like to give us with no specific goal. Overuse."

(Response) FDA disagrees with the comment suggesting that the generic information collection process enables the overuse of surveys and undermines the Paperwork Reduction Act. In response to this comment, FDA has updated Supporting Statement Part A to clarify the necessity of the information collected under this generic clearance for the proper performance of FDA CTP's function and the practical utility of collecting such information. The information collected will support FDA CTP's function by advancing CTP's Strategic Plan and its specific goals: "Goal 1: Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance" and "Goal 4: Enhance Knowledge and Understanding of the Risks Associated with Tobacco Product Use." The practical utility of the collected data is evidenced by its role in facilitating the development of clear and

accessible CTP public statements and communications, such as web content, press releases, fact sheets, and retailer resources. Furthermore, the utility is demonstrated by CTP achieving the following objectives with specific audiences:

- Educating youth about the risks of tobacco product use.
- Educating people who use tobacco products about the benefits of cessation.
- Educating adults who smoke about the relative risks of tobacco products.

This foundational research has helped FDA to understand audiences and inform message development and the testing of messages in communicating the risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco. Obtaining this information has allowed FDA to improve messages, materials and implementation strategies while revisions are still affordable and possible.

(Comment) The comment expressed the lack of specificity regarding FDA's public education goals. Specifically, the comment notes that FDA vaguely states it will collect qualitative data to "explore concepts of interest and assist in the development of quantitative research proposals" and "help identify and develop communication messages, which may be used in education campaigns." The comment stated further that they encourage "FDA to prioritize educating adults, particularly adult smokers and physicians and medical staff who advise adult smokers about tobacco harm reduction. [. . .], FDA's public education campaigns should aim to improve understanding among adult smokers where there currently exists significant uncertainty and confusion about materially important issues that are detrimental to public-health efforts. These important issues include "educating the adult public, particularly adult smokers, about the continuum of risk, and where alternatives to combustible cigarettes fall on that continuum," and "correcting misunderstandings about the absence of any direct causal link between nicotine and tobacco-related diseases."

(Response) FDA disagrees with the comment suggesting that an overarching purpose or plan for communications, information goals, or target audiences was not provided. In response to this comment, FDA has updated Supporting Statement Part A to clarify that the information collected under this generic

clearance is necessary for the proper performance of FDA CTP's function and will be of practical utility in advancing CTP's Strategic Plan and its specific goals. The information collected under this generic clearance will advance CTP's objectives to educate people who use tobacco products about the benefits of cessation and to educate adults who smoke about the relative risks of tobacco products. The following generic information collections were recently approved under 0910–0796. FDA has summarized how they address specific objectives such as educating adults about tobacco products' relative risks:

- "Consumer Perceptions of Cessation and Harm": Focus group study with established cigarette smokers ages 25 and up. The objective is to learn about consumer perceptions (and misconceptions) regarding nicotine and tobacco products.

- "Consumer Perceptions of Modified and Reduced Risk (MoRR)": Focus group study with current and established cigarette smokers ages 21 and older. The objective is to gain information to inform health communication materials dedicated to modified risk products and/or the continuum of risk. This may help reduce misperceptions and lack of awareness.

- "Menthol User Audience Research": In-depth interviews conducted with adult menthol smokers ages 21 and older. The objective is to examine demographic, sociocultural, psychographic, and behavioral characteristics of adult menthol cigarette users; to identify segments that are most likely to adopt less harmful behaviors in response to targeted messaging; and to identify communication strategies to support menthol smokers in adopting less harmful behaviors.

- "Qualitative Study of Product Category Comparison Statements—modified risk tobacco product (MRTPs) and harmful and potentially harmful constituents (HPHCs)": Focus group study with adult current and former cigarette smokers ages 18 and older. The objective is to understand participants' knowledge, attitudes, beliefs, and perceptions about different tobacco products. This includes a stimulus-driven discussion of HPHC information and MRTP claims.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-Person Individual In-depth Interviews	4,500	1	4,500	1	4,500
In-depth Interview Screener	22,500	1	22,500	0.083 (5 minutes)	1,875
Focus Group Screener	56,000	1	56,000	0.25 (15 minutes)	14,000
Focus Group Discussion	252,000	1	252,000	1.5	378,000
Discussion Board Screener	8,000	1	8,000	0.083 (5 minutes)	667
Discussion Board Participation	100	1	100	1.5	150
Total					399,192

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

Our estimated burden for the information collection reflects an overall increase of 384,258 hours and a corresponding increase of 314,926 responses. We attribute this adjustment to the number of study responses used during the current approval and now estimated for the next 3 years. A greater number of qualitative studies will be conducted over the next 3 years due to the need to develop new creative messages and content. Recent years have seen a dramatic change in media. With the shift to digital media, FDA must adapt to communicate effectively in a digital environment. As digital tobacco use prevention/interventions are still in their infancy, we must better understand the types of digital channels available. To impact public health outcomes, we need to understand how to reach our intended audience. New foundational studies are needed (including those on digital metrics, measurement, and implementation). As a result, we have adjusted our burden estimate and revised the number of respondents to the information collection.

Dated: June 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13386 Filed 6–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Social and Community Influences Across the Lifecourse.

Date: July 10, 2024.

Time: 10:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elia E. Ortenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, Bethesda, MD 20892, 301–827–7189, femiaee@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–23–318: Mobile Health: Technology and Outcomes in Low and Middle Income Countries Panel A (R21/R33—Clinical Trial Optional).

Date: July 11–12, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maria De Jesus Diaz Perez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000G, Bethesda, MD 20892, (301) 496–4227, diazperem2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroimmune and Neuroinflammation involved in Neurodegenerative Disorders.

Date: July 11–12, 2024.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mariam Zaka, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1009J, Bethesda, MD 20892, (301) 435–1042, zakam2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Clinical Informatics and Data Analytics.

Date: July 11–12, 2024.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jessica Bellinger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, (301) 827–4446, bellingerjd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Thrombosis and Blood Cells.

Date: July 12, 2024.

Time: 1:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, shahb@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 13, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–13359 Filed 6–17–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Eye Institute; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; Translational Research Program for Therapeutics.

Date: July 19, 2024.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817, 240-276-5864, jennifer.schiltz@nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel; R38 Applications.

Date: July 19, 2024.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Designated Federal Official, National Eye Institute, National Institutes of Health, Division of Extramural Research, 6700 B Rockledge Dr., Rockville, MD 20892, 301-451-2020, hoshawb@mail.nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel; Individual Training Grant Applications.

Date: July 24, 2024.

Time: 10:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Ashley Fortress, Ph.D., Designated Federal Official, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700 B Rockledge Dr., Bethesda, MD 20817, (301) 451-2020, ashley.fortress@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: June 13, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-13360 Filed 6-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group; Population Sciences Study Section Population Sciences Study Section.

Date: October 25, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814 (In-person Meeting).

Contact Person: Christiane M. Robbins, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Rm. 2121B, Bethesda, MD 20817, 301-451-4989, crobbs@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 12, 2024

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-13310 Filed 6-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Request for Information on the National Institutes of Health Draft Public Access Policy**

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: The National Institutes of Health (NIH) is soliciting comments from the public on the NIH Draft Public Access Policy and two supplemental draft guidance documents regarding government use license and rights and costs for publications. The NIH Draft Public Access Policy builds upon NIH's long history of providing public access to scholarly publications resulting from the research it supports and proposes additional steps to accelerate access.

DATES: To ensure consideration, comments must be submitted in writing by August 19, 2024.

ADDRESSES: Comments may be submitted electronically to <https://osp.od.nih.gov/comment-form-national-institutes-of-health-draft-public-access-policy/>. Comments are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response 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. After the NIH Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

FOR FURTHER INFORMATION CONTACT:

Hilary Leeds, J.D., Senior Policy Analyst for Public Access, Office of Science Policy, at (301) 496-9838 or SciencePolicy@od.nih.gov.

SUPPLEMENTARY INFORMATION:**Background**

Increasing access to publications resulting from NIH funding offers many benefits to the scientific community and the public who funded the underlying work. The ability for patients, families, and members of the public to access published findings resulting from NIH funding enables them to better understand and address the most critical public health concerns facing their communities. It also allows researchers, students, and health care

providers in all communities to have equitable access to such content. This access can accelerate future research, lead to collaboration, and allow interested readers and patients to keep up more closely with critical advances. Importantly, these goals also reflect NIH's commitment to responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research.

The NIH Public Access Policy,¹ in effect since 2008, requires that NIH-supported researchers submit their final peer-reviewed manuscripts to the PubMed Central® digital archive of full-text biomedical literature upon acceptance for publication. NIH makes manuscripts freely available to the public after an allowable embargo period of not more than 12 months after the official date of publication. The 2008 Policy implements Public Law 110–161² and has, to date, resulted in more than 1.5 million articles reporting on NIH-supported research being freely available to the public in PubMed Central.

On August 25, 2022, the Office of Science and Technology Policy (OSTP) released updated policy guidance (2022 OSTP Memorandum³) in an effort to further promote equity, advance trust in science, and continue to advance American scientific leadership. Following the 2022 OSTP Memorandum, NIH released its *Plan to Enhance Public Access to the Results of NIH-Supported Research* (hereinafter “NIH Public Access Plan” or “Plan”) in February 2023.⁴ The NIH Public Access Plan provided a roadmap for how NIH proposed to accelerate access to scholarly publications, consistent with the expectation to remove the currently allowable 12-month embargo period before public availability. Informed by public comments in response to the Plan, the NIH Draft Public Access Policy accommodates novel elements of the 2022 OSTP Memorandum related to scholarly publications.

Overview of Public Comments

A total of 143 written public comments⁵ were received on the NIH

Public Access Plan, released in 2023. In addition, NIH hosted a public listening session on the Public Access Plan in April 2023,⁶ and in November 2023, NIH sponsored a workshop held by the National Academies of Science, Engineering and Medicine (NASEM) on Enhancing Public Access to the Results of Research Supported by HHS.⁷ Commenters and attendees came from academic institutions, including institutional officials and researchers at various career stages, and professional associations (many of whom also publish academic journals). They also importantly included representatives of non-profit research organizations, general members of the public, publishers, patient advocates, health care organizations, advocacy organizations, and biotechnology/pharmaceutical companies.

NIH considered all feedback to inform and develop a new NIH Draft Public Access Policy. Upon finalization, the new Policy will replace the current 2008 NIH Public Access Policy. Notably, commenters and attendees were generally supportive of updating the 2008 Policy to remove the embargo period, allowing for accelerated access to the results of NIH-funded research.

Discussion of Public Comments and Key Provisions of the NIH Draft Public Access Policy

A discussion of the public comments on the NIH Public Access Plan and how they were incorporated into the NIH Draft Public Access Policy is provided below. This section outlines the 2008 Public Access Policy's approach on each issue, proposals in the NIH Public Access Plan, followed by Public Comments on the NIH Public Access Plan, and finally the approach proposed in the NIH Draft Public Access Policy.

Definition of “Article”

Current Public Access Policy: The current Public Access Policy does not have a general term or definition to describe the versions produced in the various stages of writing and publishing.

NIH Public Access Plan: The Plan did not propose a term or definition to describe the versions produced in writing and publishing.

Public Comments: Several commenters suggested clarity was needed to distinguish the official published version of a manuscript from previous draft versions, though no

comments suggested a specific definition or term to refer to these various versions.

NIH Draft Public Access Policy: The NIH Draft Public Access Policy includes a definition of “article” to describe, in general, the versions from the creation of the manuscript through the final published article.

Definition of “Official Date of Publication”

Current Public Access Policy: When determining the timing of public release of an article, NIH bases the official date of publication on the issue or “print” publication date.

NIH Public Access Plan: For consistency with expectations under the NIH Policy for Data Management and Sharing (NIH DMS Policy) and to reflect current practice in scholarly communications, NIH proposed to interpret “Official Date of Publication” as the date on which the publisher first makes an article available, either online or in print. This is consistent with a relevant Frequently Asked Question (FAQ)⁸ on the NIH DMS Policy.⁹

Public Comments: There were no public comments on the definition of “Official Date of Publication.” Many commenters noted the importance of easing burden and providing clarity on methods of compliance.

NIH Draft Public Access Policy: The NIH Draft Public Access Policy proposes to define “Official Date of Publication” as “the date on which the article is first made available in final, edited form, whether in print or electronic (*i.e.*, online) format,” which is slightly modified from the proposal in the NIH Public Access Plan to be more precise. Consistent understanding about what is meant by an official date of publication between the NIH DMS Policy and NIH Public Access Policy will provide clarity to those complying with both policies. NIH notes that NIH's proposed implementation of public availability without embargo will take into account processing time that may be needed before public availability in PubMed Central.

Scope of the Public Access Policy

Current Public Access Policy: The current Public Access Policy's scope includes the concept of “direct” funding by NIH. The scope of the current Public Access Policy is also not limited to manuscripts reporting research findings. Rather, the Policy's requirements apply

¹ <https://sharing.nih.gov/public-access-policy/public-access-policy-overview#public-access-policy-details>.

² <https://www.congress.gov/110/statute/STATUTE-121/STATUTE-121-Pg1844.pdf>.

³ <https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf>.

⁴ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-091.html>.

⁵ https://osp.od.nih.gov/wp-content/uploads/2023/06/NIH_Public_Access_to_the_Results_of_NIH-Supported_Research_RFI_FINAL_508.pdf.

⁶ <https://osp.od.nih.gov/events/virtual-listening-session-on-the-nih-public-access-plan/>.

⁷ <https://www.nationalacademies.org/our-work/enhancing-public-access-to-the-results-of-research-supported-by-the-department-of-health-and-human-services-a-workshop>.

⁸ <https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm?anchor=56773>.

⁹ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>.

to any peer-reviewed manuscript that arises from direct funding from the NIH and is accepted for publication in a journal on or after April 7, 2008. For example, a peer-reviewed manuscript that describes an infrastructure project that was NIH funded may be subject to the Policy, even if not reporting research findings.

NIH Public Access Plan: The Plan did not discuss the proposed scope of the NIH Draft Public Access Policy regarding “direct” funding or other related details.

Public Comments: Some public comments requested clarification on situations where NIH funding does not directly support the research reported in a publication or where researchers use NIH resources without NIH funding. Other comments suggested that only awardees above a certain funding threshold or level of contribution on a grant be subject to the Public Access Policy.

NIH Draft Public Access Policy: The NIH Draft Public Access Policy proposes to adopt the current NIH Public Access Policy’s scope and is intended to make available knowledge generated from NIH-supported discoveries. Accordingly, the NIH Draft Public Access Policy applies to any Manuscript¹⁰ accepted for publication in a journal that results from funding by NIH in whole or in part. NIH intends to clarify in FAQs that using NIH resources, such as datasets available through NIH repositories and physical resources and infrastructure supported by the NIH, when no NIH funds were used for the work upon which the Manuscript is based, does not subject a resulting Manuscript to the NIH Public Access Policy. However, NIH notes that some programs at NIH and specific agreements may add in such a requirement independent of the NIH Public Access Policy’s scope.

The NIH Draft Public Access Policy also applies regardless of whether non-NIH funds contributed to developing or writing the Manuscript. The applicability of the NIH Draft Public Access Policy depends on whether the Manuscript is the result of NIH funding in whole or in part and is not dependent on the funds that contributed to the writing of the Manuscript itself.

Finally, the NIH Draft Public Access Policy, like the current Public Access Policy, does not limit its scope to Manuscripts reporting only on research (it can include, for example, a peer-reviewed manuscript that describes an

infrastructure project that was funded by NIH).

Timeline of Public Access Policy Applicability

Current Public Access Policy: Neither the current Public Access Policy nor the law that the Policy implements specifies an end date to the Policy’s applicability to Manuscripts within scope of the Policy.¹¹ This approach is consistent with publishing practices, in which publication often happens after the end of an award.

NIH Public Access Plan: The Public Access Plan did not indicate how long the Public Access Policy would be applicable to Manuscripts.

Public Comments: There were no public comments on the Public Access Policy’s potential applicability to publications arising after the closeout of the award. Some commenters requested guidance on how to comply with the Policy when NIH-supported researchers submit articles for publication long after their NIH funding has ended.

NIH Draft Public Access Policy: NIH is not proposing an end date for applicability to Manuscripts arising out of awards. Non-compliance with the NIH Public Access Policy may be considered by NIH regarding future funding decisions for the recipient institution.

Policy Effective Date

Current Public Access Policy: The current Public Access Policy became effective for manuscripts accepted for publication on or after April 7, 2008; and which arose from direct funding from an award active in FY 2008 or beyond, a contract signed on or after April 7, 2008, or from intramural research or an NIH employee.

NIH Public Access Plan: The NIH Plan indicates “NIH plans to update the NIH Public Access Policy no later than December 31, 2024, with an effective date no later than December 31, 2025,” adhering to an expectation from the 2022 OSTP Memorandum.

Public Comments: Some public comments on the proposed effective date, noted in the NIH Public Access Plan, argued for a two-year delay in the effective date to allow time for publishers (particularly smaller society-based publishers) to adjust. Some also suggested that the timeline for an effective policy was too aggressive but did not specify or suggest a specific delay. There were no comments regarding how the effective date should align with the NIH award cycle.

NIH Draft Public Access Policy: Consistent with the current Public Access Policy, the NIH Draft Public Access Policy is proposed to become effective for Manuscripts accepted for publication on or after October 1, 2025. This approach has the benefit of capturing all Manuscripts accepted for publication regardless of whether the award or contract is new or ongoing. NIH is committed to working with the research community to prepare for implementation of the final Policy.

The proposed effective date, October 1, 2025, will follow the expectations of the 2022 OSTP Memorandum to be no later than the end of calendar year 2025.

Rights in Manuscripts

Current Public Access Policy: Currently, the FAQs to the Public Access Policy describe how and when rights in manuscripts accrue and what may be transferred. NIH provides sample language an author or institution might add to a copyright agreement with a journal. In addition, authors submitting Manuscripts to PubMed Central must agree to the NIH Manuscript Submission (NIHMS) Statement¹² that, in part, allows the Manuscript to be appropriately tagged and made available on the PubMed Central website. This ensures that Manuscripts are available in machine-readable formats that support accessibility¹³ and facilitate text mining.¹⁴

NIH Public Access Plan: In the Public Access Plan, NIH said it would clarify how NIH-supported investigators may retain sufficient rights to NIH-supported peer-reviewed manuscripts. NIH proposed to develop language that NIH-supported investigators may use for submission with their peer-reviewed manuscripts to journals to retain rights to make the peer-reviewed manuscript available in PubMed Central without an embargo period.

Public Comments: There were numerous public comments on rights retention. These comments ranged from suggesting that NIH require authors to retain rights to all versions of research products (including the preprint, the author-accepted manuscript, and the journal version of record) to advocating that NIH not provide guidance or sample language on rights retention as it will interfere with publisher practices. The most frequently observed responses referred only to the author accepted

¹² <https://support.nlm.nih.gov/knowledgebase/article/KA-05252/en-us>.

¹³ <https://www.ncbi.nlm.nih.gov/pmc/about/accessibility/>.

¹⁴ <https://www.ncbi.nlm.nih.gov/pmc/tools/amdataset/>.

¹⁰ Note that defined terms are capitalized throughout.

¹¹ <https://www.congress.gov/110/statute/STATUTE-121/STATUTE-121-Pg1844.pdf>.

manuscript (to be submitted to PubMed Central) and argued that either (1) NIH require authors to retain rights via the most open licenses (e.g., Creative Commons [CC] BY) or (2) NIH should not mandate rights retention or specific licenses but should allow authors to decide whether and how to retain their rights in the manuscript. Many comments were in favor of NIH publishing guidance around rights retention, including some suggestions to ease administrative burden by providing template language to be submitted alongside manuscript submission to the publisher.

NIH Draft Public Access Policy: NIH proposes to focus on achieving the Policy's goals regarding rights in Manuscripts through minimally burdensome pathways. First, the NIH Draft Public Access Policy proposes to clarify that government use rights are given to NIH upon acceptance of funding. A statement granting NIH rights to make Manuscripts publicly available in PubMed Central upon the Official Date of Publication is proposed to be incorporated into Notices of Award and applicable contracts. This ensures it is understood that NIH's rights are automatically established at the acceptance of funding, without requiring funded recipients to take additional steps.

Secondly, the NIH Draft Public Access Policy proposes that those submitting Manuscripts to PubMed Central will provide a license to NIH that mirrors the Government Use License as part of a revised Manuscript Submission Statement, granting NIH the right to (1) make Manuscripts publicly available in PubMed Central upon the Official Date of Publication and (2) make Manuscripts available in machine-readable formats to support accessibility and facilitate text mining, consistent with current practice.

Beyond these measures, NIH does not propose requiring authors apply a particular license to their Manuscripts. A particular license is not needed to achieve the Policy's goal of making Manuscripts available without an embargo.

In the Draft Guidance on Government Use License and Rights, NIH encourages authors to clearly communicate NIH's rights through a statement in the Manuscript itself. In this Guidance, NIH has proposed standardized language authors may choose to place in their Manuscripts.

Publication Costs

Current Public Access Policy: According to the current NIH Public Access Policy FAQs, "Publication costs,

including author fees, may be charged to NIH grants and contracts on three conditions: (1) such costs incurred are actual, allowable, and reasonable to advance the objectives of the award; (2) costs are charged consistently regardless of the source of support; (3) all other applicable rules on allowability of costs are met."¹⁵ Importantly, even if such costs were not incurred during a specific period of performance of an award, an award may still be charged before its closeout for publication costs.

NIH Public Access Plan: NIH stated in the Public Access Plan the intent to continue to allow reasonable publication costs for all NIH-supported or authored scholarly publications consistent with current policy and guidance. NIH proposed to continue monitoring trends in publication fees and policies to ensure that they remain reasonable and do not disproportionately burden one or more segments of the NIH-supported community, and that opportunities to publish are equitable and consistent with NIH's strategic priorities.

Public Comments: Many respondents argued that removal of the embargo would drive publishers to business models that charge fees to make articles openly and immediately available, and that as these fees rise, so will inequity for lower resourced institutions and investigators. Some publishers suggested that these models are the only way forward as subscriptions diminish. Others sought assurances that authors would be able to comply with the revised NIH Public Access Policy without cost through repository deposition models. Some publishers suggested that removal of the embargo and subsequent diminished subscriptions could have a significant negative effect on their operations, leading to limited choices of where to publish, which would limit accessibility.

Many comments favored monitoring the costs of publications. Some suggestions included examining application budgets and annual reports to the NIH, working with publishers to understand publishing model and/or discipline specific requirements, and exploring currently existing cost assessments. Some suggested that any appearance of dictating business models would be inappropriate and could interfere with a publisher's ability to remain in business.

Several respondents perceived fees to make articles openly and immediately available to be too high and to lack

transparency. Some of these comments encouraged NIH to cap publication-related costs. Several publishers argued that cost-capping could lead to an increase in "predatory" publishing.

Many argued that NIH should define which publication costs would be permissible under regulations and the Grants Policy Statement (GPS). Some suggested that it would be helpful to define "reasonable" costs, while others suggested that such definitions would be entirely context dependent and would necessarily evolve.

NIH Draft Public Access Policy: In the NIH Draft Public Access Policy, NIH clarifies that compliance with the Policy is free. While allowable publication costs may be budgeted, as publishing itself may incur costs, NIH maintains a free pathway for compliance with the NIH Draft Public Access Policy by submission of the Manuscript to PubMed Central. This free pathway for policy compliance helps to support the goals of equitable public access. Additionally, the benefits of eliminating costs and delays in access to publications will likely be greatest for lower resourced institutions, researchers, and the public.

The NIH Draft Public Access Policy notes that if authors are asked to pay a fee by a third party for submission of Manuscripts to PubMed Central, the NIH Draft Public Access Policy would not permit this fee to be paid from NIH funds because it is not a legitimate publication expense. The NIH Draft Public Access Policy indicates reasonable costs associated with publication that are allowable may be requested in the budget for the project as direct or indirect costs.

The Draft Guidance on Publication Costs contains examples of unallowable costs, based on existing cost principles and existing sections of the GPS. Regarding the ability to pay publication costs after an award has ended, NIH cannot pay publication costs after closeout of an award (as recently affirmed in revisions to 2 CFR 200.461¹⁶). Points to Consider are provided for authors and institutions to inform whether a publication cost is reasonable.

NIH will continue to consider appropriate methods to monitor costs for potential impacts on relevant communities once the final Public Access Policy has been implemented and any downstream effects are more readily apparent.

¹⁵ <https://sharing.nih.gov/faqs#/public-access-policy?anchor=50507>.

¹⁶ <https://www.federalregister.gov/documents/2024/04/22/2024-07496/guidance-for-federal-financial-assistance#sectno-reference-200.461>.

Compliance and Enforcement

Current Public Access Policy: The current NIH Public Access Policy notes that the awardee institution is responsible for complying with the terms and conditions of the award. Compliance may be achieved through submission of the Manuscript or through journals submitting Final Published Articles to PubMed Central based on existing agreements. NIH may take one or more enforcement actions, depending on the severity and duration of the non-compliance, in accordance with applicable statutes, regulations, and policies.

NIH Public Access Plan: The Public Access Plan did not specify enforcement actions but rather outlined the pathways to compliance of submission of the Manuscript or Final Published Article.

Public Comments: Many commenters requested that compliance with the NIH Public Access Policy be as simple as possible and not place undue burden on investigators. There were no public comments on the consequences for non-compliance.

NIH Draft Public Access Policy: The NIH Draft Public Access Policy minimizes burden by proposing to adopt the same pathways to compliance as under the current Public Access Policy. It also reinforces the requirement to properly communicate and acknowledge federal funding in Manuscripts. Importantly, the NIH Draft Public Access Policy states that non-compliance with the requirement to properly communicate and acknowledge federal funding is itself a violation of the terms and conditions of award and also may result in non-compliance with the NIH Public Access Policy. It notes that non-compliance may delay non-competing award processing and potentially affect future funding for the institution.

Accessibility and Understandability

Current Public Access Policy: NIH currently makes content in PubMed Central available in accessible and machine-readable formats. In addition, NIH currently has multiple ways to make research and research results available to the public,¹⁷ including through press releases, the Public Health Relevance Statement in grant applications, and the Outcomes section in RePORTER.

NIH Public Access Plan: The Public Access Plan proposed to continue making articles available in formats that

allow for machine-readability and through assistive devices.

Public comments: Public comments indicated that making information available is necessary but not sufficient to meet goals concerning equitable access. Consumers of the information resulting from NIH-supported studies need to be able to process and understand what they are reading. Many public comments supported NIH's goals to make information machine-readable and available on assistive devices, but there were also comments about the need to enhance understanding, such as by translating articles into multiple languages and accompanying articles with plain language summaries.

NIH Draft Public Access Policy: Accessibility of PubMed Central content is paramount and NIH will continue to make content accessible for those using assistive technologies. NIH appreciates comments noting that to make discoveries truly accessible to the public, information should be disseminated in ways that are meaningful and digestible. While NIH does not currently plan to require that authors develop or submit plain language summaries of Manuscripts or translate their content into languages other than English, as supporting technologies continue to develop, NIH will consider additional approaches to increase understanding of NIH-funded scientific research.

NIH Draft Public Access Policy

Purpose

Increasing access to publications resulting from NIH funding offers many benefits to the scientific community and the public who funded the underlying work. The ability for patients, families, and members of the public to access published findings resulting from NIH funding enables them to better understand and address the most critical public health concerns facing their communities. It also allows researchers, students, and health care providers in all communities to have equitable access to such content. This access can accelerate future research, lead to collaboration, and allow interested readers and patients to keep up more closely with critical advances. Importantly, these goals also reflect NIH's commitment to responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research.

Per the NIH Public Access Policy, effective October 1, 2025, NIH is requiring Manuscripts to be submitted to PubMed Central upon acceptance for

publication, for public availability without embargo upon the Official Date of Publication.

Definitions

Manuscript: The author's final version that has been accepted for journal publication and includes all revisions resulting from the peer review process, including all associated tables, graphics, and supplemental material

Final Published Article: The journal's authoritative copy, including journal or publisher copyediting and stylistic edits, and formatting changes

Article: A general term that encompasses the versions resulting from writing and publishing, from creation of the manuscript through final published article in a journal

Journal: A periodical publication that is either (1) included in the "journal" section of the National Library of Medicine (NLM) Catalog¹⁸ or (2) meets all of the following criteria:

- Requirements for ISSN assignment;
- Content is issued over time under a common title;
- Is a collection of articles by different authors; and
- Is intended to be published indefinitely.

Official Date of Publication: The date on which the article is first made available in final, edited form, whether in print or electronic (*i.e.*, online) format

Scope and Effective Date

The NIH Public Access Policy applies to any Manuscript accepted for publication in a journal, on or after October 1, 2025, that is the result of funding by NIH in whole or in part through:

- A grant or cooperative agreement, including training grants
- A contract,
- An Other Transaction,
- NIH intramural research, or
- The official work of an NIH employee.

The NIH Public Access Policy applies regardless of whether the NIH-funded principal investigator or project director is an author and regardless of whether non-NIH funds contributed to developing or writing the Manuscript. Upon the effective date, this Policy replaces the prior 2008 NIH Public Access Policy.

Requirements

The Public Access Policy requires:

- Submission of an electronic version of the final peer-reviewed Manuscript to

¹⁷ <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.100-how-to-use-the-application-instructions.htm#6>.

¹⁸ <https://www.ncbi.nlm.nih.gov/nlmcatalog/journals?term=periodical%5BPublication+Type%5D+AND+open%5BPublication+Status%5D>.

PubMed Central upon its acceptance for publication, for public availability without embargo upon the Official Date of Publication;

- An acknowledgment in the Manuscript and Final Published Article that satisfies the requirements in the NIH Grants Policy Statement regarding communicating and acknowledging federal funding,¹⁹ as well as analogous requirements for acknowledging federal funding as incorporated into Other Transactions and applicable contracts; and

- When a Manuscript is submitted to NIH,²⁰ providing NIH with a standard license that mirrors that of the Government Use License at 45 CFR 75.322(b),²¹ or its successor regulation, explicitly granting NIH the right to make the Manuscript publicly available through PubMed Central without embargo upon the Official Date of Publication.

Government Use License and Rights

- By accepting NIH funding, the recipient grants to NIH, as the funding agency, a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes, and to authorize others to do so. This includes making Manuscripts publicly available in PubMed Central upon the Official Date of Publication. A statement that conveys this point is incorporated into Notices of Award and applicable contracts.

- NIH encourages inclusion of a statement in the Manuscript that indicates it is subject to the NIH Public Access Policy and that this means that NIH, as the funding agency, has the right to make the Manuscript publicly available in PubMed Central upon the Official Date of Publication. NIH provides standardized language in the Draft Guidance on Government Use License and Rights that authors may include in Manuscripts. Such a statement ensures transparency and awareness that NIH has the right to make the Manuscript available in PubMed Central without embargo upon the Official Date of Publication.

- Authors are not expected to provide rights to NIH to the Final Published

Article. However, as noted in “Compliance and Enforcement,” NIH will accept submission of the Final Published Article to PubMed Central from journals with formal agreements with NLM as compliant with the Policy when its release meets public access requirements outlined in this Policy.

Costs

Reasonable costs associated with publication that are allowable may be requested in the budget for the project as direct or indirect costs, as specified in the NIH Grants Policy Statement²² and as incorporated into Other Transactions and applicable contracts (see the Draft Guidance on Publication Costs for more information). Submission of Manuscripts to PubMed Central remains free for authors under the NIH Public Access Policy. If, during the course of the publication process, an author is asked to pay a fee for submission of the Manuscript to PubMed Central, such costs are not allowable.

Compliance and Enforcement

Regarding submission to PubMed Central, compliance with the Policy may be achieved through either:

- Submission of the electronic version of the final peer-reviewed manuscript (*i.e.*, Manuscript as defined above) to PubMed Central upon its acceptance for publication, for public availability without embargo upon the official date of publication or
- Submission of the Final Published Article to PubMed Central from a journal with a formal agreement with NLM, upon the Official Date of Publication, for public availability without embargo

Communicating and acknowledging federal funding enables a clear, public-facing indication of NIH funding in Manuscripts and Final Published Articles. Failure to include required acknowledgments may result in non-compliance with the NIH Public Access Policy, in addition to resulting in non-compliance with terms and conditions of funding regarding communicating and acknowledging federal funding.

Non-compliance with the NIH Public Access Policy may be considered by NIH regarding future funding decisions for the recipient institution (*e.g.*, as authorized in the NIH Grants Policy Statement, Section 8.5, Special Award Conditions and Remedies for Noncompliance (Special Award Conditions and Enforcement

Actions)).²³ Non-competing continuation grant awards are subject to a delay in award processing for non-compliance with the NIH Public Access Policy.

Draft Guidance on Government Use License and Rights

Purpose

Federal agencies have, by law, certain rights to products resulting from federal funding. For works (*e.g.*, manuscripts) under the Government Use License (45 CFR 75.322(b)), or its successor regulation, NIH “reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.” These rights also apply as incorporated into Other Transactions and applicable contracts (*e.g.*, the rights in data clause within the contract).

NIH proposes this Draft Guidance to assist authors in navigating compliance with the NIH Public Access Policy with minimal burden. NIH also encourages authors to be clear with the journals to which they submit their Articles, to ensure journals understand that NIH has a right to make Manuscripts publicly available upon the Official Date of Publication.

Public Access Policy Requirements Related to Rights

Upon accepting NIH funding, recipients grant to NIH the right to make Manuscripts arising from the funding publicly available in PubMed Central upon the Official Date of Publication, and this is affirmed via a statement in Notices of Award and applicable contracts.

Authors approving Manuscripts for inclusion in PubMed Central must agree to a submission statement²⁴ as part of the standard PubMed Central Manuscript submission process. Under the NIH Draft Public Access Policy, authors submitting a Manuscript to PubMed Central must provide NIH with a standard license that mirrors the Government Use License. This language will be included as part of this submission statement to PubMed Central and states:

I hereby grant to NIH, a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use this work for Federal purposes, and to authorize others to do so. This grant of rights includes the right to create derivative works and make

¹⁹ NIH Grants Policy Statement 4.2.1 Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm) and 8.2.1 Rights in Data (Publication and Copyrighting) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.1_rights_in_data_publication_and_copyrighting.htm).

²⁰ This happens typically through the NIH Manuscript Submission (NIHMS) System.

²¹ <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFR78b08d9c95aad03/section-75.322>.

²² https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.9_allowability_of_costs_activities.htm (See Publication and Printing Costs).

²³ https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.5_special_award_conditions_and_remedies_for_noncompliance_special_award_conditions_and_enforcement_actions_.htm.

²⁴ <https://support.nlm.nih.gov/knowledgebase/article/KA-05252/en-us>.

the final, peer-reviewed manuscript publicly available upon the Official Date of Publication.

The language in this statement may evolve as regulations change, but it includes a grant of rights to NIH such that NIH may make the Manuscript publicly available in PubMed Central without an embargo, upon the Official Date of Publication.

Guidance for Communicating Rights in Manuscripts

NIH highly encourages authors to be transparent when submitting Articles²⁵ for consideration for publication by indicating to the journal or publisher that the Article is subject to the NIH Public Access Policy, and that this means that NIH, as the funding agency, has the right to make the Manuscript publicly available in PubMed Central upon the Official Date of Publication. NIH does not require that authors demonstrate to NIH what was communicated to publishers.

NIH suggests that authors submit the points above as a statement in the Manuscript. Such a statement may accompany the required funding acknowledgment. NIH provides the following sample language that may be included in the Manuscript:

This manuscript is the result of funding in whole or in part by the National Institutes of Health. It is subject to the NIH Public Access Policy. Through acceptance of this federal funding, NIH has been given a right to make this manuscript publicly available in PubMed Central upon the Official Date of Publication, defined by NIH as “The date on which the article is first made available in final, edited form, whether in print or electronic (*i.e.*, online) format.

Draft Guidance on Publication Costs Purpose

NIH recognizes that authors publishing in peer-reviewed journals may incur associated costs, such as article processing charges (APCs) or other charges. Publication costs are allowable when they comport with the existing NIH cost principles.²⁶ Cost principles clarify when costs should be allocated as direct versus indirect costs, and they clarify charges and fees that are allowable under the conditions outlined.

This Draft Guidance clarifies publication costs that are not allowable

based on existing cost principles that provide a framework for allowable publication costs. It also provides points to consider to assist authors and institutions as they assess whether publishing costs are reasonable.

Public Access Policy Requirements Related to Costs

All costs must comport with 45 CFR 75, or its successor regulation, as implemented in NIH GPS Sections 7.2 and 7.9.1. These principles also apply as analogous requirements in Other Transactions and applicable contracts.

The NIH Draft Public Access Policy clarifies that reasonable costs that are allowable may be requested in the budget for the project as direct or indirect costs, as specified in the NIH GPS and as incorporated into Other Transactions and applicable contracts. Importantly, the NIH Draft Public Access Policy also states that submission of Manuscripts to PubMed Central remains free for authors. Journal or publisher fees for submitting the Manuscript to PubMed Central that may arise during the course of the publication process are not allowable costs.

Other Unallowable Costs

In addition to not allowing payment of fees to submit Manuscripts to PubMed Central, examples of other unallowable costs are listed below in the context of corresponding rules that can be found in the NIH GPS. This list may be updated as needed.

- Costs for services (*e.g.*, peer review) for which there is no resulting publication are unallowable because costs must be chargeable or assignable in accordance with the relative benefits received (GPS 7.2)
- Costs for which the institution already pays a fee that would cover publication costs (*e.g.*, an agreement the institution has with a publisher whereby authors from that institution publish for free in exchange for subscription services) are unallowable because costs may not be double charged or inconsistently charged as both direct and indirect costs (GPS 7.4)
- Costs for publishing services that are charged differentially because an author's Manuscript is subject to the NIH Public Access Policy are unallowable because charges must be levied impartially on all items published by the journal, whether or not under a federal award (GPS 7.9.1, Publication and Printing Costs)
- Costs for services incurred after closeout of the award, even for a publication subject to the NIH Public

Access Policy, are unallowable because the costs of publications must be incurred before closeout (GPS 7.9.1, Publication and Printing Costs)

Points To Consider for Authors and Institutions in Assessing Reasonable Costs

As stated in Section 7.2 of the NIH GPS, a cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made. NIH promotes *reasonable* publication costs to ensure an equitable system for publishing opportunities. However, establishing a particular threshold for what is reasonable may lead to inequitable outcomes in specific circumstances. While NIH may modify this approach in the future, NIH encourages researchers and institutions to consider, when determining whether costs are reasonable:

- Size of publication cost in relation to NIH award
- Other publications researchers may wish to produce during an award period
- Professional and institutional priorities
- Sustainability in terms of the library budget, laboratory budget, etc., if such costs were to be consistently paid

In addition, NIH reiterates its Statement on Article Publication Resulting from NIH Funded Research,²⁷ a 2017 NIH Guide Notice that encourages authors to publish papers arising from NIH-funded research in reputable journals. Fees paid to journals that have characteristics described in this Statement may be considered unreasonable.

NIH seeks public comments on any aspect of the NIH Draft Public Access Policy and supplemental Draft Guidance.

Dated: June 7, 2024.

Lawrence A. Tabak,
Principal Deputy Director, National Institutes of Health.

[FR Doc. 2024–13373 Filed 6–17–24; 8:45 am]

BILLING CODE 4140-01-P

²⁵ Term used because they represent the pre-peer review stage.

²⁶ Grants Policy Statement Section 7.2. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.2_the_cost_principles.htm) and Section 7.9 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.9_allowability_of_costs_activities.htm).

²⁷ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-011.html>.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics: Brain Imaging, Vision, Bioengineering and Low Vision Technology Development.

Date: July 10, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan Gillmor, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 762-3076, susan.gillmor@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Metabolism.

Date: July 12, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301-435-1154, dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Health Services Systems and Clinical Care.

Date: July 15-16, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tara Roshell Earl, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 1007C, Bethesda, MD 20892, (301) 402-6857, earltr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cancer Immunology and Immunotherapy I.

Date: July 15-16, 2024.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7806, Bethesda, MD 20892, 301-451-4467, howardz@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Drug Discovery and Molecular Pharmacology.

Date: July 15, 2024.

Time: 10:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Subhamoy Pal, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-0926, subhamoy.pal@nih.gov.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; HIV Molecular Virology, Cell Biology, and Drug Development Study Section.

Date: July 15-16, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@csr.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; HIV/AIDS Intra- and Inter-personal Determinants and Behavioral Interventions Study Section.

Date: July 15-16, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (In Person and Virtual Meeting).

Contact Person: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-806-6596, rubertm@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 13, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-13358 Filed 6-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Opportunities for Collaborative Research at the NIH Clinical Center (U01Clinical Trial Optional).

Date: July 16, 2024.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G45, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Vanitha Sundaresa Raman, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G45, Rockville, MD 20852, 301-761-7949, vanitha.raman@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 12, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-13309 Filed 6-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: July 12, 2024.

Time: 10:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20852, (240) 669-5060, james.snyder@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: July 12, 2024.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20852, (240) 669-5060, james.snyder@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,

Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 12, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-13311 Filed 6-17-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Docket ID: FEMA-2024-0010]

Public Assistance Program and Policy Guide, FP 104-009-2

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice of availability; request for comment.

SUMMARY: The Federal Emergency Management Agency (FEMA) is accepting comments on proposed revisions to the Public Assistance Program and Policy Guide (PAPPG) Version 5.

DATES: Comments must be received no later than August 19, 2024.

ADDRESSES: You may submit comments, identified by Docket ID: FEMA-2024-0010, via the Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Robert Pesapane, Director, Public Assistance Division, Federal Emergency Management Agency, fema-recovery-policy@fema.dhs.gov, (202) 646-3834.

SUPPLEMENTARY INFORMATION:**I. Public Participation**

Interested persons are invited to submit comments and related materials. We will consider all comments and materials received during the comment period.

If you submit a comment, include the docket ID, 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 public docket at <https://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. For more about privacy and the docket, visit <https://www.regulations.gov/privacy-notice>.

The proposed policy is available in docket ID FEMA-2024-0010. For access

to the docket to read background documents or comments received, go to <https://www.regulations.gov> and search for the docket ID.

II. Background

The PAPPG contains consolidated Public Assistance (PA) Program policies for the entire disaster recovery life cycle. The PAPPG provides comprehensive PA policy to use when evaluating eligibility. The PAPPG references and provides weblinks to other FEMA policies and documents such as standard operating procedures and job aids that provide detailed instructions for individuals involved with implementing each of the various steps. This proposed version 5 of the PAPPG would streamline ways for our customers to meet requirements through reducing documentation needs to meet eligibility, increase accessibility to the PA program and funding, promote the equitable treatment and timely recovery of communities, and effectuate resilient rebuilding through additional cost-effective hazard mitigation measures. The proposed policy does not have the force and effect of law.

FEMA seeks comment on the proposed policy, which is available online at <https://www.regulations.gov> under docket ID FEMA-2024-0010. Based on the comments received, FEMA may make appropriate revisions to the proposed policy. When or if FEMA issues a final policy, FEMA will publish a notice of availability in the **Federal Register** and make the final policy available at <https://www.regulations.gov>. The final policy will not have the force and effect of law.

Authority: The Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (Stafford Act), 42 U.S.C. 5121 *et seq.*; 44 CFR part 206.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024-13306 Filed 6-17-24; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY**Agency Information Collection Activities: DHS Civil Rights Evaluation Tool, Collection Instrument DHS Form 3095, OMB Control Number 1601-0024**

AGENCY: Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; revision request.

SUMMARY: The Department of Homeland Security, Civil Rights Civil Liberties, DHS will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. DHS previously published this information collection request (ICR) in the **Federal Register** on February 8, 2024, for a 60-day public comment period. No comments were received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until July 18, 2024. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: If additional information is required contact: The Department of Homeland Security (DHS), Office for Civil Rights and Civil Liberties: Attn: Antidiscrimination Group, CRCL MS 0190, Department of Homeland Security, 2707 Martin Luther King Jr Ave. SE, Washington, DC 20528–0190, 202–401–1474, crcl@hq.dhs.gov.

SUPPLEMENTARY INFORMATION: Recipients of federal financial assistance from the Department of Homeland Security

(DHS) are required to meet certain legal requirements relating to nondiscrimination and nondiscriminatory use of federal funds. Those requirements include ensuring that entities receiving Federal financial assistance from the DHS do not deny benefits or services, or otherwise discriminate on the basis of race, color, national origin, disability, age, sex, or religion, in accordance with Title VI of the Civil Rights Act of 1964 (Title VI) Public Law 88–352, 42 U.S.C. 2000d–1 *et seq.*; 6 CFR part 21; 44 CFR part 7; Section 504 of the Rehabilitation Act of 1973 (Section 504), Public Law 93–112, as amended by Public Law 93–516, 29 U.S.C. 794; Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.*; 6 CFR part 17; 44 CFR part 19; Age Discrimination Act of 1975, Public Law 94–135, 42 U.S.C. 6101 *et seq.*; 44 CFR part 7 and 6 CFR part 19.

DHS uses DHS Form 3095: DHS Civil Rights Evaluation Tool as the primary tool to implement this information collection. DHS uses the form to collect civil rights related information from all recipients of federal financial assistance from the Department. The purpose of the information collection is to advise recipients of their civil rights obligations and collect pertinent civil rights information to ascertain if the recipient has in place adequate policies and procedures to achieve compliance, and to determine what, if any, further action may be needed (technical assistance, training, compliance review, etc.) to ensure the recipient is able to meet its civil rights requirements and will carry out its programs and activities in a nondiscriminatory manner.

DHS is revising the collection, changing *Section 1* of the form on *Instructions* to extend the deadline for initial submissions from 30 days of receipt of the Notice of Award to 60 days; to update the method of submission from email to an online portal, and to make other minor clarifying revisions. DHS is also making minor changes to *Section 2* of the form on *Organization Information* to remove the fields for reporting Grant Agreement Number and Federal Award Identification Number; DHS now obtains that information from Department data sources. In addition, DHS is making minor changes to *Section 5* of the form on *Additional Information* to streamline communication with recipients by providing a single, centralized point of contact for questions and technical assistance. Lastly, DHS is changing the name of the collection from “DHS Civil

Rights Compliance Form” to “DHS Civil Rights Evaluation Tool.”

Analysis

Agency: Department of Homeland Security (DHS).

Title: DHS Civil Rights Evaluation Tool, Collection Instrument DHS Form 3095.

OMB Number: 1601–0024.

Frequency: Annually.

Affected Public: Entities Receiving Federal Financial Assistance from DHS.

Number of Respondents: 5,000.

Estimated Time per Respondent: 3 hours.

Total Burden Hours: 10,050.

Total Burden Cost (capital/startup): 0.

Total Burden Cost (operating/maintaining): 0.

Robert Dorr,

Executive Director, Business Management Directorate.

[FR Doc. 2024–13353 Filed 6–17–24; 8:45 am]

BILLING CODE 9112–FL–P

INTER-AMERICAN FOUNDATION

Submission for OMB Review; comments request

AGENCY: Inter-American Foundation.

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the provisions of the Paperwork Reduction Act, agencies are required to publish a Notice in the **Federal Register** notifying the public that the agency is modifying an existing information collection and creating a new information collection for OMB review and approval and requests public review and comment on the submission. Comments are being solicited on the need for the information; the accuracy of the burden estimate; the quality, practical utility, and clarity of the information to be collected; and ways to minimize reporting the burden, including automated collected techniques and uses of other forms of technology.

DATES: Comments must be received by August 19, 2024.

ADDRESSES: Comments and requests for copies of the subject information collection may be sent by any of the following methods:

- *Mail:* Nicole Stinson, Associate General Counsel, Inter-American Foundation, 1331 Pennsylvania Ave. NW, Suite 1200 North, Washington, DC 20004.

- *Email:* nstinson@iaf.gov.

Instructions: All submissions received must include the agency name and

agency form name or OMB control number for this information collection. Electronic submissions must include the agency form name in the subject line to ensure proper routing. Please note that all written comments received in response to this notice will be considered public records.

FOR FURTHER INFORMATION CONTACT:

Associate General Counsel: Nicole Stinson, (202) 683-7117.

SUPPLEMENTARY INFORMATION: This notice informs the public that IAF will submit to OMB a request for approval of the following two information collections.

Summary Form Under Review

Title of Collection: Awardee Certifications and Disclosures, IAF-06.

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

OMB Control Number: 0417-0501.

Type of Respondent/Affected Public: Private Sector, Businesses or other for profits, Not-for profit institutions.

Frequency: Once.

Estimated Number of Respondents per year: 450.

Estimated Time per Respondent: .0.2 hours.

Estimated Total Annual Burden Hours: 90.

Abstract: The IAF works to promote sustainable development in Latin America and the Caribbean by directly supporting civil society organizations through funding actions, such as grants and cooperative agreements. The IAF is soliciting comments concerning the information collection of grantee certifications, assurances, and representations for the purpose of obtaining an IAF Award. The purpose of this form is to ensure that grantees are complying with the necessary federal laws and regulations to receive federal funds and give grantees an opportunity to disclose any personal or organizational conflicts of interest, or potential for conflicts of interest.

Summary Form Under Review

Title of Collection: Key Individuals Narcotics Offenses and Drug trafficking certification, IAF-07.

Type of Review: New information collection.

OMB Control Number: Not assigned, new information collection.

Type of Respondent/Affected Public: Private Sector, Businesses or other for profits, Not-for profit institutions.

Frequency: Once.

Estimated Number of Respondents per year: 450.

Estimated Time per Respondent: 0.2.

Estimated Total Annual Burden Hours: 90.

Abstract: The IAF works to promote sustainable development in Latin America and the Caribbean by directly supporting civil society organizations through funding actions, such as grants and cooperative agreements. The IAF is soliciting comments concerning the collection of information to meet the drug-trafficking prohibition requirements in Section 487 of the Foreign Assistance Act and 22 CFR 140. The purpose of this form is to ensure that key individuals and covered participants affiliated with IAF grants are not participating in narcotics offenses or drug trafficking.

Dated: June 13, 2024.

Natalia Mandrus,

Associate General Counsel, Office of the General Counsel.

[FR Doc. 2024-13369 Filed 6-17-24; 8:45 am]

BILLING CODE 7025-01-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[245A2100DD/AAKC001030/
A0A501010.999900; OMB Control Number
1076-0187]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Use of Bureau-Operated Schools by Third Parties

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Education (BIE) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before July 18, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection request (ICR) should be sent within 30 days of publication of this notice to the Office of Information and Regulatory Affairs (OIRA) through https://www.reginfo.gov/public/do/PRA/icrPublicCommentRequest?ref_nbr=202212-1076-004 or by visiting <https://www.reginfo.gov/public/do/PRAMain> and selecting "Currently under Review—Open for Public Comments" and then scrolling down to the "Department of the Interior."

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Steven Mullen, Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs, U.S. Department of the Interior, 1001 Indian School Road NW, Suite 229, Albuquerque, New Mexico 87104; comments@bia.gov; (202) 924-2650. 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. You may also view the ICR at <https://www.reginfo.gov/public/Forward?SearchTarget=PRA&textfield=1076-0187>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public, and other Federal agencies, with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on January 5, 2023 (88 FR 879). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The BIE provides standards for the appropriate use of lands and facilities by third parties under 25 CFR part 48. These standards address the following: the execution of lease agreements; the establishment and administration of mechanisms for the acceptance of consideration for the use and benefit of a Bureau-operated school; the assurance of ethical conduct; and monitoring the amount and terms of consideration received, the manner in which the consideration is used, and any results achieved by such use.

Title of Collection: Use of Bureau-Operated Schools by Third Parties.

OMB Control Number: 1076–0187.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals and private sector.

Total Estimated Number of Annual Respondents: 17.

Total Estimated Number of Annual Responses: 24.

Estimated Completion Time per Response: One to three hours.

Total Estimated Number of Annual Burden Hours: 68 hours.

Respondent's Obligation: Required to Obtain a Benefit.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: \$0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Steven Mullen,

*Information Collection Clearance Officer,
Office of Regulatory Affairs and Collaborative
Action—Indian Affairs.*

[FR Doc. 2024–13403 Filed 6–17–24; 8:45 am]

BILLING CODE 4337–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1313]

Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on June 10, 2024, the presiding administrative law judge (“ALJ”) issued an Initial Determination on Violation of Section 337. On June 10, 2024, the ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public and interested government agencies only.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3115. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. (19 U.S.C. 1337(d)(1)). A similar provision applies to cease and desist orders. (19 U.S.C. 1337(f)(1)).

The Commission is soliciting submissions on public interest issues

raised by the recommended relief should the Commission find a violation, specifically: (1) a limited exclusion order directed to certain botulinum toxin products and processes for manufacturing or relating to same imported, sold for importation, and/or sold after importation by respondents Hugel, Inc. of Seoul, Republic of Korea; Hugel America, Inc. of Irvine, California; and Croma Pharma GmbH of Leobendorf, Austria; and (2) a cease and desist order directed to certain botulinum toxin products and processes for manufacturing or relating to same imported, sold for importation, and/or sold after importation by respondent Hugel America, Inc. of Irvine, California. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public and interested government agencies are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ’s Recommended Determination on Remedy and Bonding issued in this investigation on June 10, 2024. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant’s licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on July 12, 2024.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number ("Inv. No. 337-TA-1313") in a prominent place on the cover page and/or the first page. (See *Handbook for Electronic Filing Procedures*, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. Government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337),

and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: June 12, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024-13333 Filed 6-17-24; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1377]

Certain Products Containing Tirzepatide and Products Purporting To Contain Tirzepatide; Notice of a Commission Determination Not To Review an Initial Determination Granting a Motion To Amend the Complaint and Notice of Investigation

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined not to review an initial determination ("ID") (Order No. 16) of the presiding administrative law judge ("ALJ") granting a motion to amend the complaint and notice of investigation to name an additional respondent.

FOR FURTHER INFORMATION CONTACT: Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-3316. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 27, 2023, based upon a complaint filed on behalf of Eli Lilly and Company ("Eli Lilly") of Indianapolis, Indiana. 88 FR 82914-15 (Nov. 27, 2023). The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States and the sale of certain products containing tirzepatide or purporting to contain tirzepatide by

reason of false designation of source and false and misleading advertising, the threat or effect of which is to destroy or substantially injure an industry in the United States, and based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain products containing tirzepatide or purporting to contain tirzepatide by reason of infringement of U.S. Trademark No. 6,809,369. *Id.* The complaint also alleges that a domestic industry exists pursuant to subsection (a)(2) of section 337. *Id.*

The Commission's notice of investigation named as respondents Arctic Peptides LLC of Akeny, Iowa; Audrey Beauty Co. of Hong Kong, China; Biolabshop Limited of Lancaster, United Kingdom; Mew Mews Company Limited of Hong Kong, China; Strate Labs LLC of Spring, Texas; Steroide Kaufen of Bialystok, Poland; Super Human Store of Barcelona, Spain; Supopeptide of Cedar Grove, New Jersey; Triggered Supplements LLC of Clearwater, Florida; Unewlife of Cedar Grove, New Jersey; and Xiamen Austronext Trading Co., Ltd. of Fujian, China. *Id.* at 82915. The Office of Unfair Import Investigations ("OUII") is also named as a party in this investigation. *Id.*

Respondents Unewlife, Supopeptide, and Steroide Kaufen were terminated pursuant to withdrawal of the complaint. *See* Order No. 8 (Mar. 7, 2024), *unreviewed by* Comm'n Notice (Mar. 21, 2024). Respondents Arctic Peptides LLC; Audrey Beauty Co., Ltd.; Biolabshop Limited; Mew Mews Co. Ltd.; Strate Labs LLC; Super Human Store; Triggered Supplements LLC (d/b/a The Triggered Brand); and Xiamen Austronext Trading Co., Ltd. (d/b/a AustroPeptide) have been found in default. *See* Order No. 13 (Apr. 22, 2024), *unreviewed by* Comm'n Notice (May 15, 2024).

On May 21, 2024, the complaint and notice of investigation were amended to add two respondents: Fibonacci Sequence LLC d/b/a GenX Peptides of Houston, Texas; and Paradigm Peptides of Michigan City, Indiana. Order No. 12 (Apr. 22, 2024), *unreviewed by* Comm'n Notice (May 21, 2024), 89 FR 46159-60 (May 28, 2024).

On May 8, 2024, Eli Lilly filed a motion to amend the complaint and notice of investigation to name an additional respondent, Total Compounding Pharmaceuticals of Australia. On that same date, Eli Lilly filed a motion for leave to serve Total Compounding Pharmaceuticals by alternative service via email, which was granted pursuant to Order No. 14 (May

13, 2024). On May 15, 2024, OUII filed a response to the motion to amend, which did not oppose the amendment.

On May 17, 2024, the ALJ issued the subject ID granting the motion to amend the complaint and notice of investigation to name Total Compounding Pharmaceuticals as a respondent. The ALJ found that Eli Lilly had complied with the requirements of Commission Rule 210.14(b) (19 CFR 210.14(b)) for amendment of the complaint and notice of investigation. See ID at 3–6.

No petitions for review of the subject ID were filed.

The Commission has determined not to review the subject ID. The complaint and notice of investigation are hereby amended to add respondent Total Compounding Pharmaceuticals.

The Commission vote for this determination took place on June 13, 2024.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.
Issued: June 13, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–13370 Filed 6–17–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0184]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection: School Crime Supplement (SCS) to the National Crime Victimization Survey (NCVS)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Justice Statistics, Department of Justice (DOJ) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until August 19, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Alexandra Thompson (email: Alexandra.Thompson@usdoj.gov; telephone: 202–532–5472), Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Abstract: The Bureau of Justice Statistics (BJS) 2025 School Crime Supplement (SCS) to the National Crime Victimization Survey (NCVS), cosponsored by the Department of Education's National Center for Education Statistics (NCES), asks respondents ages 12 through 18 about crimes that occurred at school and other characteristics of school crime. The SCS includes questions on preventive measures used by schools; students' participation in after school activities; students' perceptions of safety and belonging in schools; students' perception of school rules and enforcement of these rules; the presence of weapons, illegal and prescription drugs including opioids, alcohol, and gangs in school; student bullying; hate-related incidents; and attitudinal questions relating to the fear of victimization at school. This

information helps policymakers; academic researchers; practitioners at the federal, state, and local levels; and special interest groups, who are concerned with crime in schools, make informed decisions about policies and programs.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *Title of the Form/Collection:* 2025 School Crime Supplement (SCS) to the National Crime Victimization Survey (NCVS).

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form number for the questionnaire is SCS–1. The applicable component within the Department of Justice is the Bureau of Justice Statistics (BJS), in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* The survey will be administered to persons ages 12 to 18 in NCVS sample households in the United States from January through June 2025. The SCS collects information on the students' victimization, perceptions of school environment, and safety at school. The survey is voluntary, and respondents are not required to respond.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimate of the total number of respondents is 5,530 persons ages 12 to 18. Of the 5,530 SCS respondents, 87% or 4,811 are expected to complete the long SCS interview (entire SCS questionnaire) which takes an estimated 17 minutes (0.28 hours) to complete. The remaining 13% or 719 SCS respondents are expected to complete the short interview (i.e. will be screened out for not being in school), which takes an estimated 2 minutes (0.03 hours) to complete. There are an estimated 1,380 annual burden hours associated with this collection. Respondents will be asked to respond to this survey only once during the six month period. The burden estimates are based on data from the prior administration of the SCS.

6. *An estimate of the total public burden (in hours) associated with the collection:* The total burden hours for this collection is 1,380.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* \$1,728,353.

TOTAL BURDEN HOURS

Activity	Number of respondents	Time per response	Total burden (hours)
Expected SCS Interviews	5,530		
Expected SCS Short Interviews	719	0.03 (2 min) ...	20
Expected SCS Long Interviews	4,811	0.28 (17 min)	1,360
Expected SCS Noninterviews	6,598		
Total	12,129		1,380

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W-218, Washington, DC.

Dated: June 13, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024-13340 Filed 6-17-24; 8:45 am]

BILLING CODE 4410-18-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Work Schedules Supplement to the CPS

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of Labor Statistics (BLS)-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 July 18, 2024.

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: The Work Schedules Supplement to the Current Population Survey will gather information on work schedules and work at home of the employed. Information will be collected to broadly categorize work schedules, including identifying shift workers and workers with flexible schedules, and people who work at home, including those who work entirely at home. The 2024 work schedules supplement will allow researchers and policy makers to evaluate how the number and characteristics of shift workers and people who work at home has evolved. Policy makers also can use these data to inform the design of regulations for different types of workers. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 22, 2024 (89 FRN 20502).

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.

Agency: DOL-BLS.

Title of Collection: Work Schedules Supplement to the CPS.

OMB Control Number: 1220-0119.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 47,000.

Total Estimated Number of Responses: 47,000.

Total Estimated Annual Time Burden: 3,917 hours.

Total Estimated Annual Other Costs Burden: \$1,000,000.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024-13365 Filed 6-17-24; 8:45 am]

BILLING CODE 4510-24-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2011-0190]

Shipyards Employment Standards; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Shipyard Employment Standards. The purpose of the collection of information (paperwork) provisions of the Standards is to reduce worker's risk of death or serious injury by ensuring that equipment has been tested and is in safe operating condition. **DATES:** Comments must be submitted (postmarked, sent, or received) by August 19, 2024.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the

docket, go to <https://www.regulations.gov>. Documents in the docket are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the websites. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693-2350 (TTY (877) 889-5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA-2011-0190) for the Information Collection Request (ICR). OSHA will place all comments, including any personal information, in the public docket, which may be made available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the

maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The following is a description of the collection of information requirements specified in the Shipyard Employment Standards. The purpose of the collection of information (paperwork) provisions of the standards is to reduce worker's risk of death or serious injury by ensuring that equipment has been tested and is in safe operating condition.

Manila rope and manila-rope slings (paragraph 1915.112(a)(1))—The employer must ensure that manila rope and manila-rope slings have permanently affixed and legible identification markings as prescribed by the manufacturer that indicate the recommended safe working load for the type(s) of hitch(es) used, the angle upon which it is based, and the number of legs if more than one.

Wire rope and wire-rope slings (paragraph 1915.112(b)(1)(i))—The employer must ensure that wire rope and wire-rope slings have permanently affixed and legible identification markings as prescribed by the manufacturer that indicate the recommended safe working load for the type(s) of the hitch(es) used, the angle upon which it is based, and the number of legs if more than one.

Chain and chain slings (paragraph 1915.112(c)(1)(i))—The employer must ensure that chain and chain slings have permanently affixed and legible identification markings as prescribed by the manufacturer that indicate the recommended safe working load for the type(s) of hitch(es) used, the angle upon which it is based, and the number of legs if more than one.

Chain and chain slings (paragraph 1915.112(c)(2))—The employer shall visually inspect all slings chains, including end fastenings, before being used on the job, as well as every three months. The inspection shall include inspection for wear, defective welds, deformation, and increase in length or stretch. Each chain shall bear an indication of the month in which it was thoroughly inspected.

Shackles (paragraph 1915.113(a)(1))—The employer must ensure that shackles have permanently affixed and legible identification markings as prescribed by the manufacturer that indicate the recommended safe working load.

Test Records for Hooks (paragraph 1915.113(b)(1))—This paragraph requires that the manufacturer's recommendations be followed in determining the safe working loads of the various sizes and types of hooks. If the manufacturer's recommendations

are not available, the hook must be tested to twice the intended safe working load before it is initially put into use. The employer must maintain and keep readily available a certification record which includes the date of such test, the signature of the person who performed the test, and an identifier for the hook which was tested.

The records are used to assure that equipment has been properly tested. The records also provide the most efficient means for the compliance officers to determine that an employer is complying with the Standard.

Mobile Crawler or Truck Cranes Used on a Vessel (paragraph 1915.115(c))—This paragraph requires that the maximum manufacturer's rated safe working loads for the various working radii of the boom and the maximum and minimum radii at which the boom may be safely used with and without outriggers shall be conspicuously posted near the controls and shall be visible to the operator.

Examination and Test Records for Unfired Pressure Vessels (paragraphs 1915.172(b) and (d))—Paragraph (b) requires that portable, unfired pressure vessels not built to the requirements of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Section VIII, Rules for Construction of Unfired Pressure Vessels, 1963 be examined quarterly by a competent person and subjected to a yearly hydrostatic pressure test. A certification record of such examinations and tests shall be maintained as specified by paragraph (d).

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements contained in the

Shipyard Employment Standards. The agency is requesting an adjustment decrease in burden from 10,379 hours to 9,538 hours, a difference of 841 hours. This adjustment decrease is due to the decrease in the number of establishments.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: Shipyard Employment Standard.

OMB Control Number: 1218–0220.

Affected Public: Business or other for-profits.

Number of Respondents: 4,674.

Number of Responses: 24,637.

Frequency of Responses: Varies.

Average Time per Response: Varies.

Estimated Total Burden Hours: 9,538.

Estimated Cost (Operation and Maintenance): \$0.

IV. Public Participation—Submission of Comments on this Notice and internet Access to Comments and Submissions

You may submit comments in response to this document as follows:

(1) electronically at <https://www.regulations.gov>, which is the Federal eRulemaking Portal; or (2) by facsimile (fax), if your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at 202–693–1648. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (OSHA–2011–0190). You may supplement electronic submission by uploading document files electronically.

Comments and submissions are posted without change at <https://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the <https://www.regulations.gov> index, some information (e.g., copyrighted material) is not publicly available to read or download from this website. All submission, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <https://www.regulations.gov> website to submit comments and access the docket is available at the website's "User Tips" link.

Contact the OSHA Docket Office at (202) 693–2350, (TTY) (877) 889–5627 for information about materials not available from the website, and for

assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC, on June 11, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–13366 Filed 6–17–24; 8:45 am]

BILLING CODE 4510–26–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 24–03]

Renewal of the MCC Advisory Council and Call for Nominations

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Federal Advisory Committee Act, the Millennium Challenge Corporation ("MCC") has renewed the charter for the MCC Advisory Council ("Advisory Council") and is hereby soliciting representative nominations for the 2024–2026 term. The Advisory Council serves MCC in an advisory capacity only and provides insight regarding innovations in relevant sectors including technology, agriculture, land management, infrastructure, environment, climate, blended finance, public finance, health, water and sanitation, energy, gender, and social inclusion; perceived risks and opportunities in MCC partner countries; and evolving approaches to working in developing country contexts. The Advisory Council provides a platform for systematic engagement with the private sector and contributes to MCC's mission—to reduce poverty through sustainable, economic growth. MCC uses this advice, information, and recommendations to inform compact development and implementation, and broaden public and private sector partnerships for more impact and leverage. The MCC Vice President of the Department of Compact Operations affirms that the Advisory Council is necessary and in the public interest. The Advisory Council is seeking members representing a diverse group of private

sector organizations with expertise in the aforementioned sectors particularly in the countries and regions where MCC operates. Additional information about MCC and its portfolio can be found at www.mcc.gov.

DATES: Nominations for Advisory Council members must be received on or before 5:00 p.m. EDT on August 21, 2024. Further information about the nomination process is included below. MCC plans to host the first MCC Advisory Council meeting in the Fall of 2024. The Advisory Council will meet at least two times a year in Washington, DC and/or via video/teleconferencing. Members who are unable to attend in-person meetings may have the option to dial-in via video/teleconferencing.

FOR FURTHER INFORMATION CONTACT: All nomination materials or requests for additional information should be emailed to MCC's Designated Federal Officer, Bahgi Berhane, at 202–521–3600, MCCAdvisoryCouncil@mcc.gov, or mailed to Millennium Challenge Corporation, Attn: Alex Dixon, Finance, Investment, and Trade, 1099 14th St. NW, Suite 700, Washington, DC 20005.

SUPPLEMENTARY INFORMATION: The Advisory Council shall consist of not more than twenty-five (25) individuals who are recognized thought leaders, business leaders and experts representing US companies, the business community, advocacy organizations, NGOs, non-profits organizations, foundations, and industry sectors including infrastructure, ICT, industry/manufacturing and finance, as well as sustainable development/environment. Qualified individuals may self-nominate or be nominated by any individual or organization. To be considered for the Advisory Council, nominators should submit the following information:

- Name, title, organization (if applicable), and relevant contact information (including phone and email address) of the individual under consideration;
- A letter, on organization letterhead if applicable, containing a brief description why the nominee should be considered for membership; and
- CV including professional and academic credentials.

Please do not send company, trade association, or organization brochures or any other information. Materials submitted should not exceed two pages. Should more information be needed, MCC staff will contact the nominee, obtain information from the nominee's past affiliations, or obtain information from publicly available sources.

All members of the Advisory Council will be independent of the agency, representing the views and interests of their respective industry or area of expertise, and not as “special Government employees.” All Members shall serve without compensation.

A selection team comprising representatives from several MCC departments will review the nomination packages. The selection team will make recommendations regarding membership to the Vice President for Compact Operations based on criteria including: (1) professional or academic expertise, experience, and knowledge; (2) stakeholder representation; (3) availability and willingness to serve; and (4) skills working collaboratively on committees and advisory panels. Based upon the selection team’s recommendations, the Vice President for Compact Operations will select representatives.

In the selection of members for the Advisory Council, MCC will seek to ensure a balanced representation and consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the Advisory Council. Nominees selected for appointment to the Advisory Council will be notified by return email and receive a letter of appointment.

Nominations are open to all individuals without regard to race, color, religion, sex, national origin, age, mental or physical disability, marital status, or sexual orientation.

(Authority: Federal Advisory Committee Act, as amended, 5 U.S.C. chapter 10.)

Dated: June 13, 2024.

Peter E. Jaffe,

Vice President, General Counsel, and Corporate Secretary.

[FR Doc. 2024–13355 Filed 6–17–24; 8:45 am]

BILLING CODE 9211–03–P

NATIONAL SCIENCE FOUNDATION

Networking and Information Technology Research and Development Request for Information on Digital Twins Research and Development

AGENCY: Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO), National Science Foundation.

ACTION: Request for information.

SUMMARY: On behalf of Office of Science and Technology Policy (OSTP), the NITRD National Coordination Office seeks public input for the creation of a

National Digital Twins R&D Strategic Plan. The Plan will act as an organizing national document, providing guidance for government investments in digital twins related research and offering valuable insights to help guide further federal R&D coordination to advance technology and accelerate the use and early adoption of the digital twin models to address the nation’s priorities and fast-track agency missions. The Plan is scheduled to be released in mid to late 2025.

DATES: Interested persons are invited to submit comments on or before 11:59 p.m. (ET) on July 28, 2024.

ADDRESSES: Comments submitted in response to this RFI may be sent by any of the following methods:

- **Email:** DigitalTwins-ftacRFI@nitrd.gov; Email submissions should be machine-readable and not be copy-protected. Submissions should include “RFI Response: Digital Twins R&D Plan” in the subject line of the message.
- **Mail:** Attn: Melissa Cornelius, 2415 Eisenhower Avenue, Alexandria, VA 22314, USA. Telephone: 202–459–9674.

Instructions: Response to this RFI is voluntary. Each individual or institution is requested 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. Responses must include the name of the person(s) or organization(s) filing the comment and the following statement: “This document is approved for public dissemination. The document contains no business-proprietary or confidential information. Document contents may be reused by the government in the National Digital Twins R&D Strategic Plan and associated documents without attribution.” Responses to this RFI 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 to this RFI.

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.

FOR FURTHER INFORMATION CONTACT:

Craig Schlenoff, Melissa Cornelius, Simon Frechette, Stacey Levine, Steven Lee, Qing Wu at DigitalTwins-ftacRFI@nitrd.gov or (202) 459–9674. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8

p.m., Eastern time, Monday through Friday, except for U.S. Federal Government holidays.

SUPPLEMENTARY INFORMATION: The National Academies of Sciences, Engineering, and Medicine (The National Academies) released its report on digital twins, *Foundational Research Gaps and Future Directions for Digital Twins* (2024). The report makes recommendations for federal agencies to launch crosscutting programs to advance mathematical, statistical, and computational foundations for digital twins and identify collaborative opportunities. In response to this, the Fast-Track Action Committee (FTAC) on Digital Twins (DT) is developing a National Digital Twins Research and Development (R&D) Strategic Plan (the Plan) that lays out the Digital Twins R&D priorities within federal agencies.

Terminology: As defined in The National Academies report, *Foundational Research Gaps and Future Directions for Digital Twins*, A digital twin is a set of virtual information constructs that mimics the structure, context, and behavior of a natural, engineered, or social system (or system-of-systems), is dynamically updated with data from its physical twin, has a predictive capability, and informs decisions that realize value. The bidirectional interaction between the virtual and the physical is central to the digital twin. *This definition will be used for the purposes of this RFI, but respondents are welcome to provide alternate definitions if digital twins have a different meaning in their industry or field, along with the scientific rationale for specific use-cases.* Reference citation as appropriate.

Information Requested: Responsible innovation in digital twins could provide significant benefits for the American people. This RFI seeks input to shape a whole-of-government effort on research and development related to digital twins across domains. Examples include but are not limited to biomedical sciences, climate change, smart cities, and scientific discovery. This RFI is soliciting R&D topic areas in which the strategic plan should focus, as well as details that should be considered when/if the topic area is elaborated in the strategic plan. Example topics are included below, but we welcome other topics as appropriate. Respondents may provide information related to one or more of the topics outlined below and should indicate the topic to which they are responding by using the keyword in bold. Possible topics include (listed in alphabetical order):

- *Artificial Intelligence (AI)*: AI and Digital Twins: Possible focus areas: integration of digital twins with artificial intelligence (AI); leverage generative AI for digital twin modeling & simulation with the consideration of the potential impact on a digital twins' physical counterpart

- *Business: Business Case Analysis*: Possible focus areas: foundational research cost; evaluate value/return on investment; cost and time to implement

- *Data*: Encourage Adoption of Data Management Best Practices: Possible focus areas: governance methods for data collection, curation, sharing and usage; shared public datasets and repositories; real-time data integration

- *Ecosystem*: Establish a National Digital Twin R&D Ecosystem: Possible focus areas: collaborations across agencies to identify and address foundational research gaps and opportunities that spans areas such as biomedical sciences, environmental ecosystem, sustainability & climate change, smart and connected communities, scientific discovery, agriculture, military & mission planning, as well as common mathematical, statistical, and computational foundations

- *International*: International Collaborations on Digital Twins: Possible focus areas: global scale digital twins across foreign markets; global issues and digital twin development consensus standards; opportunities for international collaboration (e.g., European Union's Horizon 2020 program funding digital twin projects)

- *Long Term*: Identify Long Term Research Investments: Possible focus areas: novel approaches for interactive data-driven modeling and simulation, both crosscutting and fit for purpose; research enabling the bidirectional flow between the virtual and the physical assets; creating test environments for digital twins ensuring sufficient resources and sustainable high-performance computing

- *Regulatory*: Regulatory Science Challenges associated with the use of Digital Twins

- *Responsible*: Promote Responsible Development & Use of Digital Twins: Possible focus areas: ethical use of digital twins; identifying ethical issues, mitigating and biases with respect to data ownership, intellectual property and privacy

- *Standards*: Promote Development of Evaluation Tools, Methodologies and Consensus Standards for Digital Twin Development and Testing and Interoperability: Possible focus areas: community of practice, ontology and data exchange protocols; encryption

standards; taxonomy; address challenges related to evaluation of data-driven Digital Twin components; continuous and multi-modal data sources; personalized applications derived from Digital Twins; transferability, generalizability and robustness of Digital Twins

- *Sustainability*: Design and Develop Systems and Architectures for Digital Twin Sustainability: Possible focus areas: sustainment as the operating systems and computational models on which they are based evolve and the data which they ingest are updated; intentional organizational effort and purpose-built modeling ecosystems energy-awareness; early consideration of computational requirements and effective workflows; develop approaches for the design, development, and deployment of Digital Twins; the ability to create interoperable Digital Twins with evolving technology and standards

- *Trustworthy*: Realize Secure and Trustworthy Digital Twins: Possible focus areas: develop solutions to assure the security, cyber resilience, and trustworthiness of digital twins (taking into account all components of DTs such as their code base, data and data processing, operational environments, networking and connectivity with the physical counterpart); develop capabilities to utilize DTs to improve the security and cyber resilience of the physical counterpart, such as through threat analysis, attack modeling, risk analysis, security testing and similar analyses conducted on the Digital Twins

- *VVUQ*: Develop Rigorous Methods for Verification, Validation, and Uncertainty Quantification for Digital Twins: Possible focus areas: foundational and cross-cutting methods as well as domain specific; integration of VVUQ into all elements of the full digital twin ecosystem

- *Workforce*: Cultivate Workforce and Training to Advance Digital Twin Research and Development: Possible focus areas: diverse talent recruitment; incentivize cross-disciplinary STEM research programs across educational institutions

We encourage responses to be organized according to the preceding outline, although we also welcome responses that address only a subset of the items. Submitters are encouraged to address the topics of this RFI clearly and concisely.

References

- National Academies of Sciences, Engineering, and Medicine. 2024. Foundational Research Gaps and Future Directions for Digital Twins.

Washington, DC: The National Academies Press. <https://doi.org/10.17226/26894>.

- *A National Academies of Sciences, Engineering, and Medicine-appointed ad hoc committee*, Committee Members and Sponsors, Events, Publications.
- *Digital Twins—The Networking and Information Technology Research and Development (NITRD) Program*. Submitted by the National Science Foundation in support of the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) on June 13, 2024.

(Authority: 42 U.S.C. 1861, *et seq.*)

Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.

[FR Doc. 2024–13379 Filed 6–17–24; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; NSF Small Business Innovation Research (SBIR) Program Phase I, NSF Small Business Technology Transfer (STTR) Program Phase I, and NSF SBIR/STTR Fast-Track Pilot Pre-submission Project Pitch Form

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to establish this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by August 19, 2024 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Room E6347, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to splimpto@nsf.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24

hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: NSF Small Business Innovation Research (SBIR) Program Phase I, NSF Small Business Technology Transfer (STTR) Program Phase I, and NSF Fast-Track Pilot Pre-submission Project Pitch Form.

OMB Control No.: 3145–NEW.

Expiration Date of Approval: Not applicable.

Abstract: The NSF Small Business Innovation Research Program (SBIR) Phase I, Small Business Technology Transfer Program (STTR) Phase I, and SBIR/STTR Fast-Track Pilot Project Pitch is an NSF SBIR/STTR pre-submission process that conveys information needed to direct the proposed SBIR/STTR project to the appropriate NSF Program Director (PD) for review and possible proposal submission invitation. The Project Pitch is to be submitted by the applying small business concern (as “proposer”) to the relevant NSF SBIR/STTR Phase I or Fast-Track Pilot technology topic. The Project Pitch outlines solicitation-specific aspects of the project (such as the proposed technology innovation)) and captures the same requested information, as outlined in the NSF SBIR/STTR Phase I and Fast-Track Program solicitations, but all within one secure, web-based form. Specifically, the form collects the submitting proposer company and team information, the proposed technology innovation; the technical objectives and challenges, and the market opportunity. The form also allows the proposer to choose (from a drop-down menu) the most relevant NSF SBIR/STTR Phase I and Fast-Track Pilot technical topic area, ensuring that the submitted Project Pitch goes to the most appropriate Program Director. For the SBIR/STTR Fast-Track Pilot submission, the Project Pitch encompasses the same questions as outlined in the Phase I Project Pitch but also seeks responses to three key eligibility requirements: NSF lineage, customer-discovery experience, and confirmation that the team members are currently employed by the company. These requirements expand on the details of the previously required information on the proposed technology innovation, the market opportunity, and the company and team, respectively.

Respondents: Small business concerns who submit proposals to NSF’s SBIR/STTR Phase I and Fast-Track Pilot Programs.

Estimated Number of Annual Respondents: 2500.

Burden on the Public: 3 hours (per response) for an annual total of 7500 hours.

Dated: June 13, 2024.

Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.

[FR Doc. 2024–13380 Filed 6–17–24; 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 July 18, 2024. 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: 2025–002

1. *Applicant:* Jesse Naiman, Pathfinder Aviation, 1936 Merrill Field Drive, Anchorage, AK 99501.

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area. The applicant requests an ACA permit to enter ASPA 124—Cape Crozier using a helicopter, below 2,000 feet, should weather require. The flights are required to support U.S. Antarctic Program science and management activities in the Cape Crozier area. Helicopter flights would not occur in the vicinity of wildlife at Cape Crozier, and all activities would be consistent with the management plan for the ASPA. Up to a total of 20 flights under 2,000 ft are requested per year.

Location: ASPA 124—Cape Crozier.

Dates of Permitted Activities: October 1, 2024–March 1, 2026.

Permit Application: 2025–001

2. *Applicant:* Link Olson, University of Alaska Museum Mammal Collection, 1962 Yukon Drive, Fairbanks, AK 99775.

Activity for Which Permit is Requested: Export From USA. The applicant requests a permit to export 6 crabeater seal (*Lobodon carcinophaga*) blood samples. The samples are part of the archived specimens in the University of Alaska Museum Mammal collection and would be exported to a science collaborator at the Bielefeld University, Germany for genetic analysis. The permit applicant currently holds a Marine Mammal Protection Act permit to receive, possess, import and export the samples in their possession.

Location: None.

Dates of Permitted Activities: July 1, 2024–December 31, 2024.

Kimiko S. Bowens-Knox,

Program Analyst, Office of Polar Programs.

[FR Doc. 2024–13332 Filed 6–17–24; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0194]

Information Collection: Financial Protection Requirements and Indemnity Agreements

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, “Financial Protection

Requirements and Indemnity Agreements.”

DATES: Submit comments by August 19, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2023–0194. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION**

CONTACT section of this document.

- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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

FOR FURTHER INFORMATION CONTACT:

David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0194 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2023–0194.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to

PDR.Resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS. The supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML23319A326 and ML23319A325.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC’s Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC’s Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2023–0194, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB’s approval for the information collection summarized below.

1. *The title of the information collection:* Part 140 of title 10 of the *Code of Federal Regulations* (10 CFR), Financial Protection Requirements and Indemnity Agreements.

2. *OMB approval number:* 3150–0039.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* Annually, and on occasion, as needed for applicants and licensees to meet their responsibilities called for in Sections 170 and 193 of the Atomic Energy Act of 1954, as amended (AEA).

6. *Who will be required or asked to respond:* Each applicant for or holder of a license issued under 10 CFR parts 50 or 54, to operate a nuclear reactor, or the applicant for or holder of a combined license issued under 10 CFR parts 52 or 54, as well as licensees authorized to possess and use plutonium in a plutonium processing and fuel fabrication plant. In addition, licensees authorized to construct and operate a uranium enrichment facility in accordance with 10 CFR parts 40 and 70.

7. *The estimated number of annual responses:* 110.

8. *The estimated number of annual respondents:* 110.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 768 hours.

10. *Abstract:* 10 CFR part 140 specifies the information to be submitted by licensees that enables the NRC to assess: (a) financial protection required by licensees and for the indemnification and limitation of liability of certain licensees and other persons pursuant to Section 170 of the AEA, as amended; and (b) the liability insurance required opinion.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: June 12, 2024.

For the Nuclear Regulatory Commission.
David Cullison,
*NRC Clearance Officer, Office of the Chief
Information Officer.*
[FR Doc. 2024-13320 Filed 6-17-24; 8:45 am]
BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2023-0156]

Information Collection: NRC Form 995, Authorization for Use or Disclosure of Protected Health Information

AGENCY: Nuclear Regulatory
Commission.

ACTION: Proposed information
collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory
Commission (NRC) invites public
comment on this proposed information
collection. The information collection is
entitled, NRC Form 995, “Authorization
for Use or Disclosure of Protected
Health Information.”

DATES: Submit comments by August 19,
2024. Comments received after this date
will be considered if it is practical to do
so, but the Commission is able to ensure
consideration only for comments
received on or before this date.

ADDRESSES: You may submit comments
by any of the following methods;
however, the NRC encourages electronic
comment submission through the
Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2023-0156. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

FOR FURTHER INFORMATION CONTACT:
David Cullison, Office of the Chief
Information Officer, U.S. Nuclear
Regulatory Commission, Washington,
DC 20555-0001; telephone: 301-415-
2084; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2023-0156 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2023-0156. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2023-0156 on this website.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The supporting statement and NRC Form 995 are available in ADAMS under Accession Nos. ML23254A227 and ML23254A225.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC’s Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC’s Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2023-0156, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not

routinely edited to remove identifying or contact information.

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

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB’s approval for the information collection summarized below.

1. *The title of the information collection:* NRC Form 995, Authorization for Use or Disclosure of Protected Health Information.

2. *OMB approval number:* An OMB control number has not yet been assigned to this proposed information collection.

3. *Type of submission:* New.

4. *The form number, if applicable:* NRC Form 995.

5. How often the collection is required or requested: Information is collected as needed.

6. *Who will be required or asked to respond:* Medical providers.

7. *The estimated number of annual responses:* 30.

8. *The estimated number of annual respondents:* 30.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 37.5.

10. *Abstract:* This clearance is being requested to collect information from an employee to authorize the agency’s medical reviewing authority to contact their private health provider. This authorization will be requested to determine and clarify disability status in the following situations: (1) an employee has requested reasonable accommodation and provided medical documentation; but further clarification or detail is needed to reach an appropriate determination on the request for accommodation; or (2) an employee is requesting extended health care coverage for a disabled adult dependent beyond the age otherwise covered.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: June 12, 2024.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2024–13322 Filed 6–17–24; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before July 18, 2024.

ADDRESSES: Comments should be addressed to James Olin, FOIA/Privacy Act Officer. James Olin can be contacted by phone 202–692–2507 or email at pcf@peacecorps.gov. Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: James Olin, Peace Corps, at pcf@peacecorps.gov or by telephone at (202) 692–2507.

SUPPLEMENTARY INFORMATION:

Title: Individual Specific Medical Evaluation Forms (15).

OMB Control Number: 0420–0550.

Type of Request: Revision/New.

Affected Public: Individuals/Physicians.

Respondents Obligation to Reply: Voluntary.

Respondents: Potential and current volunteers.

Burden to the Public:

- Asthma Evaluation Form
 - (a) Estimated number of Applicants/physicians 700/700
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 75 minutes/30 minutes
 - (d) Estimated total reporting burden 875 hours/350 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection:

When an Applicant reports on the Health History Form any history of asthma, he or she will be provided an Asthma Evaluation Form for the treating physician to complete. The Asthma Evaluation Form asks for the physician to document the Applicant's condition of asthma, including any asthma symptoms, triggers, treatments, or limitations or restrictions due to the condition. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of the Applicant within reasonable proximity to a hospital in case treatment is needed for a severe asthma attack.

- Diabetes Diagnosis Form
 - (a) Estimated number of Applicants/physicians 55/55
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 75 minutes/30 minutes
 - (d) Estimated total reporting burden 69 hours/28 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection:

When an Applicant reports the condition of diabetes Type 1 on the Health History Form, the Applicant will be provided a Diabetes Diagnosis Form for the treating physician to complete. In certain cases, the Applicant may also be asked to have the treating physician complete a Diabetes Diagnosis Form if the Applicant reports the condition of diabetes Type 2 on the Health History Form. The Diabetes Diagnosis Form asks the physician to document the diabetes diagnosis, etiology, possible complications, and treatment. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to

perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of an Applicant who requires the use of insulin in order to ensure that adequate insulin storage facilities are available at the Applicant's site.

- Transfer of Care—Request for Information Form
 - (a) Estimated number of Applicants/physicians 1270/1270
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 75 minutes/30 minutes
 - (d) Estimated total reporting burden 1588 hours/635 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection:

When an Applicant reports on the Health History Form a medical condition of significant severity (other than one covered by another form), he or she may be provided the Transfer of Care—Request for Information Form for the treating physician to complete. The Transfer of Care—Request for Information Form may also be provided to an Applicant whose responses on the Health History Form indicate that the Applicant may have an unstable medical condition that requires ongoing treatment. The Transfer of Care—Request for Information Form asks the physician to document the diagnosis, current treatment, physical limitations and the likelihood of significant progression of the condition over the next three years. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation (e.g., avoidance of high altitudes or proximity to a hospital) that may be needed to manage the Applicant's medical condition.

- Mental Health Current Evaluation and Treatment Summary Form
 - (a) Estimated number of Applicants/professional 1221/1221
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 105 minutes/60 minutes
 - (d) Estimated total reporting burden 2137 hours/1221 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The Mental Health Current Evaluation Form

will be used when an Applicant reports on the Health History Form a history of certain serious mental health conditions, such as bipolar disorder, schizophrenia, mental health hospitalization, attempted suicide or cutting, or treatments or medications related to these conditions. In these cases, an Applicant will be provided a Mental Health Current Evaluation and Treatment Summary Form for a licensed mental health counselor, psychiatrist or psychologist to complete. The Mental Health Current Evaluation and Treatment Summary Form asks the counselor, psychiatrist or psychologist to document the dates and frequency of therapy sessions, clinical diagnoses, symptoms, course of treatment, psychotropic medications, mental health history, level of functioning, prognosis, risk of exacerbation or recurrence while overseas, recommendations for follow up and any concerns that would prevent the Applicant from completing 27 months of service without unreasonable disruption. A current mental health evaluation might be needed if information on the condition is outdated or previous reports on the condition do not provide enough information to adequately assess the current status of the condition. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate mental health support.

- Functional Abilities Evaluation Form
 - (a) Estimated number of Applicants/ professional 300/300
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 90 minutes/45 minutes
 - (d) Estimated total reporting burden 390 hours/225 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection:

When an Applicant reports on the Health History Form a functional ability limitation he or she will be provided this form to determine the type of accommodation and/or placement program support (e.g., proximity to program site, support support devices) that may be needed to manage the Applicant's medical condition.. This form will be used as the basis for an

individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems.

- Eating Disorder Treatment Summary Form
 - (a) Estimated number of Applicants/ physicians 282/282
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 105 minutes/60 minutes
 - (d) Estimated total reporting burden 494 hours/282 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection:

The Eating Disorder Treatment Summary will be used when an Applicant reports a past or current eating disorder diagnosis in the Health History Form. In these cases the Applicant is provided an Eating Disorder Treatment Summary Form for a mental health specialist, preferably with eating disorder training, to complete. The Eating Disorder Treatment Summary Form asks the mental health specialist to document the dates and frequency of therapy sessions, clinical diagnoses, presenting problems and precipitating factors, symptoms, Applicant's weight over the past three years, relevant family history, course of treatment, psychotropic medications, mental health history inclusive of eating disorder behaviors, level of functioning, prognosis, risk of recurrence in a stressful overseas environment, recommendations for follow up, and any concerns that would prevent the Applicant from completing 27 months of service without unreasonable disruption due to the diagnosis. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate mental health support.

- Substance-Related and Addictive Disorders Current Evaluation Form
 - (a) Estimated number of Applicants/ specialist 373/373
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 165 minutes/60 minutes
 - (d) Estimated total reporting burden

1026 hours/373 hours

- (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The Alcohol/Substance Abuse Current Evaluation Form is used when an Applicant reports in the Health History Form a history of substance abuse (i.e., alcohol or drug related problems such as blackouts, daily or heavy drinking patterns or the misuse of illegal or prescription drugs) and that this substance abuse affects the Applicant's daily living or that the Applicant has ongoing symptoms of substance abuse. In these cases, the Applicant is provided an Substance-Related and Addictive Disorders Current Evaluation Form for a substance abuse specialist to complete. The Substance-Related and Addictive Disorders Current Evaluation Form asks the substance abuse specialist to document the history of alcohol/ substance abuse, dates and frequency of any therapy sessions, which alcohol/ substance abuse assessment tools were administered, mental health diagnoses, psychotropic medications, self harm behavior, current clinical assessment of alcohol/substance use, clinical observations, risk of recurrence in a stressful overseas environment, recommendations for follow up, and any concerns that would prevent the Applicant from completing a tour of service without unreasonable disruption due to the diagnosis. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate sobriety support or counseling support.

- Mammogram Waiver Form
 - (a) Estimated number of Applicants 148
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 105 minutes
 - (d) Estimated total reporting burden 259 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection:

The Mammogram Form is used for all Applicants who have female breasts and will be 50 years of age or older during service who wish to waive routine mammogram screening during service. If an Applicant waives routine mammogram screening during service,

the Applicant's physician is asked to complete this form in order to make a general assessment of the Applicant's statistical breast cancer risk and discussed the results with the Applicant including the potential adverse health consequence of foregoing screening mammography.

- Cervical Cancer Screening Form
 - (a) Estimated number of Applicants 3600/3600
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 40 minutes/30 minutes
 - (d) Estimated total reporting burden 2400 hours/1800 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The Cervical Cancer Screening Form is used with all Applicants with a cervix. Prior to medical clearance, female Applicants are required to submit a current cervical cancer screening examination and Pap cytology report based the American Society for Colposcopy and Cervical Pathology (ASCCP) screening time-line for their age and Pap history. This form assists the Peace Corps in determining whether an Applicant with mildly abnormal Pap history will need to be placed in a country with appropriate support.

- Colon Cancer Screening Form
 - (a) Estimated number of Applicants 575
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 60 minutes–165 minutes
 - (d) Estimated total reporting burden 575 hours–1581 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The Colon Cancer Screening Form is used with all Applicants who are 50 years of age or older to provide the Peace Corps with the results of the Applicant's latest colon cancer screening. Any testing deemed appropriate by the American Cancer Society is accepted. The Peace Corps uses the information in the Colon Cancer Screening Form to determine if the Applicant currently has colon cancer. Additional instructions are included pertaining to abnormal test results.

- ECG Form
 - (a) Estimated number of Applicants/physicians 575/575
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 25 minutes/15 minutes
 - (d) Estimated total reporting burden 240 hours/144 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The ECG/EKG Form is used with all

Applicants who are 50 years of age or older to provide the Peace Corps with the results of an electrocardiogram. The Peace Corps uses the information in the electrocardiogram to assess whether the Applicant has any cardiac abnormalities that might affect the Applicant's service. Additional instructions are included pertaining to abnormal test results. The electrocardiogram is performed as part of the Applicant's physical examination.

- Reactive Tuberculin Test Evaluation Form
 - (a) Estimated number of Applicants/physicians 392/392
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 75–105 minutes/30 minutes
 - (d) Estimated total reporting burden 490–686 hours/196 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The Reactive Tuberculin Test Evaluation Form is used when an Applicant reports a history of treatment for active tuberculosis or a history of a positive tuberculosis (TB) test on their Health History Form or if a positive TB test result is noted as a component of the Applicant's physical examination findings. In these cases, the Applicant is provided a Reactive Tuberculin Test Evaluation Form for the treating physician to complete. The treating physician is asked to document the type and date of a current TB test, TB test history, diagnostic tests if indicated, treatment history, risk assessment for developing active TB, current TB symptoms, and recommendations for further evaluation and treatment. In the case of a positive result on the TB test, a chest x-ray may be required, along with treatment for latent TB.

- Insulin Dependent Supplemental Documentation Form
 - (a) Estimated number of Applicants/physicians 14/14
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 70 minutes/60 minutes
 - (d) Estimated total reporting burden 16 hours/14 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The Insulin Dependent Supplemental Documentation Form is used with Applicants who have reported on the Health History Form that they have insulin dependent diabetes. In these cases, the Applicant is provided an Insulin Dependent Supplemental Documentation Form for the treating physician to complete. The Insulin Dependent Supplemental

Documentation Form asks the treating physician to document that he or she has discussed with the Applicant medication (insulin) management, including whether an insulin pump is required, as well as the care and maintenance of all required diabetes related monitors and equipment. This form assists the Peace Corps in determining whether the Applicant will be in need of insulin storage while in service and, if so, will assist the Peace Corps in determining an appropriate placement for the Applicant.

- Prescription for Eyeglasses Form
 - (a) Estimated number of Applicants/physicians 3,293/3,293
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 60 minutes/15 minutes
 - (d) Estimated total reporting burden 3,293 hours/824 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The Prescription for Eyeglasses is used with Applicants who have reported on the Health History Form that they use corrective lenses or otherwise have uncorrected vision that is worse than 20/40. In these cases, Applicants are provided a Prescription for Eyeglasses Form for their prescriber to indicate eyeglasses frame measurements, lens instructions, type of lens, gross vision and any special instructions. This form is used in order to enable the Peace Corps to obtain replacement eyeglasses for a Volunteer during service.

- Required Peace Corps Immunizations Form
 - (a) Estimated number of Applicants/physicians 5,600
 - (b) Frequency of response one time
 - (c) Estimated average burden per response 60 minutes
 - (d) Estimated total reporting burden 5,600 hours
 - (e) Estimated annual cost to respondents Indeterminate

General Description of Collection: The Required Peace Corps Immunizations Form is used to inform Applicants of the specific vaccines and/or documented proof of immunity required for medical clearance for the specific country of service. The form advises the Applicant that all other Center for Disease Control (CDC) recommended vaccinations will be administered after arrival in-country. This form assists the Peace Corps with establishing a baseline of the Applicants immunization history and prepare for any additional vaccines recommended for country of service.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are

necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC on June 12, 2024.

James Olin,

FOIA/Privacy Act Officer.

[FR Doc. 2024-13304 Filed 6-17-24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100319; File No. SR-PEARL-2024-25]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Equities Exchange Fee Schedule To Establish Market Data Fees

June 12, 2024.

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 May 31, 2024, MIAX PEARL, LLC ("MIAX Pearl" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Pearl Equities Exchange Fee Schedule (the "Fee Schedule") to adopt fees for the Exchange's proprietary market data feeds.³

The text of the proposed rule change is available on the Exchange's website at <https://www.miaxoptions.com/rule->

filings, at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

MIAX Pearl Equities provided its proprietary market data for free to subscribers for over three and half years since it commenced operations in September 2020.⁴ Prior to the initial proposal to adopt market data fees, the Exchange solely and entirely absorbed all costs associated with compiling and disseminating its proprietary market data. The Exchange offers two standard proprietary market data products, the Top of Market ("ToM") feed and the Depth of Market ("DoM") feed (collectively, the "market data feeds"). Each of these proprietary market data products are described in Exchange Rule 2625.

Exchange Rule 2625(a) provides that the DoM feed is a data feed that contains the displayed price and size of each order in an equity security entered in the System,⁵ as well as order execution information, order cancellations, order modifications, order identification numbers, and administrative messages. Exchange Rule 2625(b) provides that the ToM feed is a data feed that contains the price and aggregate size of displayed top of book quotations, order execution information, and administrative messages for equity securities entered into the System. Section 3 of the Fee Schedule entitled, Market Data Fees, specifically provides that fees for both the ToM and DoM feeds are waived for

the Waiver Period.⁶ As described in more detail below, the Exchange proposes to remove this waiver language and adopt fees for the ToM and DoM feeds to recoup its ongoing costs going forward.⁷

The Exchange notes that there is no requirement that any Equity Member⁸ or market participant subscribe to the ToM or DoM feeds offered by the Exchange. Instead, an Equity Member may choose to maintain subscriptions to the ToM or DoM feeds based on their own business needs and trading models.

The Exchange commenced operations in September 2020 and expressly waived fees for both the ToM and DoM data feeds since that time to incentivize market participants to subscribe and make the Exchange's market data more widely available.⁹ In the three and a half years since the Exchange launched operations, its market share has grown from 0% to approximately 2.0% for the month of March 2024.¹⁰ One of the primary objectives of the Exchange is to provide competition and to provide low cost options to the industry. Consistent with this objective, the Exchange believes that this proposal reflects a simple, competitive, reasonable, and equitable pricing structure.

The Exchange believes that exchanges, in setting fees of all types,

⁶ The term "Waiver Period" means, for each applicable fee, the period of time from the initial effective date of the MIAX Pearl Equities Fee Schedule until such time that MIAX Pearl has an effective fee filing establishing the applicable fee. MIAX Pearl Equities will issue a Regulatory Circular announcing the establishment of an applicable fee that was subject to a Waiver Period at least fifteen (15) days prior to the termination of the Waiver Period and effective date of any such applicable fee. See the Definitions section of the Fee Schedule.

⁷ The Exchange initially filed the proposed fee change on March 26, 2024 for effectiveness on April 1, 2024. See Securities Exchange Act Release No. 99907 (April 4, 2024), 89 FR 25293 (April 10, 2024) (SR-PEARL-2024-15) (the "Initial Proposal"). The Exchange withdrew SR-PEARL-2024-15 on April 30, 2024 and replaced it with SR-PEARL-2024-22. See Securities Exchange Act Release No. 100109 (May 13, 2024), 89 FR 43467 (May 17, 2024) (SR-PEARL-2024-22) (the "Second Proposal"). The Exchange notes that the Second Proposal included a reduced fee for Non-Display Usage by Trading Platforms for the ToM feed from \$2,500 per month in the Initial Proposal to \$1,000 per month. The reduced fee for Non-Display Usage by Trading Platforms was effective beginning May 1, 2024. All other proposed fees continue to remain the same from the Initial Proposal. See Fee Change Alert—MIAX Pearl Equities Exchange—May 1, 2024, available at <https://www.miaxglobal.com/alert/2024/04/30/miax-pearl-equities-exchange-may-1-2024-fee-changes>.

⁸ The term "Equity Member" is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. See Exchange Rule 1901.

⁹ See *supra* note 4.

¹⁰ See the "Market Share" section of the Exchange's website, available at <https://www.miaxglobal.com/>.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ All references to the "Exchange" in this filing refer to MIAX Pearl Equities. Any references to the options trading facility of MIAX PEARL, LLC will specifically be referred to as "MIAX Pearl Options."

⁴ See Securities Exchange Act Release No. 90651 (December 11, 2020), 85 FR 81971 (December 17, 2020) (SR-PEARL-2020-33).

⁵ The term "System" means the automated trading system used by the Exchange for the trading of securities. See Exchange Rule 100.

should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the requirements of the Act that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among Equity Members and markets. The Exchange believes this high standard is especially important when an exchange imposes various fees for market participants to access an exchange's market data. The Exchange believes that it is important to demonstrate that these fees are based on its costs and reasonable business needs. Accordingly, the Exchange included a cost analysis below in connection with the proposed market data fees and the costs associated with compiling and providing the ToM and DoM feeds ("Cost Analysis").

The Exchange believes the proposed fees will allow the Exchange to offset the expenses¹¹ the Exchange has and will continue to incur associated with compiling and disseminating the ToM and DoM feeds. Further, the Exchange believes it provided sufficient transparency in the Cost Analysis provided below, which provides a basis for how the Exchange determined to charge such fees. The Exchange's proposal is described below.

Definitions

The Exchange proposes to include a Definitions section at the beginning of Section 3 of the Fee Schedule. The purpose of the Definitions section is to provide market participants greater clarity and transparency regarding the applicability of fees by defining certain terms used in connection with market data feeds within the Fee Schedule in a single location related to the Exchange's market data products. The Exchange notes that other equities exchanges include similar Definitions in their respective fee schedules,¹² and that each of the Exchange's proposed definitions are based on those exchanges. The Exchange believes that including a Definitions section for market data

products makes the Fee Schedule more user-friendly and comprehensive.

The Exchange proposes to define the following terms in Section 3 of the Fee Schedule:

- *Distributor*. Any entity that receives the Exchange data product directly from the Exchange or indirectly through another entity and then distributes it internally or externally to a third party.
- *External Distributor*. A Distributor that receives the Exchange data product and then distributes that data to a third party or one or more Users outside the Distributor's own entity.
- *Internal Distributor*. A Distributor that receives the Exchange data product and then distributes that data to one or more Users within the Distributor's own entity.
 - The Exchange notes that it proposes to use the phrase "own entity" in the definition of Internal Distributor and External Distributor because a Distributor would be permitted to share data received from an exchange data product to other legal entities affiliated with the Distributor's entity that have been disclosed to the Exchange without such distribution being considered external to a third party. For instance, if a company has multiple affiliated broker-dealers under the same holding company, that company could have one of the broker-dealers or a non-broker-dealer affiliate subscribe to an exchange data product and then share the data with other affiliates that have a need for the data. This sharing with affiliates would not be considered external distribution to a third party but instead would be considered internal distribution to data recipients within the Distributor's own entity.
- *Non-Display Usage*. Any method of accessing an Exchange data product that involves access or use by a machine or automated device without access or use of a display by a natural person or persons.
- *Non-Professional User*. A natural person or qualifying trust that uses Exchange data only for personal purposes and not for any commercial purpose and, for a natural person who works in the United States, is not: (i) registered or qualified in any capacity with the Securities and Exchange Commission, the Commodities Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an "investment adviser" as that term is defined in Section 202(a)(11) of the Investment Advisors Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a

bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt; or, for a natural person who works outside of the United States, does not perform the same functions as would disqualify such person as a Non-Professional User if he or she worked in the United States.

- *Professional User*. Any User other than a Non-Professional User.

- *Trading Platform*. Any execution platform operated as or by a registered National Securities Exchange (as defined in Section 3(a)(1) of the Exchange Act), an Alternative Trading System (as defined in Rule 300(a) of Regulation ATS), or an Electronic Communications Network (as defined in Rule 600(b)(23) of Regulation NMS).

- *User*. A Professional User or Non-Professional User.

Proposed Market Data Pricing

As described above, the ToM feed is a data feed that contains the price and aggregate size of displayed top of book quotations, order execution information, and administrative messages for equity securities entered into the System. The DoM feed is a data feed that contains the displayed price and size of each order in an equity security entered in the System, as well as order execution information, order cancellations, order modifications, order identification numbers, and administrative messages. The Exchange proposes to charge the below fees for the ToM and DoM data feeds, which, the Exchange believes are generally similar to or lower than market data fees charged by other similarly situated equities exchanges. Each of the below capitalized terms are defined above and would be included under the proposed Definitions section under Section 3, Market Data Fees, of the Fee Schedule.

1. *Internal Distributor Fee*. The Exchange proposes to charge Internal Distributors a monthly fee of \$1,000.00 for the ToM feed and \$2,000.00 for the DoM feed. The proposed Internal Distributor fees would only be charged once per month per Distributor.

2. *External Distributor Fee*. The Exchange proposes to charge External Distributors a monthly fee of \$2,000.00 for the ToM feed and \$2,500.00 for the DoM feed. The proposed External Distributor fees would only be charged once per month per Distributor.

3. *User Fees*. For the ToM feed, the Exchange proposes to charge a monthly fee of \$2.00 for each Professional User and \$0.10 for each Non-Professional

¹¹ For the avoidance of doubt, all references to expense or costs in this filing, including the cost categories discussed below, refer to costs incurred by MIAX Pearl Equities only and not MIAX Pearl Options, the options trading facility.

¹² See the market data sections of the fee schedules for the Cboe BZX Exchange, Inc. ("Cboe BZX"); Cboe BYX Exchange, Inc. ("Cboe BYX"); Cboe EDGA Exchange, Inc. ("Cboe EDGA"); and Cboe EDGX Exchange, Inc. ("Cboe EDGX"). See also the market data definition section of the MEMX LLC's ("MEMX") fee schedule; and Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR-MEMX-2023-04) ("MEMX Market Data Fee Proposal").

User. For the DoM feed, the Exchange proposes to charge a monthly fee of \$30.00 for each Professional User and \$3.00 for each Non-Professional User. The proposed User fees would apply to each person that has access to the ToM or DoM feed that is provided by a Distributor (either Internal or External) for displayed usage. Each Distributor's User count would include every individual that accesses the data regardless of the purpose for which the individual uses the data. Distributors of the ToM or DoM feed would be required to report all Professional and Non-Professional Users in accordance with the following:

- In connection with a Distributor's distribution of the ToM or DoM feed, the Distributor must count as one User each unique User that the Distributor has entitled to have access to the ToM or DoM feed.
- Distributors must report each unique individual person who receives access through multiple devices or multiple methods (e.g., a single User has multiple passwords and user identifications) as one User.
- If a Distributor entitles one or more individuals to use the same device, the Distributor must include only the individuals, and not the device, in the count. Thus, Distributors would not be required to report User device counts associated with a User's display use of the data feed.

4. *Enterprise Fee.* As an alternative to User fees, Distributors may purchase a monthly Enterprise license to receive ToM or DoM feeds for distribution to an unlimited number of Professional and Non-Professional Users. This provision would be codified under footnote "a" under the description of each the ToM and DoM feed in the Fee Schedule. The Exchange proposes to establish a monthly Enterprise fee of \$15,000.00 for ToM and \$25,000.00 for the DoM feed.

5. *Non-Display Usage Fees.* For both the ToM and DoM feeds, the Exchange proposes to establish separate Non-Display Usage fees for usage by Trading Platforms and other Users (i.e., not by Trading Platforms).

- *Non-Display Usage.* For Non-Display Usage, the Exchange proposes to establish a monthly fee of \$1,000.00 for the ToM feed and \$2,500.00 for the DoM feed.¹³

¹³ Non-Display Usage would include trading uses such as high frequency or algorithmic trading as well as any trading in any asset class, automated order or quote generation and/or order pegging, price referencing for smart order routing, operations control programs, investment analysis, order verification, surveillance programs, risk management, compliance, and portfolio management.

- Distributors of Non-Display Usage for both the ToM and DoM feed will only be subject to the Non-Display Usage fee for the DoM feed. In other words, such Distributors would receive both the ToM and DoM feeds but only be charged the Non-Display Usage fee of \$2,500.00 for the DoM feed. This provision would be codified under footnote "b" under the description of each the ToM and DoM feed in the Fee Schedule.

- *Non-Display Usage by Trading Platforms.* For Non-Display Usage by Trading Platforms, the Exchange proposes to establish a monthly fee of \$1,000.00 for the ToM feed and \$2,500.00 for the DoM feed. The Non-Displayed Usage by Trading Platform fee would only be charged per Distributor that uses the data within a Trading Platform.

- Distributors of Non-Display Usage by Trading Platforms for both the ToM and DoM feed will only be subject to the Non-Display Usage by Trading Platforms fee for the DoM feed. In other words, such Distributors would receive both the ToM and DoM feeds but only be charged the Non-Display Usage by Trading Platforms fee of \$2,500.00 for the DoM feed. This provision would be codified under footnote "c" under the description of each the ToM and DoM feed in the Fee Schedule.

- The fee would also represent the maximum charge per Distributor regardless of the number of Trading Platforms operated by the Distributor that receives the data for Non-Display Usage. This provision would be codified under footnote "d" under the description of each the ToM and DoM feed in the Fee Schedule.

- *Miscellaneous.* The proposed fees for Non-Display Usage would only be charged once per category per Distributor. In other words, with respect to Non-Display Usage Fees, a Distributor that uses the ToM feed for: (i) non-display purposes but not to operate a Trading Platform would pay \$1,000.00 per month; (ii) a Distributor that uses the ToM feed in connection with the operation of one or more Trading Platforms (but not for other purposes) would pay \$1,000.00 per month; and (iii) a Distributor that uses the ToM feed for non-display purposes other than operating a Trading Platform and for the operation of one or more Trading Platforms would pay \$2,000.00 per month.

Implementation

The Exchange issued alerts publicly announcing the proposed fees on

January 31, 2024 and March 15, 2024.¹⁴ The Exchange issued a Regulatory Circular on March 15, 2024 announcing the establishment of the proposed market data fees to satisfy the required fifteen (15) day notice period, as described in the Definitions Section of the Fee Schedule for termination of the Waiver Period.¹⁵ The fees subject to this proposal are immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) ¹⁶ of the Act in general, and furthers the objectives of Section 6(b)(4) ¹⁷ of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Equity Members and other persons using its facilities. Additionally, the Exchange believes that the proposed fees are consistent with the objectives of Section 6(b)(5) ¹⁸ of the Act in that they are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In 2019, Commission staff published guidance suggesting the types of information that self-regulatory organizations ("SROs") may use to demonstrate that their fee filings comply with the standards of the Exchange Act (the "Staff Guidance").¹⁹ While the Exchange understands that the Staff Guidance does not create new legal obligations on SROs, the Staff Guidance is consistent with the Exchange's view about the type and level of transparency

¹⁴ See Fee Change Alert, MIAx Pearl Equities Exchange—April 1, 2024 Market Data Fee Changes, available at <https://www.miaxglobal.com/alert/2024/01/31/miax-pearl-equities-exchange-april-1-2024-market-data-fee-changes>; see also Fee Change Alert, MIAx Pearl Equities Exchange—Update: April 1, 2024 Market Data Fee Changes, available at <https://www.miaxglobal.com/alert/2024/03/15/miax-pearl-equities-exchange-update-april-1-2024-market-data-fee-changes>.

¹⁵ See MIAx Pearl Equities Regulatory Circular 2024-06, *Termination of Waiver Period for Market Data Fees and Establishment of Fee Amounts*, dated March 15, 2024, available at [Pearl_Equities_RC_2024_06.pdf](https://www.miaxglobal.com/alert/2024/06/pdf) (miaxglobal.com).

¹⁶ 15 U.S.C. 78f.

¹⁷ 15 U.S.C. 78f(b)(4).

¹⁸ 15 U.S.C. 78f(b)(5).

¹⁹ See Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), available at <https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees>.

that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. The Staff Guidance provides that in assessing the reasonableness of a fee, the Staff would consider whether the fee is constrained by significant competitive forces. To determine whether a proposed fee is constrained by significant competitive forces, the Staff Guidance further provides that the Staff would consider whether the evidence provided by an SRO in a Fee Filing proposal demonstrates (i) that there are reasonable substitutes for the product or service that is the subject of a proposed fee; (ii) that “platform” competition constrains the fee; and/or (iii) that the revenue and cost analysis provided by the SRO otherwise demonstrates that the proposed fee would not result in the SRO taking supra-competitive profits.²⁰ The Exchange provides sufficient evidence below to support the findings that the proposed fees are reasonable because the projected revenue and cost analysis contained herein demonstrates that the proposed fees would not result in the Exchange taking supra-competitive profits.

Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

Accordingly, in proposing to charge fees for market data, the Exchange is especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and in carefully and transparently assessing the impact on Equity Members—both generally and in relation to other Equity Members—to ensure the fees will not create a financial burden on any participant and will not have an undue impact in particular on smaller Equity Members and competition among Equity Members in general. The Exchange does not believe it needs to otherwise address questions about market competition in the context of this filing because the proposed fees are consistent with the Act based on its Cost Analysis. The

Exchange also believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,²¹ and Rule 19b-4 thereunder,²² with respect to the types of information SROs should provide when filing fee changes, and Section 6(b) of the Act,²³ which requires, among other things, that exchange fees be reasonable and equitably allocated,²⁴ not designed to permit unfair discrimination,²⁵ and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.²⁶ This proposal addresses those requirements, and the analysis and data in this section are designed to clearly and comprehensively show how they are met.

In 2020, the Exchange completed a study of its aggregate costs to produce market data and connectivity, defined above as its Cost Analysis.²⁷ The Cost Analysis required a detailed analysis of the Exchange’s aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services, physical connectivity, and port access (which provide order entry, cancellation and modification functionality, risk functionality, the ability to receive drop copies, and other functionality). The Exchange separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.*, personnel), and certain general and administrative expenses (“cost drivers”).

As an initial step, the Exchange determined the total cost for the Exchange and its affiliated markets²⁸ for each cost driver as part of its 2024 budget review process. The 2024 budget review is a company-wide process that occurs over the course of many months, includes meetings among senior management, department heads, and the Finance Team. Each department head is

required to send a “bottom up” budget to the Finance Team allocating costs at the profit and loss account and vendor levels for the Exchange and its affiliated markets based on a number of factors, including server counts, additional hardware and software utilization, current or anticipated functional or non-functional development projects, capacity needs, end-of-life or end-of-service intervals, number of members, market model (*e.g.*, price time or pro-rata, simple only or simple and complex markets, auction functionality, etc.), which may impact message traffic, individual system architectures that impact platform size,²⁹ storage needs, dedicated infrastructure versus shared infrastructure allocated per platform based on the resources required to support each platform, number of available connections, and employees allocated time. All of these factors result in different allocation percentages among the Exchange and its affiliated markets, *i.e.*, the different percentages of the overall cost driver allocated to the Exchange and its affiliated markets will cause the dollar amount of the overall cost allocated among the Exchange and its affiliated markets to also differ. Because the Exchange’s parent company currently owns and operates four separate and distinct marketplaces, the Exchange must determine the costs associated with each actual market—as opposed to the Exchange’s parent company simply concluding that all costs drivers are the same at each individual marketplace and dividing total cost by four (4) (evenly for each marketplace). Rather, the Exchange’s parent company determines an accurate cost for each marketplace, which results in different allocations and amounts across exchanges for the same cost drivers, due to the unique factors of each marketplace as described above. This allocation methodology also ensures that no cost would be allocated twice or double-counted between the Exchange and its affiliated markets. The Exchange further confirms that there is no double counting of expenses between the options and equities platform of the Exchange. The Finance Team then consolidates the budget and sends it to senior management, including the Chief Financial Officer and Chief Executive Officer, for review and approval. Next, the budget is presented to the Board of Directors and the Finance and Audit Committees for each exchange for their

²¹ 15 U.S.C. 78s(b)(1).

²² 17 CFR 240.19b-4.

²³ 15 U.S.C. 78f(b).

²⁴ 15 U.S.C. 78f(b)(4).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ 15 U.S.C. 78f(b)(8).

²⁷ The Exchange frequently updates its Cost Analysis as strategic initiatives change, costs increase or decrease, and market participant needs and trading activity changes. The Exchange’s most recent Cost Analysis was conducted ahead of this filing.

²⁸ The affiliated markets include Miami International Securities Exchange, LLC (“MIAX”); separately, the options and equities markets of MIAX Pearl; and MIAX Emerald, LLC (“MIAX Emerald”).

²⁹ For example, MIAX maintains 24 matching engines, MIAX Pearl Options maintains 12 matching engines, MIAX Pearl Equities maintains 24 matching engines, and MIAX Emerald maintains 12 matching engines.

²⁰ *Id.*

approval. The above steps encompass the first step of the cost allocation process.

The next step involves determining what portion of the cost allocated to the Exchange pursuant to the above methodology is to be allocated to each core service, *e.g.*, connectivity and ports, market data, and transaction services. The Exchange and its affiliated markets adopted an allocation methodology with thoughtful and consistently applied principles to guide how much of a particular cost amount allocated to the Exchange should be allocated within the Exchange to each core service. This is the final step in the cost allocation process and is applied to each of the cost drivers set forth below. For instance, fixed costs that are not driven by client activity (*e.g.*, message rates), such as data center costs, were allocated more heavily to the provision of physical connectivity (for example, 60.1% of the data center total expense amount is allocated to 10Gb ULL connectivity), with smaller allocations to ToM and DoM (2.0% combined), and the remainder to the provision of other connectivity, ports, transaction execution, and membership services (37.9%). This next level of the allocation methodology at the individual exchange level also took into account factors similar to those set forth under the first step of the allocation methodology process described above, to determine the appropriate allocation to connectivity or market data versus allocations for other services. This allocation methodology was developed through an assessment of costs with senior management intimately familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an allocation of each cost driver to each core service, resulting in the cost allocations described below.³⁰

Each of the below cost allocations is unique to the Exchange and represents a percentage of overall cost that was allocated to the Exchange pursuant to the initial allocation described above.

By allocating segmented costs to each core service, the Exchange was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity and port services, membership fees, regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity; only Equity Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Equity Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and, the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below. While there is no standardized and generally accepted methodology for the allocation of an exchange's costs, the Exchange's methodology is the result of an extensive review and analysis and will be consistently applied going forward for any other cost-justified potential fee proposals. In the absence of the

Commission attempting to specify a methodology for the allocation of exchanges' interdependent costs, the Exchange will continue to be left with its best efforts to attempt to conduct such an allocation in a thoughtful and reasonable manner.

Through the Exchange's extensive Cost Analysis, which was again recently further refined, the Exchange analyzed nearly every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of market data feeds, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of market data feeds, and thus bears a relationship that is, "in nature and closeness," directly related to market data feeds. In turn, the Exchange allocated certain costs more to physical connectivity and others to ports, while certain costs were only allocated to such services at a very low percentage or not at all, using consistent allocation methodologies as described above. Based on this analysis, the Exchange estimates that the aggregate monthly cost to provide the market data feeds is \$150,031 (the Exchange divided the annual cost for each market data feed by 12 months, then added both numbers together), as further detailed below.

Costs Related To Offering the Market Data Feeds

The following chart details the individual line-item (annual) costs considered by the Exchange to be related to offering the market data feeds to its Equity Members and other customers, as well as the percentage of the Exchange's overall costs that such costs represent for such area (*e.g.*, as set forth below, the Exchange allocated approximately 8.9% of its overall Human Resources cost to offering the market data feeds).

Cost drivers	Allocated annual cost ^a	Allocated monthly cost ^b	% of all
Human Resources	\$1,577,592	\$131,466	8.9
Connectivity (external fees, cabling, switches, etc.)	933	78	2.0
Internet Services and External Market Data	0.00	0.00	0.0
Data Center	42,717	3,560	2.0
Hardware and Software Maintenance & Licenses	25,921	2,160	2.0
Depreciation	25,542	2,129	0.5
Allocated Shared Expenses	127,655	10,638	2.0
Total	1,800,360	150,031	5.1

^a The Annual Cost includes figures rounded to the nearest dollar.
^b The Monthly Cost was determined by dividing the Annual Cost for each line item by twelve (12) months and rounding up or down to the nearest dollar.

³⁰ The Exchange only offers two market data feeds, ToM and DoM. Therefore each cost allocation described below applies to market data generally since they are the only two data feeds the Exchange offers and are the subject of this proposal.

Below are additional details regarding each of the line-item costs considered by the Exchange to be related to offering the market data feeds. While some costs were attempted to be allocated as equally as possible among the Exchange and its affiliated markets, the Exchange notes that some of its cost allocation percentages for certain cost drivers differ when compared to the same cost drivers for the Exchange's affiliated markets, MIAX and MIAX Emerald, in their recent proposed fee changes for options market data.³¹ This is because the Exchange's cost allocation methodology utilizes the actual projected costs of the Exchange (which are specific to the Exchange and are independent of the costs projected and utilized by the Exchange's affiliated markets) to determine its actual costs. These costs may vary across the Exchange and its affiliated markets based on factors that are unique to each marketplace, including that the Exchange, MIAX Pearl Options, and its affiliates trade different asset classes.

Human Resources

The Exchange notes that it and its affiliated markets anticipate that by year-end 2024, there will be 289 employees (excluding employees at non-options/equities exchange subsidiaries of Miami International Holdings, Inc. ("MIH"), the holding company of the Exchange and its affiliated markets), and each department leader has direct knowledge of the time spent by each employee with respect to the various tasks necessary to operate the Exchange. Specifically, twice a year, and as needed with additional new hires and new project initiatives, in consultation with employees as needed, managers and department heads assign a percentage of time to every employee and then allocate that time amongst the Exchange and its affiliated markets to determine each market's individual Human Resources expense. Then, managers and department heads assign a percentage of each employee's time allocated to the Exchange into buckets including network connectivity, ports,

market data, and other exchange services. This process ensures that every employee is 100% allocated, ensuring there is no double counting between the Exchange and its affiliated markets.

For personnel costs (Human Resources), the Exchange calculated an allocation of employee time for employees whose functions include providing and maintaining market data feeds and performance thereof (primarily the Exchange's network infrastructure team, which spends a portion of their time performing functions necessary to provide market data). As described more fully above, the Exchange's parent company allocates costs to the Exchange and its affiliated markets and then a portion of the Human Resources costs allocated to the Exchange is then allocated to market data. From that portion allocated to the Exchange that applied to market data, the Exchange then allocated a weighted average of 9.1% of each employee's time from the above group to market data feeds (which excludes an allocation for the recently hired Head of Data Services for the Exchange and its affiliates).

The Exchange also allocated Human Resources costs to provide the market data feeds to a limited subset of personnel with ancillary functions related to establishing and maintaining such market data feeds (such as information security, sales, membership, and finance personnel). The Exchange allocated cost on an employee-by-employee basis (*i.e.*, only including those personnel who support functions related to providing market data feeds) and then applied a smaller allocation to such employees' time to market data (a weighted average of 8.8%, which includes an allocation for the Head of Data Services). This other group of personnel with a smaller allocation of Human Resources costs also have a direct nexus to providing the market data feeds, whether it is a sales person selling a market data feed, finance personnel billing for market data feeds or providing budget analysis, or information security ensuring that such market data feeds are secure and adequately defended from an outside intrusion.

The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing market data feeds, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of time such employees devote to those tasks. This includes personnel from the Exchange departments that are

predominately involved in providing the market data feeds: Business Systems Development, Trading Systems Development, Systems Operations and Network Monitoring, Network and Data Center Operations, Listings, Trading Operations, and Project Management. Again, the Exchange allocated a weighted average of 9.1% of each of their employee's time assigned to the Exchange for the market data feeds, as stated above. Employees from these departments perform numerous functions to support the market data feeds, such as the configuration and maintenance of the hardware necessary to support the market data feeds. This hardware includes servers, routers, switches, firewalls, and monitoring devices. These employees also perform software upgrades, vulnerability assessments, remediation and patch installs, equipment configuration and hardening, as well as performance and capacity management. These employees also engage in research and development analysis for equipment and software supporting market data feeds and design, and support the development and on-going maintenance of internally-developed applications as well as data capture and analysis, and Equity Member and internal Exchange reports related to network and system performance. The above list of employee functions is not exhaustive of all the functions performed by Exchange employees to support market, but illustrates the breadth of functions those employees perform in support of the above cost and time allocations.

Lastly, the Exchange notes that senior level executives' time was only allocated to the market data feeds related Human Resources costs to the extent that they are involved in overseeing tasks related to providing market data. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

Connectivity (External Fees, Cabling, Switches, etc.)

The Connectivity cost driver includes cabling and switches required to generate and disseminate the market data feeds and operate the Exchange. The Connectivity cost driver is more narrowly focused on technology used to complete Equity Member subscriptions to the market data feeds and the servers used at the Exchange's primary and back-up data centers specifically for the market data feeds. Further, as certain servers are only partially utilized to generate and disseminate the market

³¹ See Securities Exchange Act Release Nos. 99736 (March 14, 2024), 89 FR 19929 (March 20, 2024) (SR-MIAX-2024-13) and 99737 (March 14, 2024), 89 FR 19915 (March 20, 2024) (SR-EMERALD-2024-09). See also SR-MIAX-2024-25 (filed April 23, 2024) and SR-EMERALD-2024-15 (filed April 18, 2024). For example, the overall portion of Human Resource costs allocated in this proposal is higher than the recent market data proposals filed by MIAX and MIAX Emerald due to their ability to leverage the same employees for options market data because they trade the same asset class, options. The Exchange is unable to do the same because it trades a different asset class, equities, which requires dedicated employees and systems.

data feeds, only the percentage of such servers devoted to generating and disseminating the market data feeds was included (*i.e.*, the capacity of such servers allocated to the market data feeds).³²

Internet Services and External Market Data

The next cost driver consists of internet services and external market data. Internet services includes third-party service providers that provide the internet, fiber and bandwidth connections between the Exchange's networks, primary and secondary data centers, and office locations in Princeton and Miami. External market data includes fees paid to third parties, including other exchanges, to receive market data. The Exchange did not allocate any costs associated with internet services or external market data to the market data feeds.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide the market data feeds in the third-party data centers where it maintains its equipment (such as dedicated space, security services, cooling and power). The Exchange does not own the primary data center or the secondary data center, but instead leases space in data centers operated by third parties. As the Data Center costs are primarily for space, power, and cooling of servers, the Exchange allocated 2.0% to the applicable Data Center costs for the market data feeds. The Exchange believes it is reasonable to apply the same proportionate percentage of Data Center costs to that of the Connectivity cost driver.

Hardware and Software Maintenance and Licenses

Hardware and Software Maintenance and Licenses includes hardware and software licenses used to operate and monitor physical assets necessary to

offer the market data feeds.³³ Because the hardware and software license fees are correlated to the servers used by the Exchange, the Exchange again applied an allocation of 2.0% of its costs for Hardware and Software Maintenance and Licenses to the market data feeds. The Exchange notes that this allocation may differ from its affiliates because MIAX Pearl Equities maintains software licenses that are unique to its trading platform and used only for the trading of equity securities. The cost for these licenses cannot be shared with MIAX Pearl Equities' affiliated options markets because each of those platforms trade only options, not equities. MIAX Pearl Equities' affiliates are able to share the cost of many of their software licenses among the multiple options platforms (thus lowering the cost to each individual options platform), whereas MIAX Pearl Equities cannot share such cost and, therefore, bears the entire cost.

Depreciation

All physical assets, software, and hardware used to provide the market data feeds, which also includes assets used for testing and monitoring of Exchange infrastructure to provide market data, were valued at cost, and depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which are owned by the Exchange and some of which are leased by the Exchange in order to allow efficient periodic technology refreshes.

The vast majority of the software the Exchange uses for its operations to generate and disseminate the market data feeds has been developed in-house over an extended period. This software development also requires quality assurance and thorough testing to ensure the software works as intended. The Exchange also included in the Depreciation cost driver certain budgeted improvements that the Exchange intends to capitalize and depreciate with respect to the market data feeds in the near-term. As with the other allocated costs in the Exchange's updated Cost Analysis, the Depreciation cost was therefore narrowly tailored to depreciation related to the market data feeds. As noted above, the Exchange allocated 0.5% of its allocated

depreciation costs to providing the market data feeds.

This allocation is also based on MIAX Pearl Equities being a newer market and having newer physical assets and software subject to depreciation than its affiliate options exchanges. The Exchange's affiliate options exchanges are older markets that have more software and equipment that have been fully depreciated when compared to the newer software and hardware currently being depreciated by MIAX Pearl Equities at higher rates.

Allocated Shared Expenses

Finally, as with other exchange products and services, a portion of general shared expenses was allocated to the provision of the market data feeds. These general shared costs are integral to exchange operations, including its ability to provide the market data feeds. Costs included in general shared expenses include office space and office expenses (*e.g.*, occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications. Similarly, the cost of paying directors to serve on the Exchange's Board of Directors is also included in the Exchange's general shared expense cost driver.³⁴ These general shared expenses are incurred by the Exchange's parent company, MIH, as a direct result of operating the Exchange and its affiliated markets.

The Exchange employed a process to determine a reasonable percentage to allocate general shared expenses to the market data feeds pursuant to its multi-layered allocation process. First, general expenses were allocated among the Exchange and affiliated markets as described above. Then, the general shared expense assigned to the Exchange was allocated across core services of the Exchange, including market data. Then, these costs were further allocated to sub-categories within the final categories, *i.e.*, the market data feeds as sub-categories of market data. In determining the percentage of general shared expenses allocated to market data that ultimately apply to the market data feeds, the

³² The Exchange understands that the Investors Exchange, Inc. ("IEX") and MEMX LLC ("MEMX") both allocated a percentage of their servers to the production and dissemination of market data to support proposed market data feeds. See Securities Exchange Act Release Nos. 94630 (April 7, 2022), 87 FR 21945, at page 21949 (April 13, 2022) (SR-IEX-2022-02) and 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR-MEMX-2023-04). The Exchange does not have insight into either MEMX's or IEX's technology infrastructure or what their determinations were based on. However, the Exchange reviewed its own technology infrastructure and believes based on its design, it is more appropriate for the Exchange to allocate a portion of its Connectivity cost driver to market data based on a percentage of overall cost, not on a per server basis.

³³ This expense may differ from the Exchange's affiliated markets. This is because each market may maintain and utilize a different amount of hardware and software based on its market model and infrastructure needs. The Exchange allocated a percentage of the overall cost based on actual amounts of hardware and software utilized by that market, which resulted in different cost allocations and dollar amounts.

³⁴ The Exchange notes that MEMX allocated a precise amount of 10% of the overall cost for directors in a similar non-transaction fee filing. See Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR-MEMX-2023-04). The Exchange does not calculate its expenses at that granular a level. Instead, director costs are included as part of the overall general allocation.

Exchange looked at the percentage allocations of each of the cost drivers and determined a reasonable allocation percentage. The Exchange also held meetings with senior management, department heads, and the Finance Team to determine the proper amount of the shared general expense to allocate to the market data feeds. The Exchange, therefore, believes it is reasonable to assign an allocation, in the range of allocations for other cost drivers, while continuing to ensure that this expense is only allocated once. Again, the general shared expenses are incurred by the Exchange's parent company as a result of operating the Exchange and its affiliated markets and it is therefore reasonable to allocate a percentage of those expenses to the Exchange and ultimately to specific product offerings such as the market data feeds.

Again, a portion of all shared expenses were allocated to the Exchange (and its affiliated markets) which, in turn, allocated a portion of that overall allocation to all market data products offered by the Exchange. The Exchange then allocated 2.0% of the portion allocated to market data. The Exchange believes this allocation percentage is reasonable because, while the overall dollar amount may be higher than other cost drivers, the 2.0% is based on and in line with the percentage allocations of each of the Exchange's other cost drivers. The percentage allocated to the market data feeds also reflects its importance to the Exchange's strategy and necessity towards the nature of the Exchange's overall operations, which is to provide a resilient, highly deterministic trading system that relies on faster market data feeds than the Exchange's competitors to maintain premium performance. This allocation reflects the Exchange's focus on providing and maintaining high performance market data services, of which the market data feeds are main contributors.

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Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core service (including market data) and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal and the filings the Exchange recently submitted proposing fees for certain connectivity and ports offered by the Exchange. For instance, in calculating the Human Resources

expenses to be allocated to market data based upon the above described methodology, the Exchange allocated a higher percentage of dedicated network infrastructure personnel (9.1%) due to their focus on functions necessary to provide market data. The remaining 90.9% of the Human Resources expense was then allocated to connectivity services, port services, transaction services, and membership services. The Exchange did not allocate any other Human Resources expense for providing market data to any other employee group, outside of a smaller allocation of 8.8% for costs associated with certain specified personnel who work closely with and support network infrastructure personnel.

In total, the Exchange allocated 8.9% of its personnel costs (Human Resources) to providing the market data feeds. In turn, the Exchange allocated the remaining 91.1% of its Human Resources expense to membership services, transaction services, connectivity services, and port services. Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including market data, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide the market data feeds to its Equity Members and their customers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing the market data feeds, but instead allocated approximately 0.5% of the Exchange's overall depreciation and amortization expense to the market data feeds combined. The Exchange allocated the remaining depreciation and amortization expense (99.5%) toward the cost of providing transaction services, membership services, connectivity services, and port services.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such

revenue streams actually produce the revenue estimated. The Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from the market data feeds, the Exchange will have to be successful in retaining existing clients that wish to maintain subscriptions to those market data feeds or in obtaining new clients that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis is based on the Exchange's 2024 fiscal year of operations and projections. It is possible, however, that actual costs may be higher or lower. To the extent the Exchange sees growth in use of market data services it will receive additional revenue to offset future cost increases. However, if use of market data services is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange may propose to decrease fees in the event that revenue materially exceeds our current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (e.g., to monitor for costs increasing/decreasing or Distributors or Users increasing/decreasing, etc. in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Projected Revenue³⁵

The proposed fees will allow the Exchange to cover certain costs incurred by the Exchange associated with creating, generating, and disseminating the market data feeds and the fact that the Exchange will need to fund future expenditures (increased costs, improvements, etc.). The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by amending fees for market data Distributors and Users. Distributors, particularly those of the market data feeds, expect the Exchange to provide this level of support so they continue to receive the performance they expect. This differentiates the Exchange from its competitors. As detailed above, the Exchange has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue.

The Exchange's Cost Analysis estimates the annual cost to provide the market data feeds will equal \$1,800,360. Based on the projected number of Distributors and Users, the Exchange would generate annual revenue of approximately \$1,962,000 for the market data feeds. The Exchange believes this represents a modest profit of 8.2% when compared to the cost of providing the market data feeds, which the Exchange believes is fair and reasonable after taking into account the costs related to creating, generating, and disseminating the market data feeds and the fact that the Exchange will need to fund future expenditures (increased costs, improvements, etc.). To determine the projected number of Distributors and Users, the Exchange reviewed its Distributor population from February 2024, the month preceding when the Exchange filed its proposal to implement fees for the market data products, and assumed a 5% attrition rate. The 5% attrition rate was based on surveying the current Distributor

population when socializing the proposed fee structure with market participants. The Exchange also reviewed Distributor disclosures submitted to the Exchange to see how Distributors were using the market data, *e.g.*, for a Trading Platform, internal distribution, firm size, etc., and to which fee(s) they may be subject to under the proposed structure.

Based on the above discussion, the Exchange believes that even if the Exchange earns the above revenue or incrementally more or less, the proposed fees are fair and reasonable because they will not result in pricing that deviates from that of other exchanges or a supra-competitive profit, when comparing the total expense of the Exchange associated with providing the market data feeds versus the total projected revenue also associated with those market data feeds.

The Exchange did not charge any fees for the market data feeds since its inception in September 2020 and its allocation of costs to the market data feeds was part of a holistic allocation that also allocated costs to other core services without double-counting any expenses. The Exchange is owned by a holding company that is the parent company of four exchange markets and, therefore, the Exchange and its affiliated markets must allocate shared costs across all of those markets accordingly, pursuant to the above-described allocation methodology. In contrast, IEX and MEMX, which are currently each operating only one SRO, in their recent non-transaction fee filings allocate the entire amount of that same cost to a single SRO. This can result in lower profit margins for the non-transaction fees proposed by IEX and MEMX because the single allocated cost does not experience the efficiencies and synergies that result from sharing costs across multiple platforms.³⁶ The Exchange and its affiliated markets often share a single cost, which results in cost efficiencies that can cause a broader gap between the allocated cost amount and projected revenue, even though the fee levels being proposed are lower or competitive with competing markets (as

described below). To the extent that the application of a cost-based standard results in Commission Staff making determinations as to the appropriateness of certain profit margins, the Commission Staff should consider whether the proposed fee level is comparable to, or competitive with, the same fee charged by competing exchanges and how different cost allocation methodologies (such as across multiple markets) may result in different profit margins for comparable fee levels. If Commission Staff is making determinations as to appropriate profit margins, the Exchange believes that the Commission should be clear to all market participants as to what they have determined is an appropriate profit margin and should apply such determinations consistently and, in the case of certain legacy exchanges, retroactively, if such standards are to avoid having a discriminatory effect. Further, the proposal reflects the Exchange's efforts to control its costs, which the Exchange does on an ongoing basis as a matter of good business practice. A potential profit margin should not be judged alone based on its size, but is also indicative of costs management and whether the ultimate fee reflects the value of the services provided. For example, a profit margin on one exchange should not be deemed excessive where that exchange has been successful in controlling its costs, but not excessive where on another exchange where that exchange is charging comparable fees but has a lower profit margin due to higher costs. Doing so could have the perverse effect of not incentivizing cost control where higher costs alone are used to justify fees increases.

Accordingly, while the Exchange is supportive of transparency around costs and potential margins (applied across all exchanges), as well as periodic review of revenues and applicable costs (as discussed below), the Exchange does not believe that these estimates should form the sole basis of whether or not a proposed fee is reasonable or can be adopted. Instead, the Exchange believes that the information should be used solely to confirm that an Exchange is not earning—or seeking to earn—supra-competitive profits, the standard set forth in the Staff Guidance. The Exchange believes the Cost Analysis and related projections in this filing demonstrate this fact.

³⁵ To estimate the potential number of Distributors and their anticipated use after the proposed fees are implemented, the Exchange surveyed and reviewed its current Distributor base, considered the number of current potential Distributors who may unsubscribe due to the proposed fees being implemented, and sought informal feedback from Equity Members and other Distributors.

³⁶ The Exchange acknowledges that IEX included in its proposal to adopt market data fees after offering market data for free an analysis of what its projected revenue would be if all of its existing customers continued to subscribe versus what its projected revenue would be if a limited number of customers subscribed due to the new fees. *See* Securities Exchange Act Release No. 94630 (April 7, 2022), 87 FR 21945 (April 13, 2022) (SR-IEX-2022-02). MEMX did not include a similar analysis in its recent filing to adopt market data fees. *See* Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR-MEMX-2023-04).

The Proposed Fees Are Reasonable and Comparable to the Fees Charged by Other Exchanges for Similar Data Products

Overall. Among other things, the Exchange relying upon a cost-plus model to determine a reasonable fee structure that is informed by the Exchange's understanding of different uses of the products by different types of participants. In this context, the Exchange believes the proposed fees overall are fair and reasonable as a form of cost recovery plus the possibility of a reasonable return for the Exchange's aggregate costs of offering the market data feeds. The Exchange believes the proposed fees are reasonable because they are designed to generate annual revenue to recoup some or all of Exchange's annual costs of providing the market data feeds with a reasonable mark-up. As discussed above, the Exchange estimates this fee filing will result in annual revenue of approximately \$1,980,000, representing a potential mark-up of just 9.1% over the cost of providing market data feeds. Accordingly, the Exchange believes that this fee methodology is reasonable because it allows the Exchange to recoup all of its expenses for providing the market data feeds (with any additional revenue representing no more than what the Exchange believes to be a reasonable rate of return). The Exchange also believes that the proposed fees are reasonable because they are generally similar to or less than the fees charged by competing equities exchanges for comparable market data products, notwithstanding that the competing exchanges may have different system architectures that may result in different cost structures for the provision of market data.

The Exchange also believes the proposed fees are reasonable when compared to fees charged for comparable products by other exchanges, including comparable data feeds priced significantly higher than the Exchange's proposed fees. Overall, the Exchange's proposed fees are generally lower or similar to fees charged by other exchanges.³⁷ For this reason, the Exchange believes that the proposed fees are consistent with the

Act generally, and Section 6(b)(5)³⁸ of the Act in particular. The Exchange believes that denying it the ability to adopt the proposed fees that would allow the Exchange to recoup its costs with a reasonable margin in a manner that is closer to parity with other exchanges, in effect, impedes its ability to compete, including in its pricing of transaction fees and ability to invest in competitive infrastructure and other offerings.

Internal Distribution Fees. The Exchange believes it is reasonable to charge Internal Distribution fees because such data assists Internal Distributors in their profit-generating activities. The Exchange also believes that the proposed monthly Internal Distribution fees are reasonable because they are similar to the amount charged by other exchanges for comparable data products. Specifically, the Exchange proposes to charge a monthly fee of \$1,000.00 to Internal Distributors for the ToM feed and \$2,000.00 for the DoM feed, both of which include last sale information. MEMX, Cboe BZX, and Cboe EDGX each charge Internal Distributors a monthly fee of \$750.00 per month for their top-of-book products and \$1,500.00 for their depth-of-book products, and charges separately for last sale information.³⁹ The Exchange notes that while its proposed fee for Internal Distributors may be slightly higher than these other exchanges, the ToM and DoM feeds include last sale information while the comparable market data feeds from other exchanges noted above do not. The Exchange also notes that its other proposed fees are either equal to or significantly lower than other exchanges, as discussed below.

External Distribution Fees. The Exchange believes that it is reasonable to charge External Distribution fees for the market data feeds because vendors receive enumeration from redistributing the data in their business products provided to their customers. The Exchange believes that charging External Distribution fees is reasonable because the vendors that would be charged such fees profit by re-transmitting the Exchange's market data to their customers. These fees would be charged only once per month to each vendor account that redistributes any of the market data feeds, regardless of the number of customers to which that vendor redistributes the data.

The Exchange also believes that the proposed monthly External Distribution fees are reasonable because they are equal to or lower than the amount

charged by other exchanges for comparable data products. Specifically, the Exchange proposes to charge a monthly fee of \$2,000.00 to External Distributor for the ToM feed and \$2,500.00 for the DoM feed. The Exchange's proposed External Distribution fee for ToM is equal to or lower than the fees charged by MEMX, Cboe BZX, and Cboe EDGX to External Distributors of their depth-of-book products, who each charge \$2,000.00, \$2,500.00, and \$2,250.00, respectively.⁴⁰ Meanwhile, the Exchange's proposed External Distribution fee for DoM is equal to the fees charged by MEMX, Cboe BYX, Cboe EDGA, and Cboe EDGX to External Distributors of their depth-of-book products.⁴¹ Meanwhile, the Exchange's proposed External Distribution fee for DoM is lower than the \$5,000.00 fee charged by Cboe BZX to External Distributors of its depth-of-book product.⁴²

User Fees. The Exchange believes that having separate Professional and Non-Professional User fees for the market data feeds is reasonable because it will make the product more affordable for Non-Professional Users and result in greater availability overall to Professional and Non-Professional Users. Setting a modest Non-Professional User fee is reasonable because it provides an additional method for Non-Professional Users to access the market data feeds by providing the same data that is available to Professional Users. The proposed monthly Professional User and Non-Professional User fees are reasonable because they equal to or are lower than the fees charged by other exchanges for comparable data products. For example, the Exchange's proposed Professional User fees of \$2.00 for ToM and \$30.00 for DoM is lower than the same fee charged by Cboe BZX and Cboe EDGX, who each charge \$4.00 for their top-of-book products and \$40.00 for their depth-of-book products.⁴³ The Exchange's proposed Non-Professional User fees of \$0.10 for ToM is equal to the same fee charged by Cboe BZX and Cboe EDGX.⁴⁴

Meanwhile, the Exchange's proposed Non-Professional User fees of \$3.00 for DoM is equal to the same fee charged by

³⁷ See MEMX Fee Schedule, available at, <https://info.memxtrading.com/membership-fees/> ("MEMX Fee Schedule"); Cboe BYX Fee Schedule, available at, https://www.cboe.com/us/equities/membership/fee_schedule/byx/; Cboe BZX Fee Schedule, available at, https://www.cboe.com/us/equities/membership/fee_schedule/bzx/; Cboe EDGA Fee Schedule, available at, https://www.cboe.com/us/equities/membership/fee_schedule/edga/; and Cboe EDGX Fee Schedule, available at, https://www.cboe.com/us/equities/membership/fee_schedule/edgx/.

³⁸ 15 U.S.C. 78f(b)(5).

³⁹ See MEMX Fee Schedule, *supra* note 37.

⁴⁰ See MEMX Fee Schedule, Cboe BZX Fee Schedule, and Cboe EDGX Fee Schedule, *supra* note 43.

⁴¹ See MEMX Fee Schedule, Cboe BYX Fee Schedule, Cboe EDGA Fee Schedule, and Cboe EDGX Fee Schedule, *id.*

⁴² See Cboe BZX Fee Schedule, *id.*

⁴³ See Cboe BZX Fee Schedule and Cboe EDGX Fee Schedule, *id.*

⁴⁴ *Id.*

MEMX and lower than the same fee charged by Cboe BZX and Cboe EDGX, who each charge \$5.00 for their depth-of-book products.⁴⁵

The Exchange also believes its proposal to require reporting of individual Users, but not devices, is reasonable as this too will eliminate unnecessary audit risk that can arise when recipients are required to apply complex counting rules such as whether or not to count devices or whether an individual accessing the same data through multiple devices should be counted once or multiple times.

The Exchange also believes it is reasonable to adopt an Enterprise Fee because this would allow a market participant to disseminate the market data feeds to an unlimited number of Users without the necessity of counting such Users. This is an optional subscription. A data recipient is able to determine whether it prefers to count Users and report such Users to the Exchange or not, and whether it is more economically advantageous to count and pay for specific Users or to subscribe to the Enterprise Fee. The Exchange also notes that only a market participant with a substantial number of Users would likely choose to subscribe for and pay the Enterprise Fee.

The proposed monthly Enterprise fees are reasonable because they equal to or are lower than the fees charged by other exchanges for comparable data products. For example, the Exchange's proposed Enterprise fee of \$15,000.00 per month for ToM equals the same fee charged by Cboe BZX and Cboe EDGX.⁴⁶ However, the Exchange's proposed Enterprise fee of \$25,000.00 per month for DoM is much lower than the same fee charged by Cboe BZX and Cboe EDGX, who each charge \$100,000.00 per month.⁴⁷

Non-Display Usage Fees. The Exchange believes the proposed Non-Display Usage fees are reasonable because they reflect, in part, the type of use of the data to the data recipients in their profit-generating activities and do not impose the burden of counting non-display devices.

The Exchange believes that the proposed Non-Display Usage fees reflect the efficiencies that non-display data use provides data recipients, whom purchase such data on a voluntary basis. Non-display data can be used by data recipients for a wide variety of profit-generating purposes, including

proprietary and agency trading and smart order routing, as well as by data recipients that operate Trading Platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce a recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting recipients. The Exchange believes that charging for non-trading uses is reasonable because data recipients can derive efficiencies from such uses, for example, by automating tasks so that can be performed more quickly, accurately, and less expensively than if they were performed manually.

Previously, the non-display use data pricing policies of many exchanges required customers to count, and the exchanges to audit the count of, the number of non-display devices used by a customer. As non-display use grew more prevalent and varied, however, exchanges received an increasing number of complaints about the impracticality and administrative burden associated with that approach. In response, several exchanges developed a non-display use pricing structure that does not require non-display devices to be counted or those counts to be audited, and instead categorizes different types of use. The Exchange proposes to distinguish between non-display use for the operation of a Trading Platform and other non-display use, which is similar to exchanges such as MEMX, BZX, and EDGX,⁴⁸ while other exchanges maintain additional categories and in many cases charge multiple times for different types of non-display use or the operation of multiple Trading Platforms.⁴⁹

The Exchange believes that it is reasonable to segment the fee for non-display use into these two categories. As noted above, the uses to which customers can put the market data feeds are numerous and varied, and the Exchange believes that charging separate fees for these separate

categories of use is reasonable because it reflects, at least in part, the actual efficiencies the customer derives from the data, based upon how the customer makes use of the data.

The Exchange believes that the proposed fees for Non-Display Usage for ToM are reasonable because the Exchange's proposed fee of \$1,000.00 per month is less than the amounts charged by several other exchanges for comparable data products.⁵⁰ The Exchange also believes that the proposed fees for Non-Display Usage for DoM are reasonable because the Exchange's proposed fee of \$2,500.00 per month for DoM equals the same fee charged by MEMX for its depth-of-book product.⁵¹ The proposed fees are also significantly less than the amounts charged by several other exchanges for comparable data products.⁵² In fact, the Exchange's proposed fees for Non-Display Usage fee may be even lower because the Exchange would allow Distributors to the DoM feed to also receive the ToM feed for no additional charge. The Exchange believes that the proposed fees directly and appropriately reflect the efficiencies experienced by data recipients that use the data on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments. Further, the Exchange benefits from other non-display use by market participants (including the fact that the Exchange receives orders resulting from algorithms and routers) and both the Exchange and other participants benefit from other non-display use by market participants when such use is to support more broadly beneficial functions such as risk management and compliance.

The Exchange believes that the proposed fees for Non-Display Usage for ToM are reasonable because the Exchange's proposed fee of \$2,500.00 per month is less than the amounts charged by several other exchanges for comparable data products,⁵³ which also charge per Trading Platform operated by a data Distributor subject to a cap in most cases, rather than charging per Distributor, as proposed by the Exchange.⁵⁴ The Exchange also believes that it is reasonable to charge the proposed fees for non-display use for

⁴⁸ See Cboe BZX Fee Schedule and Cboe EDGX Fee Schedule, *id.*

⁴⁹ See NYSE Proprietary Market Data Pricing Guide, dated May 4, 2022, available at https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf, and the Nasdaq Global Data Products pricing list, available at <https://nasdaqtrader.com/Trader.aspx?id=DPUSdata>.

⁵⁰ *Id.*

⁵¹ See MEMX Fee Schedule, *supra* note 37.

⁵² See *supra* note 49.

⁵³ *Id.*

⁵⁴ See *supra* note 49. The Exchange notes that MEMX also charges per Distributor, as proposed herein. See MEMX Fee Schedule *supra* note 37.

⁴⁵ See MEMX Fee Schedule, Cboe BZX Fee Schedule, and Cboe EDGX Fee Schedule, *supra* note 37.

⁴⁶ See Cboe BZX Fee Schedule and Cboe EDGX Fee Schedule, *id.*

⁴⁷ *Id.*

operation of a Trading Platform of the DoM feed because its proposed fee of \$2,500.00 per month equals the same fee charged by MEMX for its depth-of-book product.⁵⁵ The proposed fees are also significantly less than the amounts charged by Cboe BZX and Cboe EDGA, who each charge \$5,000.00 per month, for comparable data products.⁵⁶ In fact, the Exchange's proposed fees for Non-Display Usage fee for Trading Platform may be even lower because the Exchange would allow Distributors to the DoM feed to also receive the ToM feed for no additional charge. The proposed fee is also significantly less than the amounts charged by several other exchanges for comparable data products, which also charge per Trading Platform operated by a data Distributor subject to a cap in most cases, rather than charging per Distributor, as proposed by the Exchange.⁵⁷ With respect to alternative trading systems, or ATSS, such platforms can utilize the Exchange Data Feeds to form prices for trading on such platforms but are not required to do so and can instead utilize SIP data. Currently, no ATS approved to trade NMS stocks subscribes to the Exchange's market data feeds.⁵⁸ With respect to other exchanges, which may choose to use the market data feeds for Regulation NMS compliance and order routing, the Exchange notes that several exchange competitors of the Exchange have not subscribed to any of the market data feeds and instead utilize SIP data for such purposes.⁵⁹ Accordingly, both ATSS and other exchanges clearly have a choice whether to subscribe to the Exchange's market data feeds.

The proposed Non-Display Usage fees are also reasonable because they take into account the benefits of receiving the data for Non-Display Usage that includes a rich set of information including top of book quotations, depth-of-book quotations, executions and other information. The Exchange believes that the proposed fees directly

and appropriately reflect, in part, the value of using the market data feeds on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.⁶⁰

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For all of the foregoing reasons, the Exchange believes that the proposed fees for the market data feeds are reasonable.

Equitable Allocation

Overall. The Exchange believes that its proposed fees are reasonable, fair, and equitable, and not unfairly discriminatory because they are designed to align fees with services provided. The Exchange believes the proposed fees for the market data feeds are allocated fairly and equitably among the various categories of users of the feeds, and any differences among categories of users are justified and appropriate.

The Exchange believes that the proposed fees are equitably allocated because they will apply uniformly to all data recipients that choose to subscribe to the market data feeds. Any market participant that chooses to subscribe to the market data feeds is subject to the same Fee Schedule, regardless of what type of business they operate, and the decision to subscribe to one or more market data feeds is based on objective differences in usage of market data feeds among different Equity Members, which are still ultimately in the control of any particular Equity Member. The Exchange believes the proposed pricing of the market data feeds is equitably allocated because it is based, in part, upon the amount of information contained in each data feed, which may have additional value to market participants.

Internal Distributor Fees. The Exchange believes the proposed monthly fees for Internal Distributors of the market data feeds are equitably allocated because they would be charged on an equal basis to all data recipients that receive the market data

feeds for internal distribution, regardless of what type of business they operate.

External Distributor Fees. The Exchange believes the proposed monthly fees for External Distributors of the market data feeds are equitably allocated and not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the market data feeds that choose to redistribute the feeds externally, regardless of what business they operate. The Exchange also believes that the proposed monthly fees for External Distributors are equitably allocated when compared to lower proposed fees for Internal Distributors because data recipients that are externally distributing market data feeds are able to monetize such distribution and spread such costs amongst multiple third party data recipients, whereas the Internal Distributor fee is applicable to use by a single data recipient (and its affiliates).

The Exchange believes that it is reasonable and equitable to assess Internal Distributors fees that are less than the fees assessed for External Distributors for subscriptions to the market data feeds because Internal Distributors have limited, restricted usage rights to the market data, as compared to External Distributors, which have more expansive usage rights. All Equity Members and non-Equity Members that decide to receive any market data feed of the Exchange must first execute, among other things, the MIA Exchange Group Exchange Data Agreement (the "Exchange Data Agreement").⁶¹ Pursuant to the Exchange Data Agreement, Internal Distributors are restricted to the "internal use" of any market data they receive. This means that Internal Distributors may only distribute the Exchange's market data to the recipient's officers and employees and its affiliates.⁶² External Distributors may distribute the Exchange's market data to persons who are not officers, employees or affiliates of the External Distributor,⁶³ and may charge their own fees for the redistribution of such market data. External Distributors may monetize their receipt of the market data feeds by charging their customers fees for receipt of the Exchange's market data feeds. Internal Distributors do not have the same ability to monetize the Exchange's market data feeds. Accordingly, the

⁵⁵ *Id.*

⁵⁶ See Cboe BZX Fee Schedule and Cboe EDGX Fee Schedule, *supra* note 37. See also *supra* note 49.

⁵⁷ See *supra* note 49. The Exchange notes that MEMX also charges per Distributor, as proposed herein. See MEMX Fee Schedule *supra* note 37.

⁵⁸ MIA Exchange Group internal data regarding non-display use by Trading Platforms. As of March 15, 2024, there were currently 32 ATSS that had filed an effective Form ATS-N with the Commission to trade NMS stocks. See <https://www.sec.gov/divisions/marketreg/form-ats-n-filings.htm#ats-n>.

⁵⁹ See, e.g., BZX Rule 11.26, EDGA Rule 13.4, EDGX Rule 13.4, and Long Term Stock Exchange, Inc. Rule 11.4010(a), each of which discloses the data feeds used by each respective exchange and state that SIP products are used with respect to MIA Exchange Group Equities.

⁶⁰ See also Exchange Act Release No. 69157 (March 18, 2013), 78 FR 17946, 17949 (March 25, 2013) (SR-CTA/CQ-2013-01) ("[D]ata feeds have become more valuable, as recipients now use them to perform a far larger array of non-display functions. Some firms even base their business models on the incorporation of data feeds into black boxes and application programming interfaces that apply trading algorithms to the data, but that do not require widespread data access by the firm's employees. As a result, these firms pay little for data usage beyond access fees, yet their data access and usage is critical to their businesses.").

⁶¹ See Exchange Data Agreement, available at <https://www.miaexchange.com/markets/us-equities/pearl-equities/market-data-vendor-agreements>.

⁶² See *id.*

⁶³ See *id.*

Exchange believes it is fair, reasonable and not unfairly discriminatory to assess External Distributors a higher fee for the Exchange's market data feeds as External Distributors have greater usage rights to commercialize such market data and can adjust their own fee structures if necessary.

The Exchange also utilizes more resources to support External Distributors versus Internal Distributors, as External Distributors have reporting and monitoring obligations that Internal Distributors do not have, thus requiring additional time and effort of Exchange staff. For example, External Distributors have monthly reporting requirements under the Exchange's Market Data Policies.⁶⁴ Exchange staff must then, in turn, process and review information reported by External Distributors to ensure the External Distributors are redistributing the market data feeds in compliance with the Exchange's Market Data Agreement and Policies.

The Exchange believes the proposed fees are equitable because the fee level results in a reasonable and equitable allocation of fees amongst Distributors for similar services, depending on whether the Distributor is an Internal or External Distributor. Moreover, the decision as to whether or not to purchase market data is entirely optional to all market participants. Potential purchasers are not required to purchase the market data, and the Exchange is not required to make the market data available. Purchasers may request the data at any time or may decline to purchase such data. The allocation of fees among users is fair and reasonable because, if market participants decide not to subscribe to the data feed, firms can discontinue their use of the market data feeds.

User Fees. The Exchange believes that the fee structure differentiating Professional User fees from Non-Professional User fees for display use is equitable. This structure has long been used by other exchanges and the SIPs to reduce the price of data to Non-Professional Users and make it more broadly available.⁶⁵ Offering the market data feeds to Non-Professional Users at a lower cost than Professional Users results in greater equity among data recipients, as Professional Users are

categorized as such based on their employment and participation in financial markets, and thus, are compensated to participate in the markets. While Non-Professional Users too can receive significant financial benefits through their participation in the markets, the Exchange believes it is reasonable to charge more to those Users who are more directly engaged in the markets.

The Exchange believes it is equitable to adopt User fees for the DoM feed that are higher than the User fees for the ToM feed because, as described above, DoM contains significantly more data than the ToM feed. The Exchange believes it is equitable to have pricing based, in part, upon the amount of information contained in each data feed and the importance of that information to market participants.

The Exchange also believes it is equitable to adopt an Enterprise Fee because this would allow a Distributors to disseminate such data feeds to an unlimited number of Users without the necessity of counting such Users. As this is an optional subscription, a data recipient is able to determine whether it prefers to count Users and report such Users to the Exchange or not, and also whether it is more economically advantageous to count and pay for specific Users or to subscribe to the Enterprise Fee.

Non-Display Usage Fees. The Exchange believes the proposed Non-Display Usage fees are equitably allocated because they would require Distributors to pay fees only for the uses they actually make of the data. As noted above, non-display data can be used by data recipients for a wide variety of profit-generating purposes (including trading and order routing) as well as purposes that do not directly generate revenues (such as risk management and compliance) but nonetheless substantially reduce the recipient's costs by automating certain functions. The Exchange believes that it is equitable to charge non-display data Distributors that use the market data feeds for purposes other than operation of a Trading Platform as proposed because all such Distributors would have the ability to use such data for as many non-display uses as they wish for one low fee. As noted above, this structure is comparable to that in place for the BZX Depth feed but several other exchanges charge multiple non-display fees to the same client to the extent they use a data feed in several different trading platforms or for several types of non-display use.⁶⁶

The Exchange further believes that the fees for non-display use for operation of a Trading Platform and for non-display use other than operation of a Trading Platform are equitable because the Exchange is imposing the same flat fee for each category of non-display use.

The Exchange believes that it is equitable to charge a single fee per Distributor rather than multiple fees for a Distributor that operates more than one Trading Platform because operators of Trading Platforms are many times viewed as a single competing venue or group, even if there are multiple liquidity pools operated by the same competitor.

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For all of the foregoing reasons, the Exchange believes that the proposed fees for the market data feeds are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. The Exchange believes that the proposed fees are not unfairly discriminatory because they would apply to all data recipients that choose to subscribe to the same market data feed(s). Any market participant, including market data vendors, that chooses to subscribe to the market data feeds is subject to the same Fee Schedule, regardless of what type of business they operate. Because the proposed fees for DoM are higher, market participants seeking lower cost options may instead choose to receive data from the SIPs or through the ToM feed for a lower cost. Alternatively, market participants can choose to pay for the DoM feed to receive data in a single feed with depth-of-book information if such information is valuable to such market participants. The Exchange notes that market participants can also choose to subscribe to a combination of data feeds for redundancy purposes or to use different feeds for different purposes. In sum, each market participant has the ability to choose the best business solution for itself. The Exchange does not believe it is unfairly discriminatory to base pricing upon the amount of information contained in each data feed and the importance of that information to market participants. As described above, the ToM feed can be utilized to trade on the Exchange but contains less

⁶⁴ See Section 6 of the Exchange's Market Data Agreement, *supra* note 61.

⁶⁵ See, e.g., Securities Exchange Act Release No. 59544 (March 9, 2009), 74 FR 11162 (March 16, 2009) (SR-NYSE-2008-131) (establishing the \$15 Non-Professional User Fee (Per User) for NYSE OpenBook); Securities Exchange Act Release No. 20002, File No. S7-433 (July 22, 1983), 48 FR 34552 (July 29, 1983) (establishing Non-Professional fees for CTA data); NASDAQ BX Equity 7 Pricing Schedule, Section 123.

⁶⁶ See *supra* note 49.

information than that is available on the DoM feed. Thus, the Exchange believes it is not unfairly discriminatory for the products to be priced as proposed, with ToM having the lowest price and DoM a higher price.

Internal Distributor Fees. The Exchange believes the proposed monthly fees for Internal Distributors are not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the same market data feed(s) for internal distribution, regardless of what type of business they operate.

External Distributor Fees. The Exchange believes the proposed monthly fees for redistributing the market data feeds are not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the same market data feed(s) that choose to redistribute the feed(s) externally. The Exchange also believes that having higher monthly fees for External Distributors than Internal Distributors is not unfairly discriminatory because data recipients that are externally distributing the market data feeds are able to monetize such distribution and spread such costs amongst multiple third party data recipients, whereas the Internal Distributor fee is applicable to use by a single data recipient (and its affiliates).

User Fees. The Exchange believes that the fee structure differentiating Professional User fees from Non-Professional User fees for display use is not unfairly discriminatory. This structure has long been used by other exchanges and the SIPs to reduce the price of data to Non-Professional Users and make it more broadly available.⁶⁷ Offering the market data feeds to Non-Professional Users with the same data as is available to Professional Users, albeit at a lower cost, results in greater equity among data recipients. These User fees would be charged uniformly to all individuals that have access to the market data feeds based on the category of User.

The Exchange also believes the proposed User fees for DoM are not unfairly discriminatory, with higher fees for Professional Users than Non-Professional Users, because Non-Professional Users may have less ability to pay for such data than Professional Users as well as less opportunity to profit from their usage of such data. The Exchange also believes the proposed User fees for DoM are not unfairly discriminatory, even though substantially higher than the proposed User fees for ToM because, as described

above, DoM has significantly more information than ToM and is thus potentially more valuable to such Users.

The Exchange further believes that its proposal to adopt an Enterprise Fee is not unfairly discriminatory because this optional alternatives to counting and paying for specific Users will provide market participants the ability to provide information from the market data feeds to large numbers of Users without counting and paying for each individual User.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees are not unfairly discriminatory because they would require Distributors for non-display use to pay fees depending on their use of the data, either for operation of a Trading Platform or not, but would not impose multiple fees to the extent a Distributor operates multiple Trading Platforms or has multiple different types of non-display use. As noted above, non-display data can be used by data recipients for a wide variety of profit-generating purposes as well as purposes that do not directly generate revenues but nonetheless substantially reduce the recipient's costs by automating certain functions. This segmented fee structure is not unfairly discriminatory because no Distributor of non-display data would be charged a fee for a category of use in which it did not actually engage.

The Exchange believes that it is not unreasonably discriminatory to charge a single fee for an operator of Trading Platforms that operates more than one Trading Platform because operators of Trading Platforms are many times viewed as a single competing venue or group, even if there a multiple liquidity pools operated by the same competitor. The Exchange again notes that certain competitors to the Exchange charge for non-display usage per Trading Platform,⁶⁸ in contrast to the Exchange's proposal. In turn, to the extent they subscribe to the market data feeds, these same competitors will benefit from the Exchange's pricing model to the extent they operate multiple Trading Platforms (as most do) by paying a single fee rather than paying for each Trading Platform that they operate that consumes the market data feeds.

* * * * *

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange's market data feeds are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,⁶⁹ the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed fees place certain market participants at a relative disadvantage to other market participants because, as noted above, the proposed fees are associated with usage of the data feed by each market participant based on whether the market participant internally or externally distributes the Exchange data, which are still ultimately in the control of any particular Equity Member, and such fees do not impose a barrier to entry to smaller participants. Accordingly, the proposed fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed fees reflects the types of data consumed by various market participants and their usage thereof.

Inter-Market Competition

The Exchange does not believe the proposed fees place an undue burden on competition on other SROs that is not necessary or appropriate. In particular, market participants are not forced to subscribe to either data feed, as described above. Additionally, other exchanges have similar market data fees with comparable rates in place for their participants.⁷⁰ The proposed fees are based on actual costs and are designed to enable the Exchange to recoup its applicable costs with the possibility of a reasonable profit on its investment as described in the Purpose and Statutory Basis sections. Competing exchanges are free to adopt comparable fee structures subject to the Commission's rule filing process.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section

⁶⁷ See *supra* note 65.

⁶⁸ See *supra* note 49.

⁶⁹ 15 U.S.C. 78f(b)(8).

⁷⁰ See *supra* note 37.

19(b)(3)(A)(ii) of the Act,⁷¹ and Rule 19b-4(f)(2)⁷² thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-PEARL-2024-25 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-PEARL-2024-25. 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 (<https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and

copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-PEARL-2024-25 and should be submitted on or before July 9, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷³

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-13318 Filed 6-17-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-349, OMB Control No. 3235-0395]

Proposed Collection; Comment Request; Extension: Rule 15g-6

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 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Rule 15g-6—Account Statements for Penny Stock Customers—(17 CFR 240.15g-6) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Rule 15g-6 requires brokers and dealers that sell penny stocks to provide their customers monthly account statements containing information with regard to the penny stocks held in customer accounts. The purpose of the rule is to increase the level of disclosure to investors concerning penny stocks generally and specific penny stock transactions.

The Commission estimates that approximately 170 broker-dealers will spend an average of approximately 78 hours annually to comply with this rule. Thus, the total compliance burden is approximately 13,260 burden-hours per year.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by August 19, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: June 12, 2024.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-13307 Filed 6-17-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100320; File No. SR-MEMX-2024-24]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule Concerning Transaction Pricing

June 12, 2024.

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 May 30, 2024, MEMX LLC ("MEMX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to

⁷¹ 15 U.S.C. 78s(b)(3)(A)(ii).

⁷² 17 CFR 240.19b-4(f)(2).

⁷³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members³ (the "Fee Schedule") pursuant to Exchange Rules 15.1(a) and (c). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal on June 3, 2024. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Fee Schedule to: (1) increase the rebate for executions of Retail Orders⁴ in securities priced at or above \$1.00 per share that add displayed liquidity to the Exchange (such orders, "Added Displayed Retail Volume"); (2) modify Retail Tier 1 by increasing the rebate provided and modifying the required criteria under such tier; and (3) modify NBBO Setter Tier 1 by modifying the required criteria under such tier, each as further described below.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a

particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 14.5% of the total market share of executed volume of equities trading.⁵ Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange currently represents approximately 2.4% of the overall market share.⁶ The Exchange in particular operates a "Maker-Taker" model whereby it provides rebates to Members that add liquidity to the Exchange and charges fees to Members that remove liquidity from the Exchange. The Fee Schedule sets forth the standard rebates and fees applied per share for orders that add and remove liquidity, respectively. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Members with opportunities to qualify for higher rebates or lower fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Increase Base Rebate for Added Displayed Retail Volume

Currently, the Exchange provides a base rebate of \$0.0032 per share for executions of Added Displayed Retail Volume. The Exchange now proposes to increase the base rebate for executions of Added Displayed Retail Volume to \$0.0034 per share.⁷ The purpose of increasing the base rebate for executions of Added Displayed Retail Volume is for business and competitive reasons, as the Exchange believes that increasing such rebate as proposed would incentivize Members to submit additional Added Displayed Retail Volume to the Exchange, which the Exchange believes

would promote price discovery and price formation, provide more trading opportunities and tighter spreads, and deepen liquidity that is subject to the Exchange's transparency, regulation and oversight, thereby enhancing market quality to the benefit of all Members and investors.

Retail Tier

As described above, the Exchange is proposing to provide a base rebate of \$0.0034 per share for executions of Added Displayed Retail Volume. The Exchange also currently offers Retail Tier 1 under which qualifying Members may receive an enhanced rebate of \$0.0034 per share for executions of Added Displayed Retail Volume by achieving a Retail Order ADAV⁸ that is equal to or greater than 0.07% of the TCV.⁹ Now, the Exchange proposes to modify Retail Tier 1 by increasing the enhanced rebate provided for executions of Added Displayed Retail Volume to \$0.0037 per share, and by modifying the required criteria such that a Member would qualify for such tier by achieving: (1) a Retail Order ADAV that is equal to or greater than 0.20% of the TCV; or (2) a Retail Order ADAV that is equal to or greater than 1,000,000 shares in the Pre-Market Session¹⁰ and/or the Post-Market Session.¹¹ Thus, such proposed change would increase the Retail Order ADAV threshold in the first required criteria and add an alternative criteria (2) that provides an incentive for Members to meet a certain Retail Order ADAV threshold outside of regular trading hours, *i.e.*, during the Pre-Market Session, the Post-Market Session, or a combination of both.

The proposed changes to the Retail Tier 1 are designed to encourage Members to increase their Retail Order flow, not only during regular trading hours but also during the Pre and Post-Market Sessions, to the Exchange in order to qualify for the enhanced rebate for executions of Added Displayed Retail Volume, thereby contributing to a

⁸ As set forth on the Fee Schedule, "ADAV" means the average daily added volume calculated as the number of shares added per day, which is calculated on a monthly basis.

⁹ As set forth on the Fee Schedule, "TCV" means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply. The pricing for Retail Tier 1 is referred to by the Exchange on the Fee Schedule under the description "Retail Tier 1" with a Fee Code of "Br1, Dr1, or Jr1, as applicable," on executions reports.

¹⁰ Exchange Rule 1.5(x) defines the Pre-Market Session as the time between 7:00 a.m. and 9:30 a.m. Eastern Time.

¹¹ Exchange Rule 1.5(w) defines the Post-Market Session as the time between 4:00 p.m. and 8:00 p.m. Eastern Time.

³ See Exchange Rule 1.5(p).

⁴ A "Retail Order" means an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization ("RMO"), provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. See Exchange Rule 11.21(a).

⁵ Market share percentage calculated as of May 28, 2024. The Exchange receives and processes data made available through consolidated data feeds (*i.e.*, CTS and UTDF).

⁶ *Id.*

⁷ The proposed base rebate for executions of Added Displayed Retail Volume is referred to by the Exchange on the Fee Schedule under the existing description "Added displayed volume, Retail Order" with a Fee Code of "Br", "Dr" or "Jr", as applicable, on execution reports.

deeper and more liquid market to the benefit of all Members and market participants. The Exchange believes that Retail Tier 1 as modified by the proposed changes described above, reflects a reasonable and competitive pricing structure that is right-sized and consistent with the Exchange's overall pricing philosophy of encouraging added and/or displayed liquidity, not only during regular trading hours but during the Pre and Post-Market Sessions.

NBBO Setter Tier

The Exchange currently offers NBBO Setter Tier 1 under which a Member may receive an additive rebate of \$0.0002 per share for a qualifying Member's executions of Added Displayed Volume (other than Retail Orders) in securities priced at or above \$1.00 per share that establish the NBBO and have a Fee Code B¹² (such orders, "Setter Volume"), and an additive rebate of \$0.0001 per share for executions of Added Displayed Volume (other than Retail Orders) that do not establish the NBBO (*i.e.*, Fee Codes D and J)¹³ by achieving: (1) an ADAV with respect to orders with Fee Code B that is equal to or greater than 5,000,000 shares; or (2) an ADAV (excluding Retail Orders) that is equal to or greater than 0.30% of the TCV.¹⁴ Now, the Exchange proposes to modify the required criteria under NBBO Setter Tier 1 such that a Member would now qualify for such tier by achieving: (1) an ADAV with respect to orders with Fee Code B that is equal to order greater than 5,000,000 shares; or (2) an ADAV in securities priced at or above \$1.00 per share (excluding Retail Orders) that is equal to or greater than 0.30% of the TCV in securities priced at or above over \$1.00 per share. Thus, such proposed change keeps the first alternative criteria intact with no changes but modifies the second alternative criteria by excluding securities priced below \$1.00 per share from the ADAV threshold and

corresponding TCV calculation.¹⁵ The Exchange is not proposing to change the amount of the additive rebates provided under the NBBO Setter Tier 1.

The Exchange believes that the proposed modified criteria provides an incremental incentive for Members to strive for higher ADAV on the Exchange, not only in orders with a Fee Code B (*i.e.*, criteria 1) but also in any security that is priced at or above \$1.00 (*i.e.*, criteria 2) to receive the additive rebate for qualifying executions of Added Displayed Volume under such tier, and thus, it is designed to encourage Members that do not currently qualify for such tier to increase their overall orders that add liquidity to the Exchange. The Exchange also believes that the criteria changes reflect a reasonable and competitive pricing structure that is right-sized and consistent with the Exchange's overall pricing philosophy of encouraging added and/or displayed liquidity. The Exchange believes that the proposed modified criteria would further incentivize increased order flow to the Exchange, thereby contributing to a deeper and more liquid market to the benefit of all Members.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,¹⁶ in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,¹⁷ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As discussed above, the Exchange operates in a highly fragmented and competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient, and the Exchange represents only a small percentage of the overall market. The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in

determining prices and SRO revenues and also recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."¹⁸

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct additional order flow to the Exchange, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members and market participants.

The Exchange notes that volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and not unfairly discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and the introduction of higher volumes of orders into the price and volume discovery process. The Exchange believes that increasing the base rebate for executions of Added Displayed Retail Volume is reasonable, equitable, and not unfairly discriminatory because, as described above, such change is designed to incentivize Members to maintain or increase their Retail Order flow to the Exchange, thus increasing liquidity and contributing to a deeper and more liquid market ecosystem on the Exchange. The Exchange believes that the Retail Tier 1 and NBBO Setter Tier 1, each as modified by the proposed changes to the rebate and/or required criteria under each such tier as described above, are reasonable, equitable and not unfairly discriminatory for these same reasons.

¹² The Exchange notes that orders with Fee Code B include orders, other than Retail Orders, that establish the NBBO.

¹³ The Exchange notes that orders with Fee Code J include orders, other than Retail Orders, that establish a new BBO on the Exchange that matches the NBBO first established on an away market. Orders with Fee Code D include orders that add displayed liquidity to the Exchange but that are not Fee Code B or J, and thus, orders with Fee Code B, D or J include all orders, other than Retail Orders, that add displayed liquidity to the Exchange.

¹⁴ The pricing is referred to by the Exchange on the Fee Schedule under the existing description "NBBO Setter Tier" with a Fee Code of "S1" to be appended to the otherwise applicable Fee Code for qualifying executions.

¹⁵ The Exchange will determine whether a security meets the "priced at or above \$1.00 per share" threshold for purposes of calculating the ADAV and TCV by using the prior day's closing price.

¹⁶ 15 U.S.C. 78f.

¹⁷ 15 U.S.C. 78f(b)(4) and (5).

¹⁸ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

Such tiers would provide Members with an incremental incentive to achieve certain volume thresholds on the Exchange, are available to all Members on an equal basis, and, as described above, are designed to encourage Members to maintain or increase their order flow, including in the form of displayed, liquidity-adding, Retail and/or NBBO-setting orders to the Exchange in order to qualify for an enhanced or additive rebate, as applicable, thereby contributing to a deeper, more liquid and well balanced market ecosystem on the Exchange to the benefit of all Members and market participants.

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act¹⁹ in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed fees and rebates described herein are appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal is intended to incentivize market participants to direct additional order flow to the Exchange, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members and market participants. As a result, the Exchange believes the proposal would enhance its competitiveness as a market that attracts actionable orders, thereby making it a more desirable destination venue for its customers. For these reasons, the Exchange believes that the proposal furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."²⁰

Intramarket Competition

As discussed above, the Exchange believes that the proposal would

incentivize Members to submit additional order flow, including displayed, liquidity-adding, Retail, and/or NBBO setting orders to the Exchange during both regular trading hours, the Pre-Market Session, and the Post-Market Session, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members, as well as enhancing the attractiveness of the Exchange as a trading venue, which the Exchange believes, in turn, would continue to encourage market participants to direct additional order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. The opportunity to qualify for the proposed higher base rebate for Added Displayed Retail Volume and each of the proposed modified Retail Tier 1 and NBBO Setter Tier 1, would be available to all Members that meet the associated volume requirements in any month. For the foregoing reasons, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

As noted above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. Members have numerous alternative venues that they may participate on and direct their order flow to, including 15 other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than approximately 14.5% of the total market share of executed volume of equities trading. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates and market participants

can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As described above, the proposed changes represent a competitive proposal through which the Exchange is seeking to generate additional revenue with respect to its transaction pricing and to encourage the submission of additional order flow to the Exchange through volume-based tiers, which have been widely adopted by exchanges, including the Exchange. Accordingly, the Exchange believes the proposal would not burden, but rather promote, intermarket competition by enabling it to better compete with other exchanges that offer similar pricing incentives to market participants.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."²¹ The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition v. SEC*, the D.C. Circuit stated as follows: "[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . ."²² Accordingly, the Exchange does not believe its proposed pricing changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

²¹ *Id.*

²² *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

¹⁹ 15 U.S.C. 78f(b)(4) and (5).

²⁰ See *supra* note 24.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act²³ and Rule 19b-4(f)(2)²⁴ thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-MEMX-2024-24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-MEMX-2024-24. 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 (<https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-MEMX-2024-24 and should be submitted on or before July 9, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-13319 Filed 6-17-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100321; File No. SR-Phlx-2024-24]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Delay Implementation of Certain Exchange Options 8 Rules and Amend Options 8, Section 34(b)

June 12, 2024.

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 May 30, 2024, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

²⁵ 17 CFR 200.30-3(a)(12).

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

The Exchange proposes to delay the implementation of SR-Phlx-2023-22³ and amend Options 8, Section 34(b), FLEX Trading (order types), which is also being delayed.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/phlx/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to delay the implementation of SR-Phlx-2023-22 and amend Options 8, Section 34(b), FLEX Trading (order types), which is also being delayed. These rules are currently effective, but not operative. Each change is described below.

Delay of Implementation

As noted herein, Phlx filed SR-Phlx-2023-22 to amend several Phlx Options 8 rules related to Phlx's trading floor and stated that the rule change would be implemented on or before March 29, 2024.⁴ Thereafter, the Exchange delayed the implementation of SR-Phlx-2023-22 to permit the Exchange additional

³ See Securities Exchange Act Release No. 97658 (June 7, 2023), 88 FR 38562 (June 13, 2023) (SR-Phlx-2023-22) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Various Options 8 Rules). See also Securities Exchange Act Release No. 98919 (November 13, 2024), 88 FR 80363 (November 17, 2023) (SR-Phlx-2023-48) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delay the Implementation of the FLEX and Cabinet Automation) ("SR-Phlx-2023-22").

⁴ See Securities Exchange Act Release No. 97658 (June 7, 2023), 88 FR 38562 (June 13, 2023) (SR-Phlx-2023-22) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Various Options 8 Rules) ("SR-Phlx-2023-22").

²³ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁴ 17 CFR 240.19b-4(f)(2).

time to code and test the functionality.⁵ These rules are currently effective, but not operative.

By way of background, with respect to FLEX Orders, SR-Phlx-2023-22 amended FLEX Orders in 3 ways. First, the Exchange amended the rules to require FLEX Orders to be reported into Phlx's Options Floor Based Management System or "FBMS," thereby further automating the execution and reporting of FLEX Options. All executed FLEX contracts will be reported to OPRA and sent to the OCC for clearing, similar to all other equity, equity index and U.S. dollar-settled foreign currency options orders executed on the Exchange's trading floor. Second, the Exchange removed its RFQ process including the BBO Improvement Interval Process, with the rule change. Third, the Exchange reorganized Options 8, Section 34 to restructure the rule to include additional information which describes current FLEX trading on Phlx. With respect to Cabinet Orders, SR-Phlx-2023-22 amended Options 8, Section 33 to require Cabinet Orders to be reported into FBMS. With this change, members and member organizations will be required to record all Cabinet Orders represented in the trading crowd into FBMS. All executed contracts will be reported to OPRA and sent to OCC for clearing similar to all other equity, equity index and U.S. dollar-settled foreign currency options orders executed on the Exchange's trading floor.

At this time, the Exchange proposes to delay the implementation of SR-Phlx-2023-22 so that it may also implement the other rule changes proposed herein at the same time and complete an OCC industry rule change prior to implementation as well as a Phlx technology migration. The Exchange proposes to implement SR-Phlx-2023-22 and the proposed changes noted in this proposal prior to the end of Q4 2025. The Exchange would issue an Options Trader Alert announcing the exact implementation date to members and member organizations at least thirty days prior to implementation.

Options 8, Section 34(b)(3)

Phlx proposes to correct a drafting error in Options 8, Section 34(b)(3) to remove one clause.⁶ Options 8, Section

34(b)(3) currently states, ". . . for a FLEX Index Option, may have a different settlement type (a.m.-settled or p.m.-settled), except each leg must have the same settlement type." At this time, Phlx proposes to delete the clause ". . . except each leg must have the same settlement type" in Options 8, Section 34(b)(3) to correct a drafting error. The rule text does not apply as Phlx does not support Asian-settled or Cliquet-settled options.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁸ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Delay of Implementation

The Exchange's proposal to delay the implementation of SR-Phlx-2023 prior to the end of Q4 2025 is consistent with the Act because it will allow Phlx time to implement the other rule changes proposed herein at the same time and complete an OCC industry rule change as well as a Phlx technology migration prior to implementation.

Options 8, Section 34(b)(3)

Phlx's proposal to amend rule text at Options 8, Section 34(b)(3) that was adopted in SR-Phlx-2023-22 is consistent with the Act because it merely corrects a drafting error.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Delay of Implementation

The Exchange's proposal to delay the implementation of SR-Phlx-2023 prior to the end of Q4 2025 does not impose an undue burden on competition because it will allow Phlx time to implement the other rule changes proposed herein at the same time and complete an OCC industry rule change

as well as a Phlx technology migration prior to implementation.

Options 8, Section 34(b)(3)

Phlx's proposal to amend rule text at Options 8, Section 34(b)(3) that was adopted in SR-Phlx-2023-22 does not impose an undue burden on competition because it merely corrects a drafting error.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act⁹ and Rule 19b-4(f)(6) thereunder.¹⁰ Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹¹ and subparagraph (f)(6) of Rule 19b-4 thereunder.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. 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.

⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁰ 17 CFR 240.19b-4(f)(6).

¹¹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹² 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.

⁵ See Securities Exchange Act Release No. 98919 (November 13, 2024), 88 FR 80363 (November 17, 2023) (SR-Phlx-2023-48) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delay the Implementation of the FLEX and Cabinet Automation).

⁶ This rule text was copied from Cboe Exchange Inc.'s Rule 5.70(b). The copied rule text included a clause related to Asian-settled or Cliquet-settled

options. This clause is not applicable to Phlx which does not utilize these settlement styles. However, part of the clause related to the Asian-settled or Cliquet-settled options was inadvertently copied with respect to its application to complex orders. This clause is being removed as it is inapplicable to Phlx.

⁷ 15 U.S.C. 78f(b)

⁸ 15 U.S.C. 78f(b)(5).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-Phlx-2024-24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-Phlx-2024-24. 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 (<https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-Phlx-2024-24 and should be submitted on or before July 9, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-13316 Filed 6-17-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. PA-62; File No. S7-2024-04]

Privacy Act of 1974; System of Records

AGENCY: Securities and Exchange Commission.

ACTION: Notice of a modified system of records.

SUMMARY: The Securities and Exchange Commission (SEC) proposes to modify system of records SEC-36, Harassment Prevention and Response Program Records, under the Privacy Act of 1974. The system of records is being modified to reflect non-substantive changes to the system title and system manager. Minor updates to the text of the notice have been made throughout to be consistent with changes to the title and system manager. Nothing in the modified SORN changes the category of individuals from whom the records are collected, the collection of records from the individuals, the authorities, the purpose for collection, or the routine uses. The changes do not impact any individual's rights to access or to amend their records pursuant to the Privacy Act.

DATES: The notice will become effective upon publication, unless the Commission receives comments that would warrant further action.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/other.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number S7-2024-04 on the subject line.

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number S7-2024-04. 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 of submission. The Commission will post all comments on the Commission's website (<https://www.sec.gov/rules/other.shtml>). Comments are also 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 a.m. and 3 p.m. Operating conditions may limit access to the Commission's Public Reference Room. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

FOR FURTHER INFORMATION CONTACT:

Ronnette McDaniel, Privacy and Information Assurance Branch, Chief, 202-551-7200 or privacyhelp@sec.gov.

SUPPLEMENTARY INFORMATION: On October 31, 2023, the SEC published system of records SEC-36, Harassment Prevention and Response Program Records. Subsequently, the program's oversight and responsibilities were moved from the Office of Equal Employment Opportunity (OEEO) to the Office of Human Resources (OHR). As a result, OHR made updates to (a) change the title of the records from *SEC-36, Harassment Prevention and Response Program* to *SEC-36, Anti-Harassment Program* and (b) change the system manager from *Director, Office of Equal Employment Opportunity*, to *Chief Human Capital Officer, Office of Human Resources*.

SYSTEM NAME AND NUMBER

SEC-36 Anti-Harassment Program Records.

SECURITY CLASSIFICATION:

Non-classified.

SYSTEM LOCATION:

U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Chief Human Capital Officer, Office of Human Resources, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Records Management by Federal Agencies, 44 U.S.C. 3101 *et seq.*; Civil Service Reform Act of 1978, 5 U.S.C. 2302(b), Prohibited Personnel Practices; Exec. Order No. 11478, 34 FR 12985 (as amended by Exec. Orders 13087, 13145 and 13152); Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e-16 *et seq.*; Age Discrimination in Employment Act of 1967, 29 U.S.C. 621 *et seq.*; Section 501 of the Rehabilitation Act of 1973, 29 U.S.C. 791; Titles I and V of the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. 12101 *et seq.*, as amended by ADA the Amendments Act of 2008; Notification and Federal

¹³ 17 CFR 200.30-3(a)(12).

Employee Antidiscrimination and Retaliation Act of 2002, Public Law 107–174, as amended by the Elijah E. Cummings Federal Employee Antidiscrimination Act of 2020; Title II of the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. 2000ff *et seq.*; Equal Pay Act of 1963, 29 U.S.C. 206(d); Equal Employment Opportunity Commission Management Directive 715 (EEO–MD–715); and Equal Employment Opportunity Commission, Enforcement Guidance on Vicarious Employer Liability for Unlawful Harassment by Supervisors (June 18, 1999).

PURPOSE(S) OF THE SYSTEM:

The Anti-Harassment Program system of records maintains records regarding allegations of workplace harassment. These records are maintained for the purpose of conducting internal inquiries and/or investigations into allegations of harassment reported to the SEC by applicants for employment, current and former SEC employees, fellows, interns, or individuals who conduct business with the SEC and resolving allegations of workplace harassment. The records contained in this system do not duplicate any existing agency or government-wide system of records, even though some of the documents might also appear in other systems of records maintained for other purposes. Particularly, records are not collected to advance claims of discrimination pursuant to processes outlined in title 29 CFR part 1614. Rather, these records are collected for administrative action relating to allegations of workplace harassment, including bases found in EEO laws and elsewhere. The agency policy and processes govern the collection and maintenance of these records to further the agency's commitment to appropriately respond to allegations of workplace harassment.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records maintains information on individuals who have reported harassing conduct by or against SEC personnel and harassing conduct by or against non-SEC personnel to the program manager for prevention of harassment and response, in accordance with the agency's administrative regulation relating to harassment prevention and response. Individuals covered include, but are not limited to applicants for SEC employment, current and former SEC employees, fellows, interns, and individuals who conduct business with the SEC. Covered individuals include those who report harassment concerns, provide

information in support of harassment inquiries or investigations, or are witnesses or are otherwise contacted as part of the fact-finding process for inquiries, investigations, and reports relating to workplace harassment.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains all records related to a report of harassment received by the SEC through the Anti-Harassment Program manager or through referrals from the Office of Equal Employment Opportunity, other SEC organizations necessary for the implementation of the SEC Anti-Harassment Program, or management officials. The records may include contact information of individuals involved in reports or allegations of harassment, statements of witnesses, exhibits, reports of interviews, findings and recommendations, close-out materials, documentation of any corrective action taken by management, and related correspondence. The specific data elements found in these records may include names, positions, social security numbers, mailing addresses, email addresses, employment histories, employee evaluations, disciplinary actions, case-related communications and notes, and audit logs of user access and activities within the SEC Anti-Harassment Program electronic databases maintained by the SEC.

RECORD SOURCE CATEGORIES:

The SEC obtains information in this system from alleged targets of harassment, alleged harassers, witnesses, members of the public, other Federal agencies, and other individuals involved in the allegations. Some information, such as name of the alleged target or harasser, personal identification number (PIN), employee identification number, position, and job location may be obtained from other SEC system of records as relevant and necessary to carry out the SEC's function. Other record sources include documents related to reports of harassment to the SEC Anti-Harassment Program staff or management; information obtained through correspondence, letters, telephone calls, emails, or any other form of communication; data obtained from investigative material and any information relevant to an investigation; materials and information gathered by staff in the performance of their duties; electronic databases maintained by the staff; other SEC files; and from individuals, including where practicable, those to whom the records relate.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records; (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

3. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

4. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry. Such disclosure is permitted in connection with civil litigation only when it is relevant and necessary to the litigation.

5. To the National Archives and Records Administration (NARA) in records management inspections conducted under 44 U.S.C. 2904 and 2906, to permit the National Archivist to inspect SEC records or inspect the SEC records management program and practices.

6. To interns, grantees, experts, contractors, and others who have been

engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

7. To Federal, State, local, and/or foreign law enforcement agencies or other appropriate entity charged with the responsibility of investigating or prosecuting a violation or potential violation of law, whether civil, criminal, or regulatory in nature.

8. To respond to subpoenas in any litigation or other proceeding.

9. To the U.S. Department of Justice (DOJ), when:

(a) The SEC or any component thereof; or

(b) Any SEC employee in his or her official capacity; or

(c) Any SEC employee in his or her individual capacity that DOJ has agreed to represent; or

(d) The United States or any agency thereof where the SEC determines the litigation is likely to affect the SEC or any of its components is a party to a litigated matter or has an interest in a litigated matter and the SEC determines that the use of such records by DOJ is relevant and necessary to the litigation.

10. In any proceeding before a court or adjudicative body before which the SEC is authorized to appear, when:

(a) The SEC or any component thereof; or

(b) Any SEC employee in his or her official capacity; or

(c) Any SEC employee in his or her individual capacity; or

(d) The United States or any agency thereof where the SEC determines the litigation is likely to affect the SEC or any of its components is a party to the proceeding or has an interest in the proceeding and SEC determines that the use of such records is relevant and necessary to the proceeding.

11. To provide information to the EEOC when requested in connection with investigations into alleged or possible discriminatory practices in the Federal sector, examination of Federal affirmative employment programs, compliance by Federal agencies with Uniformed Guidelines on Employee Selection Procedures, or other functions vested in the EEOC.

12. To provide information to officials of labor organizations recognized under

5 U.S.C. chapter 71, when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting conditions of employment.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system of records are stored electronically or on paper in secure facilities. Electronic records are stored on the SEC's secure network and/or an SEC-approved cloud storage location. Access to and use of these records is limited to those persons whose official duties require such access.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records are cross-indexed by the name of the individual who reports harassment, the name of the alleged target of harassment, if any, and the name of the alleged harasser. The records may be retrieved by any of the above three indexes and other indexes, as appropriate.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records are maintained for three years after the report of harassment is closed and are then deleted or destroyed in accordance with NARA, General Records Schedule (GRS) 023, Item 40 and the SEC Comprehensive Records Schedule. Authorized staff follow the SEC's records management procedures for safeguarding and disposing of records related to reports of harassment that have met their retention period.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras, and, at certain SEC facilities, 24-hour security guard service. Computerized records are safeguarded in a secured environment. Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include restricting access to authorized personnel who have a "need to know" and using locked file cabinets and/or locked offices or file rooms. Contractors

and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORDS ACCESS PROCEDURES:

Persons seeking to gain access to any record contained in this system of records must submit a written request in accordance with instructions in SEC Privacy Act Regulations; 17 CFR 200.301 *et seq.* Address such request to: FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Mail Stop 5100, Washington, DC 20549–2736.

CONTESTING RECORD PROCEDURES:

Persons seeking to contest the content of any record contained in this system of records may inquire in writing in accordance with instructions in SEC Privacy Act Regulations, 17 CFR 200.301 *et seq.* Address such requests to: FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Mail Stop 5100, Washington, DC 20549–2736.

NOTIFICATION PROCEDURES:

See "Record Access Procedures" above.

EXEMPTIONS PROMULGATED FOR THE:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 88 FR 74550 (Oct. 31, 2023).

By the Commission.

Dated: June 12, 2024.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–13312 Filed 6–17–24; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20388 and #20389; Mississippi Disaster Number MS–20010]

Presidential Declaration of a Major Disaster for the State of Mississippi

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Mississippi (FEMA–4790–DR), dated 06/10/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 04/08/2024 through 04/11/2024.

DATES: Issued on 06/10/2024.

Physical Loan Application Deadline Date: 08/09/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 03/10/2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 06/10/2024, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1-800-659-2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Hancock, Hinds, Humphreys, Madison, Neshoba, Scott

Contiguous Counties (Economic Injury Loans Only):

Mississippi: Attala, Claiborne, Copiah, Harrison, Holmes, Jasper, Kemper, Lauderdale, Leake, Leflore, Newton, Pearl River, Rankin, Sharkey, Simpson, Smith, Stone, Sunflower, Warren, Washington, Winston, Yazoo

Louisiana: St. Tammany Parish

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20388C and for economic injury is 203890.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024-13321 Filed 6-17-24; 8:45 am]

BILLING CODE 8026-09-P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1330X; Docket No. AB 1040 (Sub-No. 1X)]

The State of Oklahoma by and Through the Oklahoma Department of Transportation—Abandonment Exemption—in Payne County, Okla.; Stillwater Central Railroad, L.L.C.—Discontinuance Exemption—in Payne County, Okla.

The State of Oklahoma by and through the Oklahoma Department of Transportation (ODOT) and Stillwater Central Railroad, L.L.C. (SLWC), (collectively, Applicants) have jointly filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* for ODOT to abandon, and for SLWC to discontinue service over, an approximately 3.2-mile stub-ended rail line extending between milepost 30.74 and milepost 27.54 in Stillwater, Payne County, Okla. (the Line). The Line traverses U.S. Postal Service Zip Code 74074 and has one station.

Applicants have certified that: (1) no local traffic has moved over the Line since 2018; (2) because the Line is not a “through line,” there is no overhead traffic that would need to be rerouted; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7 and 1105.8 (notice of environmental and historic reports), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment or discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition

adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,¹ these exemptions will be effective on July 18, 2024, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,² formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/railbanking requests under 49 CFR 1152.29 must be filed by June 28, 2024.³ Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by July 8, 2024.

All pleadings, referring to Docket Nos. AB 1330X and AB 1040 (Sub-No. 1X), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street, SW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on ODOT's representative, Eric M. Hocky, Clark Hill, PLC, Two Commerce Square, 2001 Market Street, Suite 2620, Philadelphia, PA 19103; and SLWC's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemptions are void ab initio.

ODOT has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by June 24, 2024. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245-0294. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245-0245. Comments on environmental and historic preservation matters must be filed within 15 days

¹ Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.*, subsidy or purchase) and demonstrating that they are preliminarily financially responsible. See 49 CFR 1152.27(c)(2)(i).

² The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the effective date of the exemptions. See *Exemption of Out-of-Serv. Rail Lines*, 5 I.C.C.2d 377 (1989). Any request to stay should be filed as soon as possible so that the Board may take appropriate action before the effective date of the exemptions.

³ Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or interim trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), ODOT shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by ODOT's filing of a notice of consummation by June 18, 2025, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at www.stb.gov.

Decided: June 12, 2024.

By the Board, Valerie O. Quinn, Acting Director, Office of Proceedings.

Tammy Lowery,
Clearance Clerk.

[FR Doc. 2024-13381 Filed 6-17-24; 8:45 am]

BILLING CODE 4915-01-P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Public Availability of the Fiscal Year 2022 Service Contract Inventory

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: USTR is announcing that its fiscal year 2022 service contract inventory is publicly available.

FOR FURTHER INFORMATION CONTACT: Michelle Secrist, Financial and Accounting Analyst, at Michelle.Secrist@ustr.eop.gov or (202) 395-3505.

SUPPLEMENTARY INFORMATION: In accordance with section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111-117), USTR is providing notice that its fiscal year 2022 service contract inventory is publicly available. The inventory includes several attributes of certain service contracts such as dollar value, contract type, and place of performance. USTR developed its inventory and analysis in accordance with instructions issued by the Office of Management and Budget's Office of Federal Procurement Policy.

USTR's inventory is included in the government-wide inventory at <https://www.acquisition.gov/service-contract-inventory>. The government-wide inventory can be filtered for USTR data. In addition, analysis of fiscal year 2021 service contract data is available on the USTR website at <https://ustr.gov/about->

[us/reading-room/service-contract-inventories](#).

Fred Ames,

Assistant U.S. Trade Representative for Administration, Office of the United States Trade Representative.

[FR Doc. 2024-13302 Filed 6-17-24; 8:45 am]

BILLING CODE 3390-F4-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2017-0319]

Parts and Accessories Necessary for Safe Operation; Exemption Renewal for Agricultural and Food Transporters Conference of American Trucking Associations

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of provisional renewal of exemption; request for comments.

SUMMARY: FMCSA announces its decision to provisionally renew an exemption requested by the Agricultural and Food Transporters Conference (AFTC) of American Trucking Associations (ATA), which will allow certain alternative methods for the securement of agricultural commodities transported in wood and plastic boxes and bins and large fiberglass tubs, as well as hay, straw, and cotton bales that are grouped together into large singular units. The exemption is renewed for 6 months, unless revoked earlier.

DATES: This renewed exemption is effective April 15, 2024, through October 15, 2024, unless revoked earlier. Comments must be received on or before July 18, 2024.

ADDRESSES: You may submit comments identified by docket number FMCSA-2017-0319 using any of the following methods:

- **Federal eRulemaking Portal:** Go to <https://www.regulations.gov/docket/FMCSA-2017-0319/document>. Follow the online instructions for submitting comments.

- **Mail:** Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590-0001.

- **Hand Delivery or Courier:** Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590-0001, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

- **Fax:** (202) 493-2251.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Chief, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590-0001; (202) 366-9209; MCPSV@dot.gov. If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA-2017-0319), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to <https://www.regulations.gov/docket/FMCSA-2017-0319/document>, click on this notice, click "Comment," and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8 1/2 by 11 inches, suitable for copying and electronic filing.

If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and

that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as "PROPIN" to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590-0001 or via email at brian.g.dahlin@dot.gov. At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

B. Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to <https://www.regulations.gov/docket/FMCSA-2017-0319/document> and choose the document to review. To view comments, click this notice, then click "Browse Comments." If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

C. Privacy

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, including any personal information the commenter provides, to www.regulations.gov as described in the system of records notice DOT/ALL 14 (Federal Docket Management System (FDMS)), which can be reviewed under the "Department Wide System of Records Notices" at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b)(2) and 49 CFR 381.300(b) to renew an exemption from the FMCSRs for subsequent periods of

up to 5 years if it finds that such exemption would likely maintain a level of safety that is equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)).

III. Background

On September 27, 2002, FMCSA introduced new cargo securement regulations to require motor carriers to change the way they use cargo securement devices to prevent articles from shifting on or within or falling from commercial motor vehicles effective December 26, 2002, with a compliance date of January 1, 2004 (67 FR 61212). The cargo securement rules consist of general rules that apply to all types of cargo, with exceptions (49 CFR 393.100–393.114), as well as commodity-specific rules for cargo requiring specialized securement methods (49 CFR 393.116–393.136). Commodity-specific rules are in addition to general rules, meaning cargo securement systems must meet both general and commodity-specific requirements. In a letter dated December 17, 2015, the Agricultural and Food Transporters Conference (AFTC) of the American Trucking Associations (ATA) stated that strict application of the 2002 requirements would have resulted in a less secure agricultural commodity securement environment and highlighted the absence of commodity-specific rules for transporting agricultural commodities in wood and plastic containers, large fiberglass tubs, or grouped hay, straw, and cotton bales.¹

Testing of Alternative Securement Methods

In response to concerns raised by agricultural commodities shippers, FMCSA commissioned the Department of Transportation's Volpe Center to develop a comprehensive test plan to assess whether the alternative securement methods allowed by the California Highway Patrol (CHP) and other industry practices could meet FMCSA's cargo securement standards for agricultural commodities, focusing on protection against shifting and falling cargo, as outlined in the 2002 final rule. Volpe conducted a nationwide review of state regulations and industry practices related to the transportation of various agricultural commodities by commercial

motor vehicles (CMVs) and issued a final report.²

In November 2007, FMCSA, and Volpe, in cooperation with CHP and certain agricultural and trucking organizations, tested agricultural industry securement practices. The testing process involved lifting semitrailers to simulate various forces acting on the cargo, such as sudden accelerations, decelerations, and lateral forces during turns. Commercial semitrailers and those with converter dollies were used for testing each cargo securement method. The purpose of the test was to compare the performance of different securement methods against FMCSA's performance criteria.

The findings of the testing were summarized as follows:

- Standard agricultural commodity cargo securement practices effectively "unitize" individual components into a single cargo unit. Adding welded or bolted blocking at the front of the trailer proves highly effective for plastic and wooden bins. Lateral cargo securement devices significantly improve longitudinal and lateral cargo securement.

- The optimal method for securing agricultural commodities in plastic bins involves a combination of perimeter wire rope tiedowns and corner irons. Lateral cargo securement devices are essential for controlling lateral movement.

- Corner irons and wire rope techniques effectively unitize bins and reduce individual unit movement. Additional blocking, such as angle iron secured with bolts, effectively restricts cargo movement during longitudinal testing.

- Lateral cargo securement devices are necessary to minimize movement at the center of the load. The Washington Wrap style of securement at the rear of the load may damage the structural integrity of plastic bins and allow significant lateral movement, affecting vehicle stability.

- Although not tested, the industry practice of securing cotton bales appears effective through longitudinal wire rope and lateral rope addition.

Original Exemption Application From Specific Cargo Securement Regulations

In 2015, AFTC applied for an exemption from specific cargo securement regulations (49 CFR 393.102, 393.106, 393.110, and 393.114)

¹ Letter dated December 17, 2015, requesting 5-year temporary exemption from cargo securement requirements at 49 CFR 393.102, 106, 110, and 114 for transport of agricultural products. (Available on www.regulations.gov at document identifier FMCSA-2017-0319-0002).

² U.S. Department of Transportation Federal Motor Carrier Safety Administration (FMCSA), FMCSA-PSV-14-013, Evaluation of Cargo Securement of Agri Commodities (January 2018) (available on www.regulations.gov at document identifier FMCSA-2017-0319-0003).

to allow alternative methods for securing agricultural commodities transported in wood and plastic boxes and bins, large fiberglass tubs, and hay, straw, and cotton bales grouped into large single units. AFTC stated that agricultural haulers in California had relied on yearly exemptions from CHP which permitted the continued use of traditional cargo securement methods for transporting agricultural products. These exemptions were granted due to concerns that strictly enforcing FMCSA's 2002 cargo securement requirements would have created a less effective environment for securing agricultural commodities.

AFTC's exemption application cited the results of the 2007–2008 tests conducted jointly by FMCSA, CHP, the California Department of Food and Agriculture, the California Trucking Association and several AFTC members. The tests evaluated methods for securing a wide variety of agricultural products, including the use of plastic and wood bins, large fiberglass tubs, and hay and cotton bales. The results demonstrated the need for methods specific to the unique behavior of grouped agricultural commodities.³

AFTC sought alternative securement methods for boxes, bins, and tubs that are specifically designed to transport agricultural products from the field or storage to the initial processing point, as well as for the return or delivery of empty containers to the field or storage location. Moreover, AFTC also noted that loads transported in vans or those contained within four-sided racks, or for purposes other than agricultural operations as outlined above, must adhere to the general cargo securement regulations stated in 49 CFR 393.100–393.114.

AFTC explained that the unique nature of agricultural commodities often requires them to be into larger single units which exhibit distinct behavior when subjected to the performance requirements in 49 CFR 393.102.

AFTC stated that without the exemption, CMV operators nationwide would lack access to proven alternative securement techniques and California haulers would be forced to continue requesting annual cargo securement exemptions from CHP. Specifically, AFTC stated that the exemption would enhance safety because the alternative securement methods it proposed exceed

the cargo securement standards, both of 49 CFR 393.100–393.114 and the California exemptions the industry had been relying upon.

2019 Notice of Final Disposition; Grant of Application for Exemption

On April 15, 2019, FMCSA determined that granting the temporary exemption to allow alternative securement methods for agricultural commodities would likely result in a level of safety equivalent to, or greater than, the level achieved without the exemption. (84 FR 15279) The testing conducted in 2007 and 2008 demonstrated that the alternative securement practices proposed by AFTC met the performance requirements of 49 CFR 393.102.

FMCSA acknowledged that the cargo securement techniques for large and small hay and straw bales, evaluated in the draft cargo securement testing report, were previously addressed in a “Technical Review of Industry Cargo Securement Practices for Baled Hay and Straw, Revision1,” dated July 7, 2008.⁴ FMCSA also referred to the “Evaluation of 2002 Final Rule Cargo Securement for Agricultural Commodities” final report, as explained earlier in the document, to determine that alternative securement methods are needed that are unique to certain agricultural commodity cargoes.

2023 Application for Renewal of Exemption

AFTC has requested a 5-year renewal of the current exemption. In its renewal application, AFTC reiterated the arguments supporting its original exemption request. AFTC further noted that since the 2019 exemption was granted, the alternative methods for the securement of agricultural commodities transported in wood and plastic boxes and bins and large fiberglass tubs, as well as hay, straw, and cotton bales that are grouped together into large singular units, has been successful. A copy of AFTC's request to renew the exemption is available in the docket.

Crash and Inspection Data of Trucks With Cargo

FMCSA's Motor Carrier Management Information System (MCMIS) collects a variety of data on motor carrier violations during inspections and crash reports, with most of the data focusing on either driver, vehicle or carrier compliance. There is little or no data on the type of cargo being carried at the time of a crash. MCMIS does, however,

collect data on whether a crash happened because cargo fell off the carrier or whether a carrier hit loose cargo on the roadways. This data does not specifically identify lost cargo that caused a crash as an agricultural commodity. The agency performed inspection violations data analysis for the cargo securement requirements of 49 CFR 393.102, 393.106, 393.110 and 393.114 to understand if there was greater proportion of violations involving agricultural cargo compared to all other types of cargo. The data showed that in total, less than 0.35 percent of all violations were attributed to the cargo securement of agricultural commodities in the period between 2020 and thus far into 2024. There is no crash data to indicate whether shifting or falling of an agricultural commodity within or off the vehicle is the primary cause of crash.

IV. Equivalent Level of Safety Analysis

Based on the above analysis, FMCSA is not aware of any evidence showing that the operation of the alternative securement methods allowed by the original exemption has resulted in any degradation in safety. Moreover, the information provided by AFTC in its renewal application supports the conclusion that these alternative securement methods maintain the requisite statutory level of safety. Therefore, for the reasons discussed above and in the prior notice granting the original exemption request, while Agency receives and considers comments on the renewal request, FMCSA concludes that provisionally renewing the exemption granted on April 15, 2019, for an additional 6 months, on the terms and conditions set forth in this exemption renewal decision, would likely maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

V. Exemption Decision

A. Grant of Exemption

FMCSA provisionally renews the exemption for a subsequent period of 6 months, instead of the 5 years requested by AFTC, subject to the terms and conditions of this decision and the absence of adverse evidence sufficiently serious to cause the Agency to revoke the exemption. FMCSA anticipates granting a full 5-year exemption from the requirements of 49 CFR 393.102, 393.106, 393.110, and 393.114 when the provisional exemption expires, unless the Agency obtains evidence demonstrating that the exemption would not likely maintain an equivalent

³ FMCSA Memorandum: Technical Review Industry Cargo Securement Practices for Baled Hay and Straw (“FMCSA Tech Review Memo”) (Jul. 7, 2008) (available at: <https://www.chp.ca.gov/CommercialVehicleSectionSite/Documents/TechReviewHayStraw.pdf> and on www.regulations.gov at document identifier FMCSA–2017–0319–0005).

⁴ See FMCSA Tech Review Memo, available at: <https://www.chp.ca.gov/CommercialVehicleSectionSite/Documents/TechReviewHayStraw.pdf>.

level of safety as the existing regulations.

B. Applicability of Exemption

During the provisional exemption period, motor carriers operating CMVs may utilize certain alternative methods for the securement of agricultural commodities transported in wood and plastic boxes and bins and large fiberglass tubs, as well as hay, straw, and cotton bales that are grouped together into large singular units, as proposed by AFTC in its original exemption application.

C. Terms and Conditions

1. General:

- Motor carriers and CMVs operating under this exemption must comply with all other applicable FMCSRs (49 CFR parts 350–399), unless specifically exempted from a requirement.

2. Limitation of Exemption:

- This exemption applies exclusively to CMVs transporting agricultural commodities in wood and plastic boxes and bins and large fiberglass tubs, as well as hay, straw, and cotton bales that are grouped together into large singular units.

3. Recurring Data Reporting Requirements:

- AFTC must provide recurring yearly data submissions to include information on crashes and incidents involving a CMVs transporting agricultural commodities in wood and plastic boxes and bins and large fiberglass tubs, as well as hay, straw, and cotton bales that are grouped together into large singular units. The first submission is due 5 months after the date of publication of this exemption renewal in the **Federal Register**, and, if the exemption is extended, subsequent submissions are due every 12-months thereafter until the exemption expires or is revoked.

- The yearly data submissions must be sent via email to FMCSA at MCPSD@dot.gov.

- If AFTC lacks certain categories of information, alternative information may be discussed with FMCSA and submitted if approved.

4. Data Reporting Requirements for Crashes and Incidents:

- At the end of each 12-month period, AFTC must submit a report detailing crash rates, vehicle miles traveled, number and type of CMVs operating under the exemption, information including dates of the crash or incident, time, location, and a brief description of the event.

- AFTC must provide any available information indicating malfunction of

the alternative cargo securement methods.

5. Meetings:

- AFTC must meet with FMCSA upon request to answer questions regarding data and information provided under the exemption.

D. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation that conflicts with or is inconsistent with this exemption with respect to a person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

E. Revocation

The exemption will be valid for 6 months as provided in section V.A. above, unless revoked earlier by FMCSA. FMCSA does not believe that motor carriers, drivers, and CMVs covered by the exemption will experience any deterioration of safety below the level that would be achieved without the exemption. However, should the exemption result in a lower level of safety than was maintained before it was granted, FMCSA will take all steps necessary to protect the public interest, including revocation of the exemption without prior notice. The exemption will be immediately revoked if: (1) motor carriers, drivers, and/or CMVs fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 or chapter 313.

Interested parties possessing information that would demonstrate that this exemption or motor carriers operating CMVs utilizing certain alternative methods for the securement of agricultural commodities transported in wood and plastic boxes and bins and large fiberglass tubs, as well as hay, straw, and cotton bales that are grouped together into large singular units are not achieving the requisite statutory level of safety should immediately notify FMCSA by email at MCPSV@DOT.GOV. The Agency will evaluate any such information and, if safety is being compromised or if the continuation of the exemption is not consistent with the goals and objectives of 49 U.S.C. 31136 or chapter 313, will take immediate steps to revoke the exemption.

VI. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on AFTC's application for renewal of the exemption from 49 CFR 393.102, 393.106, 393.110, and 393.114. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Sue Lawless,

Acting Deputy Administrator.

[FR Doc. 2024–13324 Filed 6–17–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2017–0133]

Commercial Driver's License (CDL): Application for Exemption Renewal; U.S. Custom Harvesters, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; renewal of exemption.

SUMMARY: FMCSA announces its final decision to renew the U.S. Custom Harvesters, Inc. (USCHI) exemption from the intrastate restriction ("K") on commercial driver's licenses (CDLs) for custom harvester drivers operating in interstate commerce for a two-year period, with additional terms and conditions. FMCSA's regulations currently provide an exception to the minimum age requirements for drivers of commercial motor vehicles (CMVs) engaged in custom harvesting operations in interstate commerce. However, under the Agency's CDL regulations, States may impose an intrastate-only (or "K") restriction for these drivers. On October 11, 2023, FMCSA announced its decision to provisionally renew USCHI's exemption for two years, pending a review of any comments received in response to that

notice. After reviewing the four comments submitted to the docket, which are discussed later in this notice, the Agency believes that drivers who qualify for the exemption will likely achieve a level of safety that is equivalent to, or greater than, the level of safety that would be achieved by complying with the “K” restriction.

DATES: This renewed exemption became effective October 3, 2023, and continues through October 3, 2025.

FOR FURTHER INFORMATION CONTACT: La Tonya Mimms, Chief, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA; (202) 366–9220;

latonya.mimms@dot.gov. If you have questions on viewing material to the docket, contact Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation; Viewing Comments and Documents

To view comments, go to www.regulations.gov, insert the docket number “(FMCSA–2017–0133)” in the keyword box, and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.”

To view documents mentioned in this notice as being available in the docket, go to www.regulations.gov, insert the docket number “FMCSA–2017–0133” in the keyword box, click “Search,” and choose the document to review.

If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant’s safety analyses. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely maintain a level

of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision(s) from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reasons for the denial (49 CFR 381.315(c)(2)).

III. Background

Current Regulatory Requirements

The Federal Highway Administration adopted section 391.2(a) of title 49 of the Code of Federal Regulations (CFR) on December 22, 1971 (36 FR 24218). Under this provision, drivers of CMVs operated by a person engaged in custom harvesting are exempt from all of part 391, including the requirement to be at least 21 years of age to operate a CMV in interstate commerce. State Driver Licensing Agencies (SDLAs) issue a “K” restriction on drivers who are under the age of 21 to permit these drivers to operate a CMV within the issuing State only. Section 391.2(a) does not preempt State CDL regulations, such as the requirement in 49 CFR 383.23(a)(2) to “[possess] a CDL which meets the standards contained in subpart J of this part,” including any “K” restriction imposed under 49 CFR 383.153(a)(10)(vii) of subpart J.

Original Exemption

On October 3, 2018, FMCSA published a notice granting USCHI an exemption from 49 CFR 383.23(a)(2) and 49 CFR 383.153(a)(10)(vii) for a period of five years; the exemption expired on October 3, 2023 (83 FR 49977). In its 2018 decision, FMCSA noted that although it was granting the exemption, the exemption “did not require any special action or processing” by the SDLAs who would continue to place the “K” restriction when called for, but enforcement officers would disregard it in situations involving drivers who can demonstrate eligibility for the custom harvester exemption set forth in 49 CFR 391.2(a).

Application for Renewal of Exemption

USCHI requested a renewal of its exemption for a five-year period. USCHI stated that it frequently employs drivers younger than 21 years of age, who are issued CDLs with a “K” restriction. Under an exception in place since 1971, the requirement that CMV drivers must be at least 21-years old does not apply

to a CMV driver who drives a CMV while engaged in custom-harvesting operations, provided that certain conditions are met (49 CFR 391.2(a)). Under the exemption, drivers under 21 are therefore allowed to drive in interstate custom harvesting operations, notwithstanding the “K” restriction on their licenses.

USCHI states that, even though CMV drivers engaged in custom harvesting are excepted from the 21-year-old requirement, they are frequently cited during roadside inspections because of the presence of the “K” restriction on their licenses. USCHI states that this issue negatively impacts the safety records of drivers and employers.

USCHI asks the Agency to renew its exemption for another five-year period, subject to terms and conditions, that would allow law enforcement officers to determine that the driver is operating in custom harvester operations. For example, USCHI proposes that the driver be required to provide at least three methods of verification while *en route*. A copy of USCHI’s request for an exemption renewal is available for review in the docket for this notice.

IV. Provisional Renewal of Exemption

On October 11, 2023, after review of USCHI’s renewal application, FMCSA published its decision to provisionally grant a two-year renewal of the exemption effective October 3, 2023, through October 3, 2025, and requested public comment (88 FR 70431). The Agency makes that renewal final for the remainder of the two-year period.

The October 11 notice of provisional renewal announced terms and conditions that applied to operations for the first 90 days after the notice and, separately, certain replacement or additional requirements that would apply beginning 90 days later, *i.e.*, after January 9, 2024 (88 FR at 70433). Today’s notice supersedes the October 11, 2023, notice and finalizes the provisionally granted two-year exemption, through October 3, 2025.

V. Public Comments

Four comments were submitted to the docket, all in support of renewing the exemption. USCHI acknowledged the terms and conditions in the exemption renewal, stating “USCHI understands the required and critical need to achieve a level of safety equivalent to, or greater than, the level that would be achieved by the currently (sic) regulation under this exemption.” USCHI also contended that its members operate with the utmost regard for safety and responsibility, stating that USCHI members “provide additional

mentorship and on the job training for younger drivers once they receive their CDL. USCHI also hosts multiple safety events for its members each year.” Heil Harvesting, LLC’s supporting comment emphasized the need for the exemption stating that “[w]orkers to help harvest the nation’s crops are increasingly difficult to locate and hire, and eliminating drivers younger than age 21 from the employee pool creates a severe hardship for harvesters’ businesses.” Beau Froese said “[w]e travel through Texas, Oklahoma, Kansas, Colorado and Nebraska and would have a serious problem meeting the harvesting needs of the producers that we serve were we unable to use 18, 19 and 20 year old drivers.” Lastly, Mychal Neumiller provided the following supporting statement: “[o]ur business spends many hours training young employees on back roads and around our farm before allowing any of them to get on the road with us. Without these young people, most harvesters wouldn’t be able to get the crops out of the fields for our farmers.”

VI. Response to Public Comments and Agency Decision

FMCSA has evaluated the public comments and now issues this final decision affirming its provisional decision to renew the exemption for a two-year period. USCHI fulfilled the 30-day requirement of the provisional exemption’s terms and conditions and has provided a list of USDOT numbers of the motor carriers that will be operating under this exemption; this list is available in the docket. FMCSA is not aware of any evidence showing that allowing the exemption from the intrastate-only “K” restriction has resulted in any degradation in safety. Interstate operations for non-CDL custom harvester drivers younger than 21 are currently allowed pursuant to 49 CFR 391.2(a), and intrastate operations for CDL custom harvester drivers under the age of 21 can be accomplished under 49 CFR 383.23(a)(2) and 383.153(a)(10)(vii).

The Agency notes that, likely through miscommunications and misunderstandings among the Agency, USCHI, and its membership, certain crashes involving the drivers operating under the exemption were not reported to the Agency during the first five-year exemption. FMCSA’s review of USCHI members’ data indicates there have been crashes that could be considered preventable. The Agency obtained 14 police crash reports involving custom harvester operators under the age of 21. However, given the five-year period of the previous exemption, the size of

USCHI’s membership,¹ and a lack of information on the age peer group within the agricultural driver population as a baseline, the Agency does not find sufficient information to conclude that the previous 5-year exemption resulted in a degradation of safety.

Nevertheless, as a safety precaution, FMCSA is extending the exemption for two years instead of the requested five years and enhancing the terms and conditions of the exemption to assist the Agency’s oversight. Under the modified exemption, custom harvester drivers will likely maintain a level of safety that is equivalent to, or greater than, the level of safety that would be achieved without the exemption.

During the two-year period of the extended exemption, in addition to enhancing the terms and conditions of the exemption, FMCSA will initiate a data analysis project to examine the safety performance of custom harvester drivers under the age of 21, in comparison to other drivers in the agriculture sector of the motor carrier industry. The data collection for this project has been initiated, and FMCSA has begun analyzing the data as referenced in the provisional exemption notice. The Agency currently has violation data on motor carriers that utilize the transportation of agricultural commodities exception to the hours-of-service rules, and the new study will assist the Agency in conducting a more in-depth analysis of their safety performance as a group and the safety performance of the subset of custom harvester drivers under the age of 21. This information will aid in assessing the safety impacts of the USCHI exemption prior to the expiration of the two-year renewal.

VII. Exemption Decision

A. Grant of Two-Year Exemption

FMCSA renews the exemption for a period of two years, subject to the terms and conditions of this decision. The exemption from the “K” intrastate restriction on CDLs held by custom harvester drivers operating in interstate commerce is otherwise effective October 3, 2023, through October 3, 2025, at 11:59 p.m. local time, unless renewed or rescinded.

B. Applicability of Exemption

Custom Harvester Drivers

Custom harvester drivers under 21 years of age will be able to display this

exemption notice to help explain that when operating in that capacity, they are permitted to operate outside the State issuing their CDL even though the license has a “K” (intrastate only) restriction.

Enforcement Officers

This exemption notice will explain to law enforcement officers that 49 CFR 391.2(a) authorizes custom harvester drivers to operate in interstate commerce even though they are under 21 years of age. The notice will explain that a “K” restriction on these drivers’ CDLs does not limit them from driving outside the CDL-issuing State when they are operating as custom harvesters in accordance with 49 CFR 391.2(a) and this exemption.

State Driver Licensing Agencies

This exemption requires no action or inaction on the part of the SDLAs. They will continue to issue CDLs with a “K” restriction to drivers under the age of 21.

C. Terms and Conditions

Motor carriers and drivers operating under the exemption are subject to the following terms and conditions:

(1) Drivers engaged in custom harvesting operations in interstate commerce shall be exempt from any intrastate-only “K” restriction on their CDLs when operating under the provisions of this exemption.

(2) Drivers must have a copy of this notice in their possession while operating under the terms of the exemption. The exemption document must be presented to law enforcement officials upon request.

(3) Drivers to whom this exemption applies are identified in 49 CFR 391.2(a) as those operating a CMV to transport farm machinery, supplies, or both, to or from a farm for custom harvesting operations on a farm; or transporting custom-harvested crops to storage or market.

(4) To ensure that the drivers are legitimately operating as a custom harvester, they should be able to provide at least three of the following methods of verification:

(a) The driver may have on hand a valid custom harvesting document such as a current-date agricultural commodity scale sheet, a current-date custom harvesting load sheet, an official company document stating the company’s purpose, etc.;

(b) The CMV may have license plates specific to custom, or the verbiage “Harvesting” may be part of the business signage on the vehicle;

¹ USCHI’s website indicates they have approximately 420 Regular members and 180 Associate members.

(c) The CMV may be designed to haul a harvested agricultural commodity or equipment for harvesting or be a support vehicle for custom-harvesting operations, such as a service truck;

(d) The CMV may be hauling a harvested agricultural commodity or equipment for the purpose of custom harvesting;

(e) The CMV may have a newly harvested commodity or remnants on board;

(f) The driver will be able to provide a verifiable location of the current harvesting operation or delivery location for a harvested commodity.

(5) The USCHI must provide FMCSA with a list of motor carrier USDOT numbers that are engaged in custom farm operations every 90 days. The driver must be working for a motor carrier with a USDOT number identified in the most current list provided to FMCSA by USCHI. See additional FMCSA notification requirements in Section VII.E below. This exemption applies to USCHI members only.

D. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

E. Notification to FMCSA

Starting in May of 2024 and every 90 days thereafter, USCHI must provide FMCSA with the USDOT numbers of the motor carriers that will be operating under this exemption. The USCHI must notify FMCSA within five business days of any crash (as defined in 49 CFR 390.5), involving any of the drivers operating under the terms of the exemption. The notification must include the following information:

(a) Identity of Exemption: "USCHI Renewal,"

(b) Name of the custom harvester employer and USDOT number,

(c) Date of the crash,

(d) Origin and intended destination of the USCHI driver's trip and the distance (in miles) of the crash from the driver's home terminal,

(e) Driver's name, license number, and age,

(f) Vehicle number and State license number,

(g) Number of individuals suffering physical injury

(h) Number of fatalities,

(i) The police-reported circumstances of the crash,

(j) Whether the driver was cited for violation of any traffic laws or motor carrier safety regulations,

(k) The driver's total driving time and total on-duty time period prior to the accident,

(l) Information about what safety training, if any, was provided to drivers operating under this exemption after the driver obtained a CDL, and

(m) A scanned copy of the police accident report.

Reports filed under this provision shall be emailed to MCPSD@DOT.GOV.

F. Termination

The exemption will be rescinded if: (1) the USCHI, motor carriers, and drivers operating under the exemption fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objects of 49 U.S.C. 31136(e) and 31315.

Should FMCSA receive notice of any potential adverse safety impacts, FMCSA will take all steps necessary to protect the public interest, including revocation or restriction of the exemption if necessary. FMCSA may immediately revoke or restrict the exemption for failure to comply with its terms and conditions.

Sue Lawless,

Acting Deputy Administrator.

[FR Doc. 2024-13323 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2022-0122]

Entry-Level Driver Training: Application for Exemption; State of Alaska

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of application for renewal of exemption; request for comments.

SUMMARY: FMCSA announces that it has received an application from the State of Alaska for a renewal of its exemption from the limitations imposed by the commercial driver's license (CDL) regulations on the State's ability to issue

restricted CDLs. The exemption renewal would allow the State to waive specified portions of the CDL skills test for drivers who reside and operate in 14 defined geographic areas that lack the infrastructure to allow completion of the full skills test. Drivers who receive a restricted CDL under the provisions of the current exemption would also be exempt from the Entry-Level Driver Training (ELDT) regulations. The State of Alaska currently holds an exemption for the period December 28, 2022, through December 30, 2024, and requests a five-year renewal of the exemption. FMCSA requests public comment on Alaska's request for exemption.

DATES: Comments must be received on or before July 18, 2024.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA-2022-0122 using any of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. See the Public Participation and Request for Comments section below for further information.

- **Mail:** Docket Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590-0001.

- **Hand Delivery or Courier:** West Building, Ground Floor, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

- **Fax:** (202) 493-2251.

Each submission must include the Agency name and the docket number for this notice (FMCSA-2022-0122). Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL-14 FDMS, which can be reviewed at

<https://www.transportation.gov/privacy>. The comments are posted without edit and are searchable by the name of the submitter.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver, and Vehicle Safety Standards; (202) 366–2722; richard.clemente@dot.gov. If you have questions on viewing or submitting material to the docket, contact Dockets Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2022–0122), indicate the specific section of this document to which the comment applies, and provide a reason for your suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number, “FMCSA–2022–0122” in the “Keyword” box, and click “Search.” When the new screen appears, click on the “Comment” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the

information relevant to the application, including safety analyses submitted by the applicant. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulatory Requirements

Under 49 CFR 383.3(e), Alaska may waive certain knowledge and skills tests requirements and issue restricted CDLs. These restricted CDLs are valid only within the State and are subject to certain conditions. To be eligible for a restricted CDL, drivers must operate exclusively over roads that are not connected to the State highway system and are not connected to any highway or vehicular way with an average daily traffic volume greater than 499 (49 CFR 383.3(e)(2)). The Federal Highway Administration, FMCSA’s predecessor agency, set the daily traffic volume limit at 499 in its grant of a request for a waiver in 1989 (54 FR 33230) and codified it in the FMCSRs in 1996 (61 FR 9546). Relatedly, the ELDT regulations set forth in 49 CFR 380, subparts F and G, establish minimum training standards for individuals applying for certain CDLs and define curriculum standards for theory and behind-the-wheel training. The ELDT curriculum in 49 CFR part 380, appendix A, section A3.1, requires Class A CDL applicants to demonstrate proficiency in proper techniques for initiating vehicle movement, executing left and right turns, changing lanes, navigating curves at speed, entry and exit on the interstate or controlled-access highway, and stopping the vehicle in a controlled manner. Under 49 CFR 380.603(a)(2), drivers issued a restricted CDL by the State of Alaska are exempt from the ELDT requirements.

Under the CDL regulations, before receiving a CDL from a State, a driver must pass a safe on-road driving test.

Requisite skills include: the ability to adjust speed to various driving conditions (49 CFR 383.113(c)(4); and the ability to choose a safe gap when driving around other vehicles (49 CFR 383.113(c)(4)).

IV. Request for Exemption Renewal

On July 6, 2022, the Agency published a notice seeking comment on Alaska’s request for an exemption from the portion of the ELDT curriculum that requires a Class A CDL applicant to demonstrate proficiency in proper techniques for initiating vehicle movement, executing left and right turns, changing lanes, navigating curves at speed, entry and exit on the interstate or controlled-access highway, and stopping the vehicle in a controlled manner (87 FR 40334). The application stated that compelling the State to comply with these requirements would “have devastating impacts on rural Alaska’s movement of produce, prescriptions, people, and other goods.” According to the application, parts of rural Alaska do not fit the requirements for the restricted CDL in 49 CFR 383.3(e), since they contain roads with an average daily traffic volume that is greater than 499.

On December 28, 2022, after analyzing the application and public comments, the Agency published its decision (87 FR 79932). FMCSA opted not to grant the exemption from the ELDT curriculum in 49 CFR part 380, appendix A, section A3.1, as requested by the State, stating that under the requested exemption drivers, who had not received the full ELDT curriculum, would be eligible for CDLs that were unrestricted and valid outside of Alaska. Instead, FMCSA granted Alaska a two-year exemption from some of the conditions required under 49 CFR 383.3(e) for the issuance of a restricted CDL. The exemption allows the State to waive the portions of the CDL skills test enumerated in 49 CFR 383.113(c)(3) and (4) for drivers who reside in one of 14 defined geographic areas. These areas lack the infrastructure to allow completion of the full skills test. Drivers who receive a restricted CDL under the provisions of the exemption under this exemption may not operate outside of the 14 defined geographic areas. Also, under 49 CFR 380.603(a)(2), these drivers are not subject to the ELDT regulations. FMCSA concluded that granting the exemption, subject to the stated terms and conditions, was likely to achieve a level of safety equivalent to, or greater than, the level of safety that would be achieved absent the exemption.

Application for Renewal of Exemption

Citing the same reasons as the initial request, the State of Alaska has applied for a renewal of the current exemption for a period of five years.

V. Applicant's Method To Ensure an Equivalent or Greater Level of Safety

The applicant states that its commitment to safety remains unchanged and adds that it is not aware of any decline in safety during the current exemption. As required of the terms and conditions, the applicant provided to FMCSA a list of drivers that were issued a CDL under this exemption. The drivers' safety records as well as the comments received to this notice will be reviewed and analyzed by the Agency. A copy of the State of Alaska's application for renewal of its exemption is available for review in the docket for this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on the State of Alaska's application for an extension of an exemption from some of the conditions required for the issuance of a restricted CDL. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024-13325 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2019-0041; Notice 2]

FCA US LLC, Denial of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition.

SUMMARY: FCA US LLC (f/k/a Chrysler Group LLC) (FCA), has determined that certain MY 2014–2019 Fiat 500 motor vehicles do not comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 138, *Tire Pressure Monitoring Systems*. FCA filed a noncompliance report dated April 11, 2019, and subsequently petitioned NHTSA on May 3, 2019, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces and explains the denial of FCA's petition.

FOR FURTHER INFORMATION CONTACT: Kamna Ralhan, Office of Vehicle Safety Compliance, NHTSA, (202) 366-7236.

SUPPLEMENTARY INFORMATION:

I. Overview

FCA has determined that certain MY 2014–2019 Fiat 500 motor vehicles do not comply with paragraph S4.2(a) of FMVSS No. 138, *Tire Pressure Monitoring Systems* (49 CFR 571.138). FCA filed a noncompliance report dated April 11, 2019, pursuant to 49 CFR 573, *Defect and Noncompliance Responsibility and Reports*, and subsequently petitioned NHTSA on May 3, 2019, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 40 U.S.C. 30118 and 49 U.S.C. 30120, *Exemption for Inconsequential Defect or Noncompliance*.

Notice of receipt of FCA's petition was published with a 30-day public comment period, on September 12, 2019, in the **Federal Register** (84 FR 48208). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. Then follow the online search instructions to locate docket number "NHTSA-2019-0041."

II. Vehicles Involved

Approximately 12,675 MY 2014–2019 Fiat 500 motor vehicles, manufactured between July 27, 2013, and February 9, 2019, are potentially involved.

III. Noncompliance

FCA explains that the noncompliance is that the subject vehicles are equipped with incorrectly programmed tire pressure monitor system (TPMS) sensors that do not meet the minimum activation pressure requirements of paragraph S4.2(a) of FMVSS No. 138. Specifically, the TPMS sensors may not

illuminate the low tire pressure warning telltale until the inflation pressure is one to two pounds per square inch (PSI) below the minimum allowable activation pressure.

IV. Rule Requirements

Paragraph S4.2(a) of FMVSS No. 138 provides the requirements relevant to this petition. The TPMS must illuminate a low tire pressure warning telltale not more than 20 minutes after the inflation pressure in one or more of the vehicle's tires, up to a total of four tires, is equal to or less than either the pressure 25 percent below the vehicle manufacturer's recommended cold inflation pressure, or the pressure specified in the 3rd column of Table 1 of FMVSS No. 138 for the corresponding sort of tire, whichever is higher.

V. Summary of FCA's Petition

The following views and arguments presented in this section, "V. Summary of FCA's petition," are the views and arguments provided by FCA and do not reflect the views of the Agency. FCA describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

FCA states that the subject vehicles comply with FMVSS No. 110 which requires that the vehicle maximum load on the tire not be greater than the applicable maximum load rating as marked on the sidewall of the tire. In addition, FCA states that the vehicles are equipped with tires that meet FMVSS No. 139 requirements which include performance testing for low tire inflation pressure. In accordance with this performance testing, a tire is loaded to its maximum tire load capacity and is then inflated to 140 kPa, (20 PSI). While inflated to 20 PSI, the tire is loaded to 100 percent of the tire's maximum load carrying capacity and run on a test axle for 1.5 hours.

FCA explains that the subject vehicles are noncompliant because the low tire pressure warning telltale illuminates when the pressure decreases to 28–27 PSI but is required to illuminate when the pressure decreases to 28.5 PSI. FCA states that 28–27 PSI is more than the 20 PSI required in FMVSS No. 139 testing. Therefore, according to FCA, a driver of the subject vehicle would have "sufficient time to check and inflate tires well before the tires would be susceptible to appreciable damage."

FCA adds that it is not aware of any crashes, injuries, or customer complaints associated with the condition. FCA says that NHTSA has granted a prior inconsequentiality petition that involved a similar

noncompliance. Finally, FCA notes that the subject noncompliance is being corrected in the affected vehicles that have not yet been sold.

FCA concludes by stating its belief that the subject noncompliance is inconsequential as it relates to motor vehicle safety and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

FCA's complete petition and all supporting documents are available by logging onto the Federal Docket Management System (FDMS) website at <https://www.regulations.gov/>. and following the online search instructions to locate the docket number listed in the title of this notice.

VI. NHTSA's Analysis

The burden of establishing the inconsequentiality of a failure to comply with a *performance requirement* in an FMVSS is substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.¹

In determining inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.² In general, NHTSA does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety issue, nor does it mean that there will not be safety issues in the future.³ Further, because each

inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety. Moreover, while we believe that consistency is a laudable goal, safety remains the paramount concern and the agency's view of the weight of different factors may change.

NHTSA has evaluated the merits of FCA's petition and has decided to deny the petition. FCA explains that the noncompliance is that the subject vehicles' TPMS may not illuminate the warning telltale as required by FMVSS No. 138 paragraph S4.2(a) until the inflation pressure is one to two psi below the minimum activation pressure requirement. In support of its petition, FCA cited a previously submitted inconsequential noncompliance petition submitted by the American Honda Motor Company (77 FR 43145, July 23, 2012). In the case of the American Honda Motor Company petition, the TPMS warning similarly did not activate until approximately 1 to 2 psi below FMVSS No. 138's required threshold of activation at 25% below the manufacturer's recommended cold inflation tire pressure.

NHTSA granted Honda's petition based on the fact that even at the lower TPMS threshold, adequate load capacity remained for the tires on the subject vehicles. The subject vehicles were equipped at the dealership with the manufacturer's accessory tires (215/40RZ18 85Y) and wheels without adjusting the TPMS inflation warning threshold at the correct pressure to accommodate these tires. The TPMS warning threshold remained set to the standard equipped tires (215/45RZ17 84W) for the subject vehicles at a pressure of not less than 175 kPa (25 PSI). The recommended tire inflation pressure of the standard tires was 230 kPa (33 PSI) which would require, in accordance with S4.2(a), the minimum allowable TPMS activation threshold to be set at 190 kPa (27 PSI). The minimum allowable TPMS threshold for the 18-inch accessory wheels should have been 190 kPa (27 PSI), based on the recommended pressure of 250 kPa (36 PSI) as indicated on the replacement tire pressure placard.

NHTSA concluded that, as relates to FMVSS No. 110, the optional 18-inch diameter tires had adequate load carrying capacity for the gross axle weight ratings (GAWR) assigned to any of the subject vehicles equipped with

the dealer-installed tires. The load carrying capacity of the of the accessory tires was 500 kilograms (1,100 lbs) at 230 kPa (33 PSI) while the GAWR for each front tire was 477 kilograms (1,050 lbs) and each rear tire was 425 kilograms (938 lbs). The accessory tires were also found to have a higher load carrying capacity than the standard tires at 180 kPa (26 PSI) which was 435 kilograms (959 lbs) compared to 425 kilograms (937 lbs) for the standard tires.

In comparison, NHTSA disagrees that the lower TPMS activation pressure of the FCA subject vehicles will provide comparable safety protection given that the reduced pressure lowers the load carrying capacity of the same standard equipped tires. According to the Japan Automobile Tyre Manufacturers Association (JATMA) method, as recognized by NHTSA in FMVSS No. 110, the load carrying capacity of the standard tires of the 2014–2019 Fiat 500 (195/45R16 80W) at 195kPa (28.3 PSI) would be appropriately 400 lbs. compared to 388 lbs. at 186kPa (27 PSI). This represents a reduction of 3-percent in the load carrying capacity of the tires.

The agency has reconsidered the purpose and requirements of FMVSS Nos 110, 138 and 139 as it relates to inconsequentiality to safety. FMVSS No. 139 assesses the performance of a tire under severe conditions for a short period of time. While in comparison, FMVSS No. 138's stated purpose is: "This standard specifies performance requirements for tire pressure monitoring systems (TPMSs) to warn drivers of significant under-inflation of tires and the resulting safety problems." Although FMVSS No. 139 establishes minimum performance requirements for tires and addresses tire failures that may occur in the course of the specified test, the conditions present in that testing are necessarily narrower than those that may be present in long term consumer use. Further, as a vehicle standard, FMVSS No. 138 dictates that the vehicle present a warning to drivers when the degree of under-inflation present is severe enough lead to other unsafe operating conditions such as a loss of vehicle maneuverability and increased tread wear leading to the possibility of crashes. Decreased tire pressure causes the sidewalls of the tire to flex more especially while turning causing reduced steering response timing and significantly impacts the vehicle's maneuverability during cornering. Tire sidewalls contacting the road can also lead to premature and uneven tire tread wear and possible damage to the tire. Lower tire pressure can also increase braking stopping distances and

¹ Cf. *Gen. Motors Corporation; Ruling on Petition for Determination of Inconsequential Noncompliance*, 69 FR 19897, 19899 (Apr. 14, 2004) (citing prior cases where noncompliance was expected to be imperceptible, or nearly so, to vehicle occupants or approaching drivers).

² See *Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance*, 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

³ See *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance*, 81 FR 21663, 21666 (Apr. 12, 2016); see also *United States v. Gen. Motors Corp.*, 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it "results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future").

increases the likelihood of hydroplaning while driving in wet conditions as well as increased tire tread wear which can lead to more frequent tire maintenance, repairs, and replacements.

NHTSA's Decision

In consideration of the foregoing, NHTSA has decided that FCA has not met its burden of persuasion that the subject FMVSS No. 138 noncompliance is inconsequential to motor vehicle safety. Accordingly, FCA's petition is hereby denied and FCA is consequently obligated to provide notification of and free remedy for that noncompliance under 49 U.S.C. 30118 and 30120.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8)

Eileen Sullivan,

Associate Administrator for Enforcement.

[FR Doc. 2024-13337 Filed 6-17-24; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0266]

Agency Information Collection Activity: Application for Reimbursement of Headstone or Marker Expense

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each reinstatement of a previously approved collection, and allow 60 days for public comment in response to the notice.

DATES: Comments must be received on or before August 19, 2024.

ADDRESSES: Comments must be submitted through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy Kessinger, 202-632-8924, nancy.kessinger@va.gov.

VA PRA information: Maribel Aponte, 202-461-8900, vacopaperworkreduact@va.gov.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must

obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Application for Reimbursement of Headstone or Marker Expense, VA Form 21P-8834.

OMB Control Number: 2900-0266
<https://www.reginfo.gov/public/do/PRASearch> (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Reinstatement of a Previously Approved Collection.

Abstract: VA Form 21P-8834 is used to gather the necessary information to determine eligibility for reimbursement of expenses for a non-government headstone or marker upon the death of a Veteran under the authority of 38 U.S.C chapter 2306.

Affected Public: Individuals and households.

Estimated Annual Burden: 167 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 1,000.

Authority: 44 U.S.C. 3501 *et seq.*

Dorothy Glasgow,

VA PRA Clearance Officer, (Alt.) Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024-13375 Filed 6-17-24; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0034]

Agency Information Collection Activity: Trainee Request for Leave (Chapter 31, Veteran Readiness and Employment)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Comments must be received on or before August 19, 2024.

ADDRESSES: Comments must be submitted through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy Kessinger, 202-632-8924, nancy.kessinger@va.gov.

VA PRA information: Maribel Aponte, 202-461-8900, vacopaperworkreduact@va.gov.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: VA Form 28-1905h, Trainee Request for Leave (Chapter 31, Veteran Readiness and Employment).

OMB Control Number: 2900–0034.
<https://www.reginfo.gov/public/do/PRASearch> (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Revision of a currently approved collection.

Abstract: Both the Department of Veterans Affairs staff from Veteran Readiness and Employment (VR&E) Division, VR&E program participant, and trainer or authorized school official completes the VA Form 28–1905h, Trainee Request for Leave (Chapter 31, Veteran Readiness and Employment). VA Form 28–1905h serves as the only document for requesting leave and for

providing the information necessary to determine whether to approve the leave request. A trainer or authorized school official must verify on the form the effect the absence will have on the program participant's progress in the training program. The case manager (normally a Vocational Rehabilitation Counselor) assigned to the program participant's case overseeing the training program approves or denies the leave request. Upon approval, the program participant can receive subsistence allowance and other program services during the leave period as if he or she were continuing to attend training under Title 38 (CFR) § 21.270.

Affected Public: Individuals and households.

Estimated Annual Burden: 9,750 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Once, on occasion.

Estimated Number of Respondents: 39,000.

Authority: 44 U.S.C. 3501 *et seq.*

Dorothy Glasgow,

VA PRA Clearance Officer, (Alt.) Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–13327 Filed 6–17–24; 8:45 am]

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Part II

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 216

Regulations Governing the Taking of Marine Mammals; Final Rule

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 216**

[Docket No. 240604–0152]

RIN 0648–BI58

Regulations Governing the Taking of Marine Mammals

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

ACTION: Final rule.

SUMMARY: Following formal rulemaking proceedings including an on-the-record hearing before an administrative law judge, NMFS is waiving the Marine Mammal Protection Act (MMPA) moratorium on taking Eastern North Pacific (ENP) gray whales (*Eschrichtius robustus*) to allow the Makah Indian Tribe to conduct a limited ceremonial and subsistence hunt of up to 25 ENP gray whales over a 10-year period in accordance with the Treaty of Neah Bay of 1855 and the quota first established by the International Whaling Commission in 1997. NMFS is also promulgating regulations to govern the issuance of hunt permits and the hunt itself.

DATES:

Effective date: This rule is effective June 18, 2024.

Waiver period: The 10-year waiver period begins the first day of the first season after issuance of the initial hunt permit.

Expiration date: These regulations will expire 10 years after the effective date of the initial hunt permit specified under § 216.113(b), unless extended.

ADDRESSES: Copies of the Final Environmental Impacts Statement (FEIS) including the Record of Decision as well as supporting documents are accessible via the internet on the Makah Tribal Whale Hunt Chronology web page at: <https://www.fisheries.noaa.gov/west-coast/marine-mammal-protection/makah-tribal-whale-hunt-chronology> or you may request copies by email from ellen.keane@noaa.gov.

FOR FURTHER INFORMATION CONTACT:

Ellen Keane, 978–282–8476.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. List of Acronyms
- II. Introduction
- III. Background and History of Proceedings
- IV. Overview of the Tribunal's Recommended Decision

- V. Responses to Comments
- VI. Measures in the Final Regulations
- VII. Changes to Final Regulations
- VIII. Application of the Statutory Criteria to the Final Waiver and Regulations
- IX. Scientific Information and Analysis Developed After the Recommended Decision
- X. Required Statements Related to Final Regulations
- XI. Classifications

I. List of Acronyms and Abbreviations

- Agency National Marine Fisheries Service
- ALJ Administrative Law Judge
- APA Administrative Procedure Act
- AS-IA Assistant Secretary—Indian Affairs, Department of the Interior
- AWI Animal Welfare Institute
- CFR Code of Federal Regulations
- COSEWIC Committee on the Status of Endangered Wildlife in Canada
- CZMA Coastal Zone Management Act
- DEIS Draft Environmental Impact Statement
- DPS Distinct Population Segment
- E.O. Executive Order
- Ecology State of Washington Department of Ecology
- EIS Environmental Impact Statement
- ENP Eastern North Pacific
- ESA Endangered Species Act
- FEIS Final Environmental Impact Statement
- FR Federal Register
- FWS U.S. Fish and Wildlife Service
- GAMMS Guidelines for Assessing Marine Mammal Stocks
- I Assistant Administrator for Fisheries
- ITA Incidental Take Authorization, which include incidental harassment authorizations and letters of authorization
- IWC International Whaling Commission
- LSIESP Laguna San Ignacio Ecosystem Science Program
- MMC Marine Mammal Commission
- MMPA Marine Mammal Protection Act
- MNPL Maximum Net Productivity Level
- MUA Makah Usual and Accustomed Fishing Grounds
- NCA–NBC Northern California through Northern Vancouver/British Columbia
- NEPA National Environmental Policy Act
- NFG Northern Feeding Group
- NMFS National Marine Fisheries Service
- NOAA National Oceanic and Atmospheric Administration
- OR–SVI Southern Oregon through Southern Vancouver Island
- OSP Optimum Sustainable Population
- PBR Potential Biological Removal
- PCFG Pacific Coast Feeding Group
- PCPW Peninsula Citizens for the Protection of Whales
- PSRG Pacific Scientific Review Group
- RD Recommended Decision from the Tribunal
- ROD Record of Decision
- RFA Regulatory Flexibility Act
- SARs Stock Assessment Reports
- SDEIS Supplemental Draft Impact Statement
- SRT Status Review Team
- Tab Tab number in the hearing record
- U&A Usual and Accustomed Fishing Grounds
- U.S.C. United States Code

- UME Unusual Mortality Event
- WCA Whaling Convention Act
- WCZMP Washington State's Coastal Zone Management Program
- WCR NMFS's West Coast Regional Office
- WFG Western Feeding Group
- WNP Western North Pacific

II. Introduction

On February 14, 2005, NMFS received a request from the Makah Indian Tribe of Neah Bay, Washington (Makah Tribe, Makah, or Tribe), to waive the moratorium in the MMPA on taking marine mammals and issue regulations allowing a Tribal hunt for ENP gray whales (*Eschrichtius robustus*) in waters of the northwest coast of Washington State. The Tribe has also requested that NMFS authorize the making and sale of handicraft items from whales taken during Tribal whaling.

In 1994, ENP gray whales were removed from the “endangered” species list under the ESA because the population successfully rebounded after the end of the commercial whaling era. ENP gray whales remain protected by the MMPA. The MMPA imposes a general moratorium on the taking of marine mammals but authorizes the Secretary of Commerce to waive the moratorium and issue regulations governing the take of marine mammals if certain statutory criteria are met. The decision to waive the moratorium and issue regulations is made on the record after an opportunity for an agency hearing on the proposed waiver and regulations. The Secretary has delegated the responsibility to determine whether the waiver application meets the MMPA's standards to the NOAA Administrator who then delegated this authority to the Assistant Administrator for Fisheries. As the Assistant Administrator for Fisheries, I am responsible for rendering the Final Decision in this matter. For the reasons set forth in this Final Decision, I have determined that the MMPA waiver should be granted and implementing regulations should be adopted to manage the hunt. The waiver and regulations I adopt in this document establish a framework for the Makah Tribe to exercise their treaty right to whale in accordance with the MMPA, but additional steps are necessary under the MMPA and the WCA before hunting resumes.

The waiver and accompanying final regulations (see section VI of this Final Decision) authorize a limited hunt for ENP gray whales over a 10-year period, during which no more than 25 ENP gray whales could be killed, in the coastal portion of the Makah's U&A. ENP gray whales will be harvested from the quota

already established by the IWC for the Makah and Chukotkan Natives. The IWC first adopted the joint request of the United States and the Russian Federation for an ENP gray whale catch limit in 1997. RD at 9. The Chukotkan are indigenous to the Russian Federation and harvested an average of 125 ENP gray whales from the Bering Sea per year from 2008–2017, when the average number that could be taken each year while remaining below the IWC catch limit was 124. Tab 60F at 6. In September 2018, the IWC approved the latest catch limit of 980 ENP gray whales, with an annual cap of 140 whales, for the Makah and Chukotka for the period 2019–2025. Tab 3 at 5.

A separate bilateral agreement between the United States and Russian Federation sets overall and annual limits for the two countries. Tab 3E through 3I. The Makah Tribe are entitled to harvest no more than 5 whales per year under the agreement with the Russian Federation which also specifies that any country's unused quota may be transferred to the other. RD at 9. In past years, the United States transferred its entire quota to Russian Federation for the Chukotkan hunt while NMFS completed the necessary steps under domestic law to consider the Tribe's request for a waiver from the MMPA. Tab 3 at 5–6. This practice will likely continue if the Makah are unable to hunt. Under these circumstances, the entire quota authorized by the IWC could be harvested by Chukotkan Natives regardless of whether the Makah Tribe conducts a hunt. While the number of whales the Chukotkan Natives take each year varies due to hunt management practices and their ability to successfully strike whales in a given year, they have exceeded the quota in some years. RD at 128. In addition, the level of take by the Makah Tribe is small relative to the abundance of ENP gray whales (see section VIII). Thus, the hunt authorized under the waiver and final regulations will likely have no effect on the overall population of ENP gray whales. By issuing this waiver, the Makah Tribe will be able to use their allotment for ENP gray whales, which has in past years been transferred to the Russian Federation.

Although the overall population of ENP gray whales is unlikely to be affected by the final waiver and regulations, additional management measures are necessary to protect the ENP gray whales' subpopulation known as the PCFG. Additional measures are also necessary to protect the separate WNP stock of gray whales, which is listed as endangered under the ESA. Accordingly, two key management goals

shaped many of the provisions in the proposed and final regulations: (1) ensuring that hunting does not reduce the PCFG abundance below recent stable levels and (2) limiting the likelihood that Tribal hunters would strike or otherwise harm a WNP gray whale.

Regarding the first management goal, the MMPA requires that I give due regard to, among other things, the distribution and abundance of the stock subject to the waiver and that the waiver is in accord with the purposes and policies of the MMPA, which include maintaining marine mammals as a functioning element of their ecosystem. 16 U.S.C. 1371(a)(3)(A). PCFG whales exhibit site fidelity during the feeding season to a unique area within the range of the ENP gray whale stock—the northern California current ecosystem, which is generally described as extending from Northern California to Vancouver Island and encompasses the hunt area. Tab 3 at 8–9, 29. The final regulations are designed to limit lethal and sub-lethal effects to PCFG whales to maintain their abundance and distribution within the PCFG range.

Regarding the second management goal, in adopting regulations to implement a waiver, I considered all factors that may affect the allowable level of take of ENP gray whales, which includes the extent to which hunting activities for ENP gray whales may inadvertently impact WNP gray whales. While uncommon, there are documented occurrences of WNP gray whales transiting the Makah U&A, and hunters may not be able to visually distinguish WNP whales from ENP whales during a hunt. The regulations are designed to minimize the risk of a WNP whale being struck or harmed over the duration of the waiver.

III. Background and History of the Proceeding

The Makah Tribe's whaling tradition is older than the United States by well over 1,000 years. RD at 7; Tab 24 at 46. The hunt and associated practices define who the Makah are, and harvesting a whale cannot be separated from the cultural aspects. Tab 24 at 78; Tab 103 at 5–37. Makah accounts and stories illustrate how whaling shaped their culture and identity. Tab 24 at 78. The traditions have important ceremonial and social functions for the Tribal community. Crew members undergo rigorous ceremonial and spiritual preparations prior to a hunt, and the community at large plays an important role in the hunt's success. Tab 103 at 5–37. Training encompasses a series of ceremonies to become

spiritually, emotionally, and physically ready and involve the whalers' families and community. Tab 103 at 8–9. These traditions have an important role in maintaining cultural identity and uniting the community. Tab 26 at 3–4.

The Treaty of Neah Bay of 1855 secures the Makah's whaling tradition. In the Treaty, the Makah relinquished significant land holdings to the United States but expressly reserved the right to whale. Section 4 of the Treaty specifically provides: "The right of taking fish and of whaling or sealing at usual and accustomed grounds and stations is further secured to said Indians in common with all citizens of the United States. . . ."

After signing the Treaty of Neah Bay, the Makah Tribe continued to hunt whales, but over time, they saw their whaling returns dwindle due to overhunting by non-native commercial whalers. Tab 90F–Appendix A at 8; Tab 24 at 191. As early as the 1850s, it was harder for the Makah Tribe to find whales. Tab 24 at 190. In 1928, the Makah Tribe voluntarily suspended their whaling activities. *Id.* at 191. Factors contributing to this decision included demographics (e.g., moving into other fields due to restricted access to fisheries), loss of whaling canoes and equipment due to a natural disaster, and, perhaps the most important factor, dwindling cetacean populations due to commercial whaling. *Id.* at 191–193. The Makah Tribe's decision to suspend whaling until whale numbers began to climb was chosen as a temporary conservation measure to allow whale populations to rebound. *Id.* at 193. The Makah took this conservation measure nearly 20 years before the United States and other governments signed the Regulation of Whaling in 1946, which established an international moratorium on the hunting of gray whales and right whales. Tab 1F at 44.

The MMPA, enacted in 1972, established a national policy to prevent marine mammal species and population stocks from declining beyond the point at which they cease to be a significant functioning element in the ecosystem of which they are a part and enacted a moratorium on the taking and importing of marine mammals. 16 U.S.C. 1361(2), (6); 1371(a). "Take" is defined broadly and means to "harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal." 16 U.S.C. 1362(13).

The moratorium contains several exceptions. One exception authorizes the agencies that implement the MMPA to waive the moratorium as appropriate and adopt implementing regulations

governing the take of marine mammals. 16 U.S.C. 1371(a)(3)(A); 1373. Both the decision to waive the moratorium and adopt implementing regulations must be based on “the best scientific evidence available,” and NMFS must consult with the MMC in making these decisions. *Id.* In order to waive the moratorium for a stock of marine mammals, NMFS is required to give due regard to the distribution, abundance, breeding habits, and times and lines of migratory movements of such marine mammals. 16 U.S.C. 1371(a)(3)(A). NMFS must also be assured that the taking under the waiver is in accord with sound principles of resource protection and conservation as provided in the purposes and policies of the MMPA. *Id.* The purposes and policies of the MMPA include maintaining marine mammals as a significant functioning element of the ecosystem of which they are a part, maintaining the health and stability of the marine ecosystem, and obtaining and maintaining OSP for marine mammal stocks keeping in mind the carrying capacity of the habitat. 16 U.S.C. 1361(2), (6).

When prescribing regulations to implement a waiver, NMFS must insure the taking will be consistent with the purposes and policies of the MMPA and will not disadvantage the stock subject to take pursuant to the waiver. 16 U.S.C. 1373(a). NMFS must also fully consider all factors that may affect the extent of the authorized take, including existing and future levels of marine mammal species and population stocks; existing international treaty and agreement obligations of the United States; the marine ecosystem and related environmental considerations; the conservation, development, and utilization of fishery resources; and the economic and technological feasibility of implementation. 16 U.S.C. 1373(b).

In *Anderson v. Evans*, 371 F.3d 475, 501–02 (9th Cir. 2004), the U.S. Court of Appeals for the Ninth Circuit held that the Makah Tribe and NMFS must comply with the MMPA’s waiver process in order for the Tribe to exercise their right to whale pursuant to the Treaty of Neah Bay of 1855. The Court also held that NMFS must complete an EIS under the NEPA before authorizing a hunt. *Id.* at 494. In light of the decision in *Anderson*, in 2005 the Makah Tribe asked NMFS to waive the MMPA’s moratorium and authorize a limited ceremonial and subsistence hunt for ENP gray whales.

In 2015, the NMFS WCR published a DEIS analyzing several alternatives for the proposed hunt. On April 5, 2019, the WCR published a proposed waiver and regulations for a hunt (84 FR 13604)

in accordance with a delegation from the Assistant Administrator for Fisheries. The publication of the proposed regulations and waiver initiated a formal rulemaking process, which included a hearing before a tribunal overseen by an ALJ. The tribunal was responsible for issuing a recommended decision for the Assistant Administrator for Fisheries who is responsible for rendering a final decision.

The waiver and regulations proposed by the WCR would allow limited ceremonial and subsistence hunting for ENP gray whales over a 10-year period in the coastal portion of the Makah’s U&A. This area comprises approximately 1 percent of the lineal distance of the migratory range of ENP gray whales, which runs along the Pacific Coast of North America and encompasses feeding grounds in the Bering Sea, calving grounds in the Gulf of California, and a coastal migratory route between these areas. RD at 83, 91. During the 10-year waiver period, no more than 25 ENP gray whales could be killed, with an average annual mortality limit of 2.5 animals. The current population of ENP gray whales is 19,260 (Eguchi *et al.* 2024), but when the proposed regulations were issued the population was much higher at approximately 27,000 animals. RD at 95.

The proposed regulations included measures to protect endangered WNP gray whales and ensure that hunting does not reduce the abundance of the PCFG below recent stable levels. While uncommon, there are documented occurrences of endangered WNP whales transiting the U&A during the migratory season (December–May), creating a risk that a WNP gray whale could be inadvertently harmed in a hunt during the migratory season. RD at 110–111. The population of WNP gray whales is 290 animals (excluding calves). RD at 117; Tab 81L at 168.

Most ENP gray whales migrate north to the Bering Sea to feed during the summer and fall; however, a subgroup of ENP gray whales, known as the PCFG, do not make this full migration each year, stopping instead to feed in the waters off the Pacific Northwest. RD at 84–85. The IWC and NMFS consider whales to belong to the PCFG if they are photo-identified within the region between northern California and northern Vancouver Island (from 41° N latitude to 52° N latitude) during the summer feeding period of June 1 to November 30, in two or more years. *Id.* at 60–61. PCFG gray whales are part of the ENP stock but exhibit site fidelity to the northern California current ecosystem during the feeding season

(June–November). The PCFG abundance estimate was 243 animals at the time of the proposed regulations and 232 at the time of the hearing. *Id.* at 96. The PCFG is currently estimated at 212 animals and has been relatively stable over the last 20 years (Harris *et al.* 2022).

The proposed regulations included measures to protect PCFG and WNP gray whales, including alternating hunt seasons, ENP strike limits, PCFG strike limits, landing limits, and a PCFG abundance trigger. As proposed, the hunting would be divided between two alternating seasons. Winter/spring hunts (December 1 through May 31) would occur during the migration season to reduce risk to PCFG whales during their feeding season. Summer/fall hunts (July 1 through October 31) would occur during the feeding season to reduce risk to WNP whales, which only occur in the U&A during the migration season. Additional details on the proposed waiver and regulations and the rationale for the proposal may be found in the **Federal Register** notice for the proposed waiver and regulations (84 FR 13604, April 5, 2019).

Since waiving the moratorium and adopting implementing regulations requires formal rulemaking, NMFS held a 6-day hearing in November 2019. A United States Coast Guard ALJ presided over the tribunal. Six specific parties actively participated in the hearing: MMC, PCPW, AWI, Sea Shepherd Legal representing Sea Shepherd Conservation Society, the Makah Tribe, and the WCR. Each party was given the opportunity to present testimonial and documentary evidence and cross-examine the 17 witnesses who testified.

Before the hearing, NMFS, in consultation with the MMPA-mandated Working Group on Marine Mammal Unusual Mortality Events (Working Group), declared a UME for ENP gray whales on May 29, 2019, after several ENP gray whales died within a close time frame along the West Coast of North America from Mexico to Alaska. Tab 53F at 5–6. A UME is defined under the MMPA as “a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response.” 16 U.S.C. 1421h(9). The UME received considerable attention at the hearing and in the parties’ filings for the formal rulemaking. The UME continued for several years, with peak strandings occurring between December 17, 2018, and December 31, 2020, and was declared over as of November 2023.

Following the hearing, the public had the opportunity to submit comments to the ALJ, and the parties were entitled to submit post-hearing briefs and proposed

findings of fact and conclusions of law. During the public comment period following the hearing, NMFS announced its intention to prepare an SDEIS to satisfy NMFS's obligations under NEPA. The **Federal Register** notice announcing the planned SDEIS stated: "Because information concerning the ongoing 2019 UME was presented at the agency hearing but not expressly addressed in the 2015 DEIS, NMFS has determined that it would now benefit both the public and agency decision making to prepare a supplement to the DEIS." 85 FR 11347, February 27, 2020. On March 3, 2020, three of the parties to the formal rulemaking (AWI, Sea Shepherd Legal, and PCPW) jointly submitted a Motion to Stay the Waiver Proceeding. Tab 108. They argued that the SDEIS would include new information on the UME and the proceedings should be stayed to allow this information to be addressed in a recommended decision. The tribunal denied the motion, finding there was sufficient evidence in the record to determine whether the UME for ENP gray whales should preclude issuance of a waiver. The tribunal also determined that the arguments of harm to the moving parties were either speculative or premature and that further delay associated with the moving parties' proposed stay would prejudice the Makah. Tab 118 at 7–8.

On September 23, 2021, the tribunal issued a Recommended Decision (see Tab 121) and concluded "the best scientific evidence available supports a waiver of the MMPA's moratorium of the take of marine mammals to allow the Makah Tribe to engage in a limited hunt for ENP gray whales." RD at 155. The tribunal recommended that I grant the waiver with some changes to the proposed regulations. These recommendations included reorganizing the regulations for clarity, setting a low abundance threshold for ENP gray whales that would stop the hunt, expressly requiring the Makah to obtain authorization under other provisions of the MMPA for the take of WNP gray whales, and prohibiting approaches on calves and mother-calf pairs.

As required by MMPA regulations, NMFS published a notification in the **Federal Register** on September 29, 2021, announcing a 20-day public comment period on the Recommended Decision (86 FR 53949), which was extended until November 13, 2021. 86 FR 57639, October 18, 2021. Following the close of the comment period on the Recommended Decision, NMFS completed actions related to the Tribe's waiver request pursuant to NEPA, the CZMA, and the ESA. On July 1, 2022,

EPA announced the availability of the SDEIS (87 FR 39517) and, on July 5, 2022, NMFS announced a 45-day comment period (87 FR 39804), which was extended until October 14, 2022 (87 FR 50319, August 16, 2022), and then reopened from October 28, 2022, through November 3, 2022 (87 FR 64454, October 25, 2022). Pursuant to section 307(c)(3) of the CZMA, on June 2, 2023, the State of Washington Department of Ecology concurred with NMFS's determination that the hunt described in the Recommended Decision was consistent with the enforceable policies in Washington's Coastal Zone Management Plan. On March 15, 2023, NMFS concluded inter-agency consultation under section 7 of the ESA for species under the jurisdiction of the FWS when FWS issued a Letter of Concurrence to NMFS. On November 8, 2023, NMFS concluded intra-agency consultation under section 7 of the ESA for species under the jurisdiction of NMFS by issuing a Letter of Concurrence. A few days later, on November 17, 2023, NMFS released a FEIS under NEPA.

After making the Letters of Concurrence and FEIS publicly available, I solicited additional comments from the parties on November 27, 2023, so they would have an opportunity to address additional scientific analyses on the gray whale population that became available after the comment period on the SDEIS concluded in late 2022. This comment period also provided the parties with an opportunity to explain whether any other procedures should be implemented before this Final Decision. The parties' opportunity to comment ended on December 20, 2023, but was followed by an additional opportunity to respond to each other's comments. The response period closed on January 17, 2024. NMFS then developed this Final Decision, which will provide an overview of the tribunal's Recommended Decision followed by responses to comments, a summary of the final regulations, changes to the final regulations from the tribunal's recommendations, application of the statutory criteria, review of additional scientific information, required statements under the MMPA, ultimate findings and conclusions, and classifications.

IV. Overview of the Tribunal's Recommended Decision

Following is an overview of the Recommended Decision's key findings, analyses, and recommendations, which were issued on September 23, 2021. (<https://www.fisheries.noaa.gov/s3/>

2021-09/recommended-decision-19nmfs0001.pdf) The first three sections of the tribunal's Recommended Decision provided an introduction and overview of the proceeding. Sections I and II described the proceeding, background information, and procedural history. Section III provided a summary of the findings in the Recommended Decision. Section IV described the substantive requirements of the MMPA and then analyzed several threshold issues, including the scientific evidence in the record, consultation with the MMC, and gray whale stock structure.

Section IV.B of the Recommended Decision described "the best scientific evidence available" standard, which governs the statutory analyses NMFS must conduct under sections 101(a)(3)(A) and 103(a) of the MMPA. The Recommended Decision highlighted several touchstones of the standard. First, NMFS cannot disregard "scientifically superior evidence" that does not support its position. RD at 31. Second, "a scientific inference or assertion" must be "derived by the scientific method" and "based on scientifically valid principles" but need not be proven with "absolute certainty." *Id.* Third, "agencies are only required to evaluate existing data and need not speculate on whether their conclusions would change if new or different evidence was adduced." *Id.* Indeed, as the tribunal explained, if "agencies were required to continually develop new data to supplement the information presented in a proceeding, there would be no end to the decision-making process." *Id.*

Section IV.B also evaluated the credibility of the scientific experts who testified at the hearing. The tribunal found NMFS's gray whale experts to be credible witnesses and gave their testimony "great weight" and a "great deal of weight." RD 35–38. The Makah's marine mammal biologist also testified in support of the waiver, and the tribunal accorded his testimony "substantial weight," noting that he conducts "independent, peer-reviewed research" and "his testimony relies on a broad range of sources, including those whose findings he disagrees with." *Id.* at 41–42. Conversely, the tribunal found that AWI's only witness was a less credible witness, explaining that his "opinions are based solely on literature reviews, as he does not conduct any independent research or produce scientific publications, and he appears to have relied heavily on a subset of the available literature that best supports AWI's position in this matter." *Id.* at 46.

After assessing the credibility of the scientific testimony offered at the hearing, the tribunal provided an overview of the studies and reports entered into evidence and the data collection methods used in gray whale research. The tribunal generally found peer-reviewed studies “more reliable scientific evidence than other studies” and that NMFS’s SARs developed in accordance with section 117 of the MMPA were “highly relevant and reliable sources of information.” RD at 48–49. The tribunal also noted that the findings of the IWC’s Scientific Committee, an international body of experts on whale biology, were “highly reliable,” and it was appropriate to give NMFS’s findings “great deference” if they were consistent with those of the IWC. *Id.* at 52.

Section IV.C of the Recommended Decision discussed consultation between the MMC and NMFS and concluded “[t]here is ample evidence in the record that NMFS sought comments from the MMC and made its determination in consultation with the MMC.” RD at 57.

Section IV.D of the Recommended Decision addressed gray whale stock structure. The tribunal began this section by addressing a dispute between the MMC and WCR regarding the extent to which the parties could challenge NMFS’s stock designations, as reflected in SARs, through the formal rulemaking proceeding. The dispute centered on the effect of section 117 of the MMPA, which provides detailed procedures for producing SARs and is the process NMFS uses to designate marine mammal stocks. WCR argued section 117 of the MMPA provides the exclusive mechanism for designating stocks, while the MMC argued SARs produced under section 117 are relevant but not determinative in a formal rulemaking proceeding considering a waiver. RD 58–59.

The tribunal determined that in order to make the required findings under the MMPA, it must make a threshold determination that NMFS’s stock structure for gray whales is “scientifically sound” and allowed the parties to challenge the stock determinations in the SARs in the formal rulemaking proceeding. RD at 59. However, if it were shown that NMFS’s stock assessments were inaccurate or outdated, the Recommended Decision concluded that the formal rulemaking proceeding is not the appropriate forum to make new stock assessments. *Id.* Rather, the proper procedure would be to deny the waiver and remand the case to NMFS to produce new SARs. *Id.* NMFS could then decide whether to

reinitiate the waiver after producing new stock assessments. *Id.*

The tribunal did not remand the case to NMFS to produce new stock assessments. The Recommended Decision concluded that the best available scientific evidence supports NMFS’s determination, as reflected in the SARs, that there are two stocks of gray whales—the ENP stock and the WNP stock—and that the PCFG is a feeding aggregation in the ENP stock. RD at 60–69. The tribunal cited uncertainty with respect to the origins of WNP gray whales but ultimately held that the best available scientific evidence supports NMFS’s conclusion that WNP gray whales “are distinct from the ENP stock as a whole,” noting the significant differences between the nuclear DNA found in ENP gray whales and WNP gray whales. *Id.* at 68–69.

Several parties argued that the PCFG gray whales should be considered a separate stock, but the tribunal disagreed. PCFG gray whales and other ENP gray whales have differences in their mitochondrial DNA, but there is no significant difference in their nuclear DNA. RD at 63–64. Both parents pass nuclear DNA to their offspring, but gray whales and other animals only inherit mitochondrial DNA from their mothers. *Id.* Some parties argued that the differences in mitochondrial DNA show demographic independence; others argued this distinction is only evidence of calves following their mothers to the feeding grounds for which the PCFG are named. *Id.* The tribunal weighed the evidence and arguments of the parties and determined that calves born to PCFG mothers support the PCFG population but external recruitment—that is, other ENP whales joining the PCFG—plays a role too. *Id.* On this point, the tribunal noted, “[w]hile the evidence on recruitment levels is not conclusive, it does convincingly show that external recruitment plays a major role in maintaining or increasing the size of the PCFG” and that this evidence “weighs strongly against demographic independence, a key assessment factor for stock status under the current stock assessment guidelines.” *Id.* at 65.

Regarding PCFG breeding, the tribunal explained “a determinative factor in making stock determinations is whether a population’s members interbreed when mature.” RD at 62. The tribunal found that the “the scientific evidence is still strong that PCFG gray whales have ample opportunity to mate with non-PCFG ENP whales, and in fact continue to do so.” *Id.* at 63. The tribunal also relied on the 2018 SAR, analysis by the IWC, and the testimony of other scientific experts in concluding

“the evidence strongly supports NMFS’s conclusion, and that of the IWC, the PCFG are a feeding aggregation and not a separate stock or management unit.” *Id.* at 65–66.

After summarizing the parties’ arguments for and against the waiver in section V of the Recommended Decision, section VI of the Recommended Decision analyzed the statutory factors set forth in section 101(a)(3)(A) of the MMPA. Section IV.A addressed the enumerated biological factors (distribution, abundance, breeding, and times and lines of migratory movements) and concluded that the proposed waiver and regulations gave due regard to these factors. Regarding distribution, the tribunal concluded: “Based on the best available scientific evidence, I find the hunt will not affect the overall distribution of the ENP gray whale stock, nor will it have a significant, lasting, or detrimental effect on the distribution of PCFG whales.” RD at 93. Regarding abundance, the tribunal concluded “at a population level, the removal of approximately 2.5 whales per year (assuming the Makah Tribe takes the full number of whales allowed) would not significantly affect the ENP stock.” *Id.* at 103. The tribunal also concluded “the best available scientific evidence is the UME should not preclude issuance of a waiver.” *Id.* However, it found “the regulations may warrant modification to further limit hunting activities during an active UME or if the stock does not rapidly recover from a UME.” *Id.* Regarding breeding, the tribunal concluded “there is no scientific evidence showing approaches or training harpoon throws would prevent whales from mating.” *Id.* at 106. Regarding migratory movements, the tribunal noted “there is no credible evidence that the whales encountered during a hunt will cease migration or change their migratory path in future years to avoid the hunt.” *Id.* at 111–112.

Section VI.B of the Recommended Decision next considered how the proposed waiver would affect the health and stability of the marine ecosystem and the functioning of marine mammals in their ecosystem. After reviewing the evidence related to ecosystem effects at various scales associated with the removal of 25 gray whales over 10 years, the Recommended Decision determined that it was “reasonable for NMFS to conclude that the health and stability of the ecosystems in which gray whales function will not be adversely affected by the proposed waiver and regulations.” RD at 116.

In section VI.C of the Recommended Decision, the tribunal conducted an

OSP analysis. OSP is defined by the MMPA as “with respect to any population stock, the number of animals which 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). Citing section 2 of the MMPA, the Recommended Decision determined that when assessing a waiver, the “MMPA requires the Secretary to consider the ability of marine mammal ‘species and population stocks’ to attain and maintain OSP, when doing so is consistent with the Act’s primary objective of preserving the health of the marine ecosystem.” RD at 116. The tribunal determined that this inquiry is not limited to the “stock subject to the waiver.” *Id.* Rather, “NMFS must show that it considered not only the ENP stock’s ability to attain and maintain its OSP, but also the WNP stock’s ability to do so.” *Id.*

The tribunal concluded that the ENP stock has attained OSP and that it is likely to maintain OSP after the hunt contemplated by the proposed waiver and regulations. *Id.* With respect to WNP gray whales, the tribunal explained:

AWI argues the near-certainty of at least one WNP whale being approached at some point during the ten-year validity period of this waiver, and the minimal chance of one being struck, prevents NMFS from issuing the waiver. I disagree. A mere approach on a WNP gray whale, which is the most likely scenario under the proposed waiver and regulations, is not expected to have any effect on the stock’s ability to attain and maintain its OSP.

RD at 120. Regarding WNP gray whales and OSP, the tribunal further explained that, “loss of a WNP whale due to a hunt-related strike would certainly have a deleterious effect on the stock due to its low abundance.” *Id.* However, it ultimately recommended that the waiver be granted, explaining that the waiver criteria in section 101(a)(3)(A) does not require NMFS to “conclusively rule out any possibility that an animal from a depleted stock could be taken.” *Id.* at 132. NMFS produced a risk analysis for gray whales (Moore and Weller 2018), which found there is “a 30% chance of an unsuccessful strike attempt on a WNP whale if all authorized attempts are made, which equates to one every 33 years” and “approximately 14 WNP whales would be approached over 10 years if all available approaches are used (essentially 100% probability).” *Id.* at 118. Moore and Weller (2019) updated this analysis “based on the

higher WNP abundance estimate in the 2018 SAR.” As described in the Recommended Decision, this was the best available science at the time of the hearing and showed a “0.5% chance of striking a WNP on any given strike” and “a probability over the entire hunt period of 7.4%.” *Id.* at 119.

The tribunal addressed the implication of *Kokechik Fishermen’s Ass’n v. Sec’y of Com.*, 839 F.2d 795 (D.C. Cir. 1988), on the proposed waiver and regulations in section IV.D of the Recommended Decision. In *Kokechik*, NMFS issued a permit to a federation of Japanese fishermen to take Dall’s porpoise incidentally while salmon fishing with gillnets. 839 F.2d at 799. The permit authorized the take of Dall’s porpoise only, even though it was foreseeable that other species of marine mammals would also be taken. *Id.* at 799–800. The court held that the permit NMFS issued “was contrary to the requirements of the MMPA in that it allowed incidental taking of various species of protected marine mammals without first ascertaining as to each such species whether or not the population of that species was at the OSP level.” *Kokechik*, 839 F.2d at 802. The tribunal concluded the holding in *Kokechik* applies to the permitting stage of the waiver process, which is not within its jurisdiction (RD at 123), and also noted that *Kokechik* is distinguishable, since it “involved a factual scenario where the killing of depleted marine mammals was ‘not merely a remote possibility but a certainty,’ and the court did not address other specific situations where a permit could possibly be issued,” such as under provisions of the MMPA addressing incidental take. RD at 122 quoting *Kokechik*, 839 F.2d at 802.

After considering the evidence in the record and the arguments of the parties, the tribunal ultimately recommended that NMFS grant the waiver, explaining:

NMFS has presented ample evidence, which the other parties have not rebutted, to show that the ENP stock of gray whales will not be disadvantaged by the issuance of a waiver here. The authorized take will not affect the ENP stock’s ability to maintain its OSP, and will not meaningfully affect its distribution, breeding, or migratory habits.

RD at 132.

The tribunal then turned to the implementing regulations in section VII of the Recommended Decision and analyzed them pursuant to section 103 of the MMPA. The tribunal’s analysis in section VII of the Recommended Decision largely focused on section 103(b) of the MMPA, which requires NMFS to fully consider “all factors which may affect the extent to which

such animals may be taken or imported” in promulgating regulations under this provision of the MMPA. The required consideration under section 103(b) includes, but is not limited to, the effect of the regulations on five enumerated factors:

- (1) Existing and future levels of marine mammal species and population stocks;
- (2) Existing international treaty and agreement obligations of the United States;
- (3) The marine ecosystem and related environmental considerations;
- (4) The conservation, development, and utilization of fishery resources; and
- (5) The economic and technological feasibility of implementation.

In consideration of the first factor, existing and future levels of marine mammals, the tribunal recommended requiring that the Makah obtain an ITA under section 101(a)(5) of the MMPA for WNP gray whales before hunting during the winter/spring season, which runs from December through May. RD at 136–137. The tribunal explained that doing so “will help assure any court that may review this rulemaking in the future that NMFS has fully considered the existing and future levels of the WNP stock and has drafted its regulations accordingly.” *Id.* at 137. The tribunal did not find it necessary to require incidental take authorizations for WNPs during the summer/fall hunting period because WNP gray whales are not expected to be present in the hunt area during that time of the year. *Id.*

The Recommended Decision concluded that NMFS satisfied its burden under the other enumerated factors in section 103(b) of the MMPA. Under the second factor, international treaty and agreement obligations, the tribunal explained that “NMFS is not proposing to exceed the agreed-upon catch limits . . . and the IWC Scientific Committee’s Standing Work Group on Aboriginal Subsistence Whaling Management Procedures evaluated the proposed hunt and determined it would meet the IWC’s conservation objectives for ENP, WNP, and PCFG Whales.” RD at 137. The tribunal determined NMFS addressed the third factor, consideration of the marine ecosystem and related environmental considerations, as explained in section VI.B of the Recommended Decision and through its analysis in the DEIS. RD at 138. Under the fourth factor, the tribunal determined there would be no impact on “the conservation, development, and utilization of fishery resources” and noted that the hunt is unlikely to affect whale-watching businesses. RD at 138–139. Finally, the tribunal concluded the hunt was economically and

technologically feasible, although there may be some technical issues associated with obtaining clear and timely photographs of gray whales for monitoring. RD at 139–140.

Having considered the five required factors, in section VII.B the tribunal turned to a motion filed by the WCR to amend the regulations, which proposed amending the definition of strike to make clear that multiple strikes on the same whale only counted as a single strike for purposes of strike limits. RD at 140. The motion also proposed allowing the Makah to share edible whale products with non-Tribal members outside of their reservation. *Id.* The tribunal granted the motion. RD at 143.

In section VII.C, the tribunal recommended several key changes to the regulations. First, it proposed some structural changes to improve the organization and clarity of the regulations. RD at 146. Second, it recommended specific changes to ensure there is no hunting or training in the winter or spring unless and until the Makah Tribe obtains an ITA. *Id.* at 147–148. Third, citing the UME that was ongoing at the time of its deliberations, the tribunal recommended that NMFS set an abundance threshold for ENP gray whales but did not recommend a specific threshold. *Id.* at 150–151. Finally, the tribunal proposed to prohibit the Makah from approaching gray whale calves or gray whale mothers with their calves. *Id.* at 154.

The tribunal rejected several other proposals advanced by the parties. AWI took issue with the provisions of the proposed regulations that separate lethal and non-lethal hunting activities and argued the term hunt should be defined as any pursuit of a whale. The tribunal rejected this suggestion because it “would likely cause confusion, as it is unclear what other terminology NMFS could use to convey the different limitations on non-lethal training activities and potentially lethal hunting activities.” RD at 146.

MMC proposed adding a PCFG “dimmer-switch” to the regulations, which would reduce PCFG strike limits gradually if PCFG abundance declines, but the tribunal determined that NMFS already had authority to make such reductions if necessary under the proposed regulations. *Id.* at 150–151. PCPW raised concerns related to hunt safety, but the tribunal determined NMFS has discretion to defer its consideration of safety issues to the permitting phase of the process. RD at 151–152.

Section VIII of the Recommended Decision ultimately concluded that the

waiver should be approved and explained:

Having considered the evidence presented at the hearing and the briefs and comments received, I find that the best scientific evidence available supports a waiver of the MMPA’s moratorium of the take of marine mammals to allow the Makah Tribe to engage in a limited hunt for ENP gray whales. The takings authorized under the waiver will have only a negligible effect on the stock and will therefore not disadvantage the stock. In developing the proposed waiver, NMFS followed the dictates of the MMPA by considering the “distribution, abundance, breeding habits, and times and lines of migratory movements of such marine mammals,” the potential effects on the ecosystem, and the ability of stocks to attain and maintain their OSP.

RD at 155. The tribunal also concluded that NMFS adequately considered “the distribution, abundance, breeding habits, and times and lines of migratory movements of WNP gray whales in making this determination, and the regulations include adequate protections for the WNP stock.” *Id.* The tribunal further held that “NMFS’s determination that PCFG whales do not constitute a separate stock is supported by best scientific evidence currently available and that NMFS included adequate protections for PCFG whales in the proposed regulations.” *Id.*

In rendering the Recommended Decision, the tribunal gave no additional weight to the Treaty of Neah Bay of 1855. The Recommended Decision stated:

The Ninth Circuit held that the Makah Tribe’s proposed hunt must comply with the MMPA, notwithstanding its treaty rights, and acknowledged the possibility that NMFS would weigh the treaty rights in deciding whether to bring a waiver proceeding. NMFS has done so. (Tab 101 at 39:9–11 (Yates) (“Absent [the Makah’s] treaty right and absent that quota from the International Whaling Commission, we would not be moving forward with a MMPA waiver for gray whales.”). The remaining issues for decision are prescribed by statute, and do not include consideration of the treaty rights.

RD at 79. The tribunal emphasized that the Treaty “has no bearing on the specific statutory and regulatory issues I am tasked with deciding here.” RD at 137.

V. Responses to Comments on the Recommended Decision

On September 29, 2021, NMFS announced a 20-day comment period on the tribunal’s Recommended Decision. 86 FR 53949. This comment period was extended on October 18, 2021, providing an additional 25 days for public review and feedback. 86 FR

57639. NMFS received 186 comments with 62 supporting and 115 opposing the granting of the waiver. The remaining comments did not express support or opposition but provided specific comments. The Makah Tribe, Northwest Indian Fisheries Commission, Tulalip Tribes, Jamestown S’Klallam Tribe, Puyallup Tribe of Indians, Squaxin Island Tribe, Lower Elwha Klallam Tribe, Suquamish Tribe, Swinomish Indian Tribal Community, Washington Indian Gaming Association, Department of Interior’s Office of the Assistant Secretary-Indian Affairs (Office of the AS-IA), NMFS WCR, MMC, MORI-ko LLC, Sierra Club, and a number of individual commenters were generally supportive of the Recommended Decision. Opponents of the tribunal’s Recommended Decision included AWI, Marine Mammal Conservation of Mexico (COMARINO), Marine Connection, PCPW, and a number of individual commenters. Below, we summarize and respond to the relevant comments. Some comments were outside the scope of this action and are not addressed here.

Comments on the Requirements of Sections 101(a)(3)(A) and 103 of the MMPA

Comment 1: The WCR disagrees with the tribunal’s determination that NMFS must show it considered the WNP stock’s ability to obtain and maintain OSP under section 101(a)(3)(A) of the MMPA.

Response: In section 101(a)(3)(A), Congress granted the Agency the authority to waive the moratorium “so as to allow taking, or importing of any marine mammal, or marine mammal product, and to adopt suitable regulations, issue permits, and make determinations in accordance with sections 102, 103, 104, and 111 permitting and governing such taking and importing, in accordance with such determinations . . .” There are two provisos in section 101(a)(3)(A) following this grant of authority. The first proviso is relevant here and states that the Agency “must be assured that the taking of such marine mammal is in accord with sound principles of resource protection and conservation as provided in the purposes and policies of this Act” in making the determinations associated with waiving the moratorium. Sections 2(2) and (6) of the MMPA include “purposes and policies” related to obtaining and maintaining OSP for all marine mammal species and population stocks. However, the first proviso in section 101(a)(3)(A) does not refer to all marine mammal species and stocks. The proviso refers to “such

marine mammal.” The requirement to be assured that taking “is in accord with sound principles of resource protection and conservation as provided in the purposes and policies of this Act” only applies to the taking of “such marine mammal” under section 101(a)(3)(A).

The term “such” means “of a kind or character to be indicated or suggested.” <https://www.merriam-webster.com/dictionary/such> (last visited March 19, 2024). The term can also mean “[t]hat or those; having just been mentioned.” Black’s Law Dictionary (11th ed. 2019). The Oxford English Dictionary further provides: “Such is a demonstrative word used to indicate the quality or quantity of a thing by reference to that of another or with respect to the effect that it produces or is capable of producing. Thus, syntactically, such may have backward or forward reference. . . .” Oxford English Dictionary Online (last visited March 21, 2024). Likewise, a dictionary published a few years after the MMPA was adopted explains that “such” includes “of a kind or character about to be indicated, suggested, or exemplified” as well as “having a quality already or just specified.” Webster’s Third New International Dictionary (3rd ed. 1976). Thus, the phrase “such marine mammal” in the first proviso in section 101(a)(3)(A) refers to marine mammals “to be indicated” or marine mammals “having just been mentioned,” not marine mammals described in other sections of the Act.

The reference to “such marine mammal” in the first proviso of section 101(a)(3)(A) refers back to NMFS’s authority to allow taking of “any marine mammal.” Under section 101(a)(3)(A), NMFS has the authority to waive the moratorium for a single stock of marine mammals, as NMFS has proposed here. When NMFS chooses to exercise that discretion, the text of section 101(a)(3)(A) limits the analysis required by the first proviso of section 101(a)(3)(A) to the marine mammal stock subject to taking under the proposed waiver. Here, that is the ENP stock, not the WNP stock.

The tribunal construed the statute differently. Citing the purposes and policies in section 2 of the MMPA, the tribunal explained:

The MMPA requires the Secretary to consider the ability of marine mammal “species and population stocks” to attain and maintain OSP, when doing so is consistent with the Act’s primary objective of preserving the health of the marine ecosystem. 16 U.S.C. 1361. This is an overarching principle and does not focus

solely on the stock that is the subject of the waiver.

RD at 116. The WCR disagreed with this interpretation and explained in their comments on the Recommended Decision:

NMFS WCR does not agree with Judge Jordan’s statutory interpretation, that NMFS must consider both the ENP stock’s and WNP stock’s abilities to attain and maintain OSP levels in deciding whether to issue a waiver for ENP gray whales under MMPA section 101(a)(3)(A). See Recommended Decision at 116 (relying on MMPA section 2, Congressional findings and declaration of policy). While we agree that an overarching policy of the MMPA is to maintain all marine mammal stocks at or above OSP levels, here, the specific requirements of section 101(a)(3)(A), which govern issuance of waivers, control. Because NMFS is not proposing to waive the MMPA take moratorium with respect to the WNP gray whale stock, NMFS was not required to undertake an analysis of potential effects on the WNP stock’s OSP levels.

I agree with the WCR. The tribunal’s interpretation deprives the phrase “such marine mammal” in the first proviso of section 101(a)(3)(A) of its normal meaning. The overriding purposes and policies of the MMPA cannot alter the text of section 101(a)(3)(A).

Furthermore, the WCR’s interpretation is consistent with the structure of the statute. Section 103(b) requires a broader evaluation of the “effect of such regulations” implementing a waiver. Section 101(a)(3)(A) uses narrower language and requires only that “the taking of such marine mammal is in accord with the sound principles of resource protection and conservation as provided in the purposes and policies” of the Act. As explained above, “such marine mammal” refers to ENP gray whales, the stock subject to taking pursuant to the waiver. In any event, for the reasons explained in section VIII (*Risk to WNP Gray Whales*), any effects of the final waiver and regulations on WNP gray whales are not expected to impact the ecosystem or the ability of WNP gray whales to obtain or maintain OSP.

Comment 2: With respect to WNP gray whales, the WCR disagrees with the tribunal’s characterization of the disadvantage test in section 103(a) of the MMPA, citing discrepancies in the Recommended Decision. For example, page 117 of the Recommended Decision states: “any take of a WNP would necessarily disadvantage the stock,” whereas page 136 of the Recommended Decision states “not all takes of depleted stocks necessarily disadvantage those stocks.” Relatedly, the Makah Tribe comments that the Recommended Decision’s assertion that the removal of

one WNP whale would disadvantage the stock is contrary to the evidence in the record.

Response: The Recommended Decision uses the term “disadvantage” when discussing WNP gray whales and depleted marine mammals, raising questions about the application of the disadvantage test in section 103(a) to the endangered WNP stock. When implementing a waiver, section 103(a) of the MMPA provides: “The Secretary . . . shall prescribe such regulations with respect to the taking and importing of animals from each species of marine mammal (including regulations on the taking and importing of individuals within population stocks)” as the Secretary “deems necessary and appropriate to insure that such taking will not be to the disadvantage of those species and population stocks and will be consistent with the purposes and policies set forth in section 2 of this Act.” The disadvantage test in section 103(a) applies to “such taking” of “those species and population stocks.” “Such taking” under section 103(a) refers to the taking described earlier in the section, which is the regulated “taking and importing of animals from each species of marine mammal (including regulations on the taking and importing of individuals within population stocks). . . .” This text allows NMFS to regulate taking at the species-level or the stock-level. In this action, NMFS is waiving the moratorium and providing for the regulated taking of gray whales from the ENP stock only. Therefore, NMFS must satisfy the disadvantage test for the ENP stock. NMFS is not waiving the moratorium for WNP gray whales under section 101(a)(3)(A) or providing for regulated taking of this stock under section 103(a). Under these circumstances, NMFS is not required to comply with the disadvantage test for the WNP stock in this action.

The reference to “those species and population stocks” in section 103(a) expresses the idea that if taking is authorized at the species level, then the authorized taking cannot disadvantage the species. If the taking is authorized at the stock level, as NMFS has proposed in this case, then the taking cannot disadvantage the stock. This language does not require NMFS to apply the disadvantage test at the species level if NMFS is only proposing to waive the moratorium and regulate a single stock within a species that consists of multiple stocks. Accordingly, in reviewing the final regulations, I must “insure” that the take of marine mammals from the ENP stock will not disadvantage the ENP stock and will be

consistent with the purposes and policies of section 2 of the MMPA. 16 U.S.C. 1373(a).

Any ambiguity regarding the application of the disadvantage test to WNP gray whales in this case is resolved by the legislative history of the MMPA. When Congress first adopted the exception for incidental take in section 101(a)(5), the House Report for the Bill (H.R. 4084) stated: “Sections 103 and 104 of the Act do not apply to the taking of marine mammals occurring under the authority of section 101(a)(5).” House Report No. 97–228, at 13 (1981). Under the final regulations, any taking from the WNP stock that is anticipated during the permitting stage could only be authorized under section 101(a)(5) under the current circumstances. As such, the legislative history confirms that the disadvantage test in section 103(a) does not apply to WNP gray whales in this case.

Impacts to WNP gray whales are not properly addressed under sections 103(a) or 101(a)(3)(A) in this case, but that does not mean that impacts to WNP gray whales are irrelevant in NMFS’s evaluation of the waiver and implementing regulations. Section 103(b) addresses the regulations NMFS must adopt to implement a waiver and states: “In prescribing such regulations, the Secretary shall give full consideration to all factors which may affect the extent to which such animals may be taken or imported, including but not limited to the effect of such regulations” on five enumerated factors. The language of section 103(b) makes clear that these five factors are not exhaustive and focuses on the effect of the regulations implementing a waiver. Regulations implementing a waiver could affect marine mammals that are not subject to regulated taking under a waiver. In section 103(b), Congress required NMFS to consider these effects. In this case, the regulations implementing a hunt for ENP gray whales may incidentally take endangered WNP gray whales. I must give, and have given, full consideration to this issue under section 103(b).

In summary, the analyses required by sections 101(a)(3)(A) and 103(a) of the MMPA focus on the stock subject to regulated taking under a waiver, which is ENP gray whales. However, the broader language of section 103(b) requires consideration of the effects of the regulations on WNP gray whales. I address the effects of the regulations on WNP gray whales in section VIII of this Final Decision.

Comment 3: The WCR comments that whales are not fishery resources for the purposes of MMPA section 103(b) and

disagrees with the Recommended Decision that the whale watching industry falls within the scope of this factor of the MMPA.

Response: As described in section VIII of this Final Decision, I agree that impacts to whale watching should not be analyzed under section 103(b).

Comment 4: Several comments on the Recommended Decision suggest I must apply the precautionary principle when evaluating various aspects of the Makah’s waiver request.

Response: The statutory criteria that must be evaluated to grant the waiver and adopt implementing regulations are indeed protective, but if the criteria are satisfied, NMFS is not required to apply an additional measure of precaution to comply with the MMPA.

Comments on Gray Whale Stock Structure

Comment 5: The WCR comments that the MMPA’s detailed procedures in section 117 for identifying population stocks take precedence and govern stock determinations for other MMPA purposes, such as issuance of a waiver, and are not subject to *de novo* review in this formal rulemaking.

Response: Section 117 of the MMPA establishes the framework through which NMFS identifies marine mammal stocks and assesses their status. Through this process, which culminates in the publication of SARs, NMFS has identified two stocks of gray whales, the eastern and western North Pacific populations. The tribunal explained the role that SARs play in the waiver process as follows:

In order to make the requisite findings about the proposed waiver and regulations, I must make a threshold determination that the stock structure NMFS used is scientifically sound. While NMFS’s existing stock determinations, as contained in the SARs, are entitled to substantial deference, other parties may attempt to show the SARs rely on outdated or inaccurate scientific evidence. (See Tab 84 at 10; *Brower II*, 257 F.3d at 1067). However, if I were to determine NMFS’s current stock assessments are not based on the best available scientific evidence, this would not be the appropriate forum to make new assessments. Instead, the proper course of action would be to deny the waiver. NMFS would then have the opportunity to produce new stock assessments before deciding whether to propose a future waiver.

RD at 59. I agree with this assessment, which is consistent with the requirements under both sections 101(a)(3)(A) and 103(a) that I base my decision on the waiver and the implementing regulations on the “best scientific evidence available.”

SARs play a critical role in marine mammal management, but if Congress had intended for NMFS to give conclusive effect to the stock determinations in SARs when assessing a waiver application, it would have directed NMFS to do so. Other provisions of the MMPA specifically direct NMFS to use information from SARs. Sections 118(f)(5), (7), and (8) of the MMPA direct NMFS to use the PBR “established under section 117” for certain aspects of take reduction plans. This language clearly instructs NMFS to use information from SARs. There is no similar language related to stock designation in the provisions of the MMPA governing this proceeding. Rather, in both sections 101(a)(3)(A) and 103(a), Congress directed NMFS to use the “best scientific evidence available” when evaluating a waiver and implementing regulation which will often, but not always, be the scientific evidence in SARs. Because SARs are not constantly updated, the scientific information in a SAR can become outdated before the next SAR is published. Therefore, I agree with the tribunal’s decision to allow the parties to challenge the gray whale stock structure reflected in the 2017 and 2018 SARs (Tabs 2K; Tab 54D) during this formal rulemaking proceeding and its ultimate conclusion that the stock structure reflected in NMFS’s SARs is scientifically sound.

Comment 6: NMFS received a number of comments on whether PCFG gray whales should be considered a stock under the MMPA, with the Makah Tribe, MMC, and WCR region arguing that the PCFG are not a stock and AWI, Sea Shepherd, and PCPW arguing the opposite. Some parties and commenters argue that the PCFG must be designated as a stock pursuant to the purposes and policies of the MMPA and the precautionary principle.

Response: I agree with the tribunal’s determination that the PCFG is a feeding aggregation within the ENP stock for the reasons stated in section IV.D.1 of the Recommended Decision. The tribunal found that “the evidence strongly supports NMFS’s conclusion, and that of the IWC, that the PCFG are a feeding aggregation and not a separate stock or management unit.” RD at 65–66. Since the evidence is strong on this issue, NMFS’s determinations related to the PCFG’s status are consistent with the MMPA. Conservation of the PCFG is addressed through the numerous conservation measures in the final regulations that will ensure the hunt does not cause the PCFG to fall below recent levels, including PCFG abundance thresholds that prohibit

authorizing hunting if the PCFG population is below those thresholds.

Comment 7: AWI comments that the Recommended Decision primarily relies on recruitment levels in determining that the PCFG are a feeding aggregation within the ENP stock, rather than a separate stock.

Response: I disagree. The Recommended Decision relies on multiple lines of evidence in reaching the conclusion that the PCFG are a feeding aggregation with the ENP stock, including breeding habits, genetic information, and immigration into and emigration out of the group. RD at 62–67.

Comment 8: AWI argues that NMFS's failure to heed the recommendation of the PSRG and convene a workshop to address whether the PCFG should be considered a stock is arbitrary and capricious.

Response: AWI mischaracterizes the PSRG's recommendation. In 2018, the PSRG recommended that "NMFS reconsider the characteristics and status of the Pacific Coast Feeding Group (PCFG) of gray whales and whether it should be recognized and managed as a full stock" without requesting that the agency convene a workshop to address the issue. Tab 2L at 11. NMFS responded to the 2018 PSRG recommendation by explaining that the available information did not support classifying the PCFG as a "full stock" under the MMPA and that NMFS scientists keep apprised of new information pertaining to the PCFG and are actively engaged in field studies and gray whale assessments/workshops, including participation in four workshops convened by the IWC to review the range-wide status and structure of the North Pacific gray whales. Tab 2L at 11–12. NMFS scientists continue to be actively engaged in gray whale research and assessments. These assessments continue to support that the PCFG is a feeding aggregation of the ENP gray whale stock (see FEIS subsection 3.4.3).

While the PSRG is an important part of the process described in section 117 of the MMPA, they do not have a formal role in this proceeding and have not participated. Even if the PSRG had recommended establishing another workgroup to consider the status of the PCFG as a stock, I do not have the discretion to delay this proceeding to do so. The regulations governing this matter only allow me to make a final decision or remand this matter to the tribunal at this stage in the proceeding. 50 CFR 228.21(a).

Section 117 of the MMPA requires the development of SARs, based on the best

scientific information available, for all marine mammal stocks in U.S. waters. These reports are reviewed annually for "strategic stocks" and stocks for which significant new information is available and at least every 3 years for all other stocks. Through section 117 of the MMPA, NMFS regularly reviews the stock status of marine mammals, including gray whales, and will continue to do so.

Comment 9: MMC recommends that I address the implications for the waiver if the PCFG are designated a stock and include a contingency clause in the regulations that would suspend the authorization to conduct a whale hunt if the PCFG are determined to be a separate stock.

Response: If the PCFG are designated a stock at some future time, the same MMPA provisions that apply to waiving the take moratorium for the ENP stock would apply to a newly designated stock. The Tribe would need to apply for a waiver of the moratorium on take for the new stock, the request would be considered through the formal rulemaking process, and a decision rendered. If designated as a stock, PCFG whales could not be intentionally hunted unless a waiver is granted and implementing regulations are promulgated.

Comment 10: The Makah Tribe comments that it believes the WNP stock is not a listed species under the ESA because its essential attributes are "fundamentally different" from the stock that remained listed as endangered in 1994 when the ENP stock was delisted, and therefore the WNP stock should not be considered depleted under the MMPA.

Response: The entire gray whale population was first listed as endangered in 1970 (35 FR 18319, December 2, 1970), and it was both endangered under the ESA and depleted under the MMPA at that time. In 1994, the ENP stock was removed from the ESA's list of endangered and threatened species and no longer considered depleted under the MMPA because it had recovered. However, the WNP stock remained both endangered under the ESA and depleted under the MMPA because NMFS determined that the WNP gray whale population was geographically and reproductively isolated from the ENP population, remained small, and had not recovered. 59 FR 31094, June 16, 1994. Although it is now clear that the WNP and ENP gray whale populations are not geographically isolated (see section IX, Stock Structure), I agree with the Recommended Decision's determination that "the best available scientific

evidence" is that WNP gray whales are "distinct from the ENP stock as a whole." RD at 69. The tribunal noted uncertainty regarding the origins of the WNP gray whales but highlighted the "statistically significant" genetic differences between WNP gray whales and ENP gray whales. RD at 67–69. Analysis of photo-identification data, including data on mother-calf pairs, and paternity assessments, suggest that gray whales summering in the WNP may constitute a demographically self-contained subpopulation where mating occurs at least preferentially and possibly exclusively within the subpopulation. Several studies have found differences in the mitochondrial and nuclear DNA between ENP and WNP gray whales. RD at 67–69; Tab 59B at 12. I agree that these differences in the nuclear DNA found in ENP gray whales and WNP gray whales counsel in favor of treating the two stocks separately, even though it is now clear that their ranges overlap to some degree.

Comments on the Status of Gray Whales

Comment 11: Several comments address the status of the ENP gray whale stock. These include comments that the population should be considered endangered and not sustainable as well as comments that the population has fully recovered and a hunt would have negligible effects.

Response: ENP gray whales are not listed as endangered. The status of the ENP gray whale stock is addressed in sections IV–V and VII–IX of this Final Decision.

Abundance Threshold for ENP Gray Whales and the UME

Comment 12: The tribunal found that "the scientific evidence weighs in favor of an overall abundance threshold" for ENP gray whales and recommended I consider establishing one in the final regulations, "[p]articularly in light of the current UME." RD at 151. Several commenters addressed the tribunal's recommendation to include an abundance threshold in the final regulations and proposed specific population levels, ranging from 11,000 to 18,000, below which hunting would be prohibited. The Makah Tribe and the WCR believe an abundance threshold is not necessary but suggested thresholds should NMFS choose to implement one. MMC and PCPW support a low abundance threshold. AWI, while arguing that legal obstacles preclude adoption of the Recommended Decision, is generally supportive of a low abundance threshold.

Response: I have included requirements in the final regulation

setting an abundance threshold based on OSP. NMFS is required to confirm that the ENP gray whale stock is within OSP before issuing a hunt permit and ensure that the level of hunting under the hunt permit will not cause the stock to fall below its OSP. If the stock falls below OSP, NMFS must notify the Tribe and hunting is prohibited until NMFS notifies the Tribe that the stock is within OSP.

Comment 13: Several commenters suggest that the waiver should not be granted during a UME.

Response: The Working Group on Marine Mammal Unusual Mortality Events determined the most recent UME involving ENP gray whales was biologically over as of November 2023. There is no longer an ongoing UME for ENP gray whales. The population of ENP gray whales is known to experience large-scale fluctuations in abundance and has recovered from prior declines, including a prior UME that occurred over 20 years ago. The most recent abundance estimate for the 2023/2024 season shows a 32.6 percent increase from the 2022/2023 season (Eguchi *et al.* 2024). The abundance threshold for ENP gray whales in the final regulations addresses these fluctuations and concerns related to UMEs by prohibiting lethal hunting if the stock is not within its OSP.

PCFG Gray Whales

Comment 14: Some commenters suggest that the hunt will primarily impact the PCFG. Commenters also suggest that PCFG whales may not be able to recover from human-caused mortalities.

Response: The effects of the hunt were thoroughly evaluated at a range of scales, including the ENP, PCFG, OR-SVI (PCFG whales observed from southern Oregon to southern Vancouver Island survey areas), and Makah U&A (PCFG whales observed in north Washington or Strait of Juan de Fuca survey areas) whales (see FEIS Chapter 4). The regulations contain several protections for PCFG whales, including an alternating hunt season, limits on the harvest and mortality of PCFG whales, and low abundance thresholds for PCFG whales below which hunting would not be authorized.

Comment 15: PCPW and MMC recommend adopting a “dimmer switch provision” that would gradually reduce the harvest of gray whales before the abundance reaches the thresholds set in the regulations. Other commenters assert that this provision is unnecessary as the proposed regulations allow NMFS discretion to limit PCFG strikes below the full level through the hunt permit.

Response: The regulations include a number of measures to protect PCFG gray whales including a low abundance threshold. As noted in the Recommended Decision, NMFS also has discretion through the hunt permit process to grant less than the full number of strikes that would otherwise be allowed. If necessary, this discretion could be used to protect PCFG gray whales. RD 150–151. Given this, I have determined that a “dimmer switch” provision is not warranted.

Comment 16: PCPW comments that the accounting and identification methods (e.g., photo-identification) for PCFG whales are not 100 percent reliable and that the assumptions in accounting for PCFG whales are “questionable formulas.” PCPW also asserts that the number of whales at a particular time is impossible to know and models used for estimating the PCFG abundance are full of “assumptions” and in the hands of “anonymous modelers.”

Response: I have kept the requirement that the Tribal hunt observer collect digital photographs for identification but have modified it slightly to specify the Tribal hunt observer “must make every reasonable attempt” to collect digital photos. The regulations at § 216.115 specify the methods used to account for a whale that cannot be affirmatively identified. These methods are based on the best available scientific information. The PCFG abundance estimate is based on data derived from photo-identification surveys and catalog data. These estimates and the methods to derive them are fully described in peer reviewed, published literature. See, for example, Tabs 3AA, 3HH. The survey and catalog data will also be used as the basis for projecting PCFG abundance estimates into future hunting.

Comment 17: A commenter suggests the UME had a disproportionate effect on PCFG gray whales.

Response: There is no evidence that the UME had a disproportionate effect on PCFG gray whales. Since declaring a UME in May 2019, NMFS worked with partners in Canada and Mexico to review data and sample stranded gray whales. RD at 99. Only one whale has been matched by photo-identification to the PCFG. Genetic analysis of samples collected from stranded whales has not been completed. Although the abundance estimate for the ENP stock declined significantly from the 2015/2016 to the 2022/2023 abundance surveys, the PCFG abundance estimate has not experienced a proportional decline from pre-UME levels to 2020 (Harris *et al.* 2022).

Comment 18: Two commenters note inconsistencies in the statement in the Recommended Decision describing PCFG as occurring “in the PCFG range between April 1 and November 30 of two consecutive years.” RD at 85. April 1 should read June 1. While a whale must be sighted in 2 or more years to be designated a PCFG whale, these sightings do not need to be in consecutive years.

Response: I agree that the statement is inconsistent with the definition of the PCFG and correct this error in section VIII of this Final Decision.

Comment 19: PCPW comments that human-caused mortalities, including mortalities related to the hunt, are likely to exceed PBR for PCFG gray whales in some years, notes uncertainty in abundance estimates, and questions how NMFS will determine and respond if PBR is exceeded. PCPW also compares the PCFG to other marine mammal species with small population sizes as a caution about the impacts of human actions on these species.

Response: While PCFG whales are not a stock or prospective stock under the MMPA, the SARs include estimates of abundance, human-caused, mortality, and PBR for informational purposes. The estimates reflect the best available scientific information as required by the MMPA. The regulations include a number of measures to minimize the effects of the hunt on the PCFG specifically, including strike limits, low abundance thresholds, and reporting and accounting requirements. To the extent that the informational PBR for PCFG raises management concerns, there are processes for addressing those concerns in the regulations. The regulations provide that the Regional Administrator will notify the Tribe of the maximum number of PCFG whales, including females, that may be struck during the upcoming hunting season, providing a mechanism to respond to and adaptively manage based on the best available information.

WNP Gray Whales

Comment 20: Several commenters maintain that the approval of the waiver is inappropriate in terms of conservation of endangered WNP gray whales.

Response: I disagree. The effects of a Tribal hunt on WNP gray whales have been fully considered. The regulations are designed to minimize the risk of a WNP whale being struck or harmed over the duration of the waiver. Approaches, the most likely type of interaction with a WNP gray whale, are not lethal, nor are approaches likely to cause more disturbance than close approaches

associated with typical biopsy sampling for research purposes. RD at 123.

Comment 21: Several commenters address the tribunal's recommendation that I expressly require the Makah Tribe to obtain an ITA for WNP gray whales during the winter/spring season (December through May) when the WNP gray whales might be present in the Makah U&A. The MMC supports the tribunal's recommendation expressly requiring an ITA, commenting: "For purposes of this rulemaking, it is sufficient for the regulations to require that the taking of ENP whales not be allowed if there is a high enough likelihood that *unauthorized* taking of WNP whales will also occur." The Makah Tribe questions whether an express requirement for an ITA for WNP gray whales is necessary, arguing that the regulations include significant protections for WNP gray whales and pointing to provisions in the proposed regulations requiring NMFS to determine that relevant incidental take authorization for other marine mammals have been obtained before a hunt permit can be issued.

Response: The final regulations require NMFS to evaluate whether the hunting proposed by the Makah Tribe in their permit application will result in the take of WNP gray whales. If the take of WNP gray whales is anticipated by NMFS, then NMFS must include measures in the hunt permit requiring a separate take authorization for those whales during the winter/spring season. Depending upon what the latest science shows, additional measures that could prevent anticipated take of WNP gray whales may include, for example, limiting the number of hunting and training days, restricting the location of hunting and training, or banning hunting and training during the winter/spring season if other measures are not effective.

Comment 22: AWI and another commenter assert that the Recommended Decision must be rejected because the take of WNP gray whales during the course of a hunt for ENP gray whales cannot be authorized under the MMPA's exception for incidental take.

Response: I disagree. For the reasons explained below, if NMFS determines that the take of WNP gray whales is anticipated during the permitting process, the Makah could qualify for an ITA under section 101(a)(5) for the "incidental, but not intentional, taking" of WNP gray whales during the course of their hunt for ENP gray whales. To respond to this comment, I will first summarize the requirements for ITAs and relevant legislative history and then

explain how the Makah could meet the threshold requirements for an ITA.

Section 101(a)(5) describes two types of ITAs for non-military activities that are relevant here. One type allows NMFS to issue an incidental harassment authorization for up to 1 year. 16 U.S.C. 1371(a)(5)(D). The other allows NMFS to issue regulations and a letter of authorization that would allow incidental take for up to 5 years. 16 U.S.C. 1371(a)(5)(A). Collectively, I will refer to these two exceptions as an ITA. Only U.S. citizens "who engage in a specified activity (other than commercial fishing) within a specified geographical region" can apply for an ITA. 16 U.S.C. 1371(a)(5)(A), (D). Taking marine mammals under an ITA must be "incidental, but not intentional, taking." *Id.* NMFS can authorize take of only "small numbers" of marine mammals, and the authorized take can have only a "negligible impact" on the species or stock. *Id.* The take cannot have an "unmitigable adverse impact" on the availability of marine mammals for subsistence uses, and NMFS must prescribe "means of effecting the least practicable adverse impact on such species or stock and its habitat." *Id.*

Several important terms are further defined by regulations implementing section 101(a)(5). The terms "[i]ncidental harassment, incidental taking and incidental, but not intentional, taking all mean an accidental taking." 50 CFR 216.103. The regulatory definition makes clear that "[t]his does not mean that the taking is unexpected, but rather it includes those takings that are infrequent, unavoidable or accidental." *Id.*

The definition of "incidental, but not intentional, taking" closely tracks relevant legislative history. Congress first adopted the incidental take exception for specified activities in the 1981 amendments to the MMPA. The 1981 amendments to the MMPA also included a similar exception for incidental takes committed during commercial fishing. Regarding these new exceptions, the House Report for the Bill explained:

Both sections 101(a)(4) and (5) authorize the incidental, but not the intentional, taking of small numbers of marine mammals. The phrase "incidental, but not intentional" is intended to mean accidental taking. The words "not intentional" should not be read to mean that persons who know there is some possibility of taking marine mammals incidental to commercial fishing operations or other specified activities are precluded from proceeding under the authority of sections.

House Report No. 97–228, at 13 (1981). Referring to the new incidental

take exceptions, the House Report for the 1981 amendments to the MMPA further explained: "The Committee intends that these provisions be available for persons whose taking of marine mammals is infrequent, unavoidable, or accidental." *Id.*

Implementing regulations also define the term "specified activity," which means "any activity, other than commercial fishing, that takes place in a specified geographical region and potentially involves the taking of small numbers of marine mammals." 50 CFR 216.103. The House Report to the 1981 amendments to the MMPA explains:

It is the intention of the Committee that both the specified activity and the specified region referred to in section 101(a)(5) be narrowly identified so that the anticipated effects will be substantially similar. Thus, for example, it would not be appropriate for the Secretary to specify an activity as broad and diverse as outer continental shelf oil and gas development. Rather, the particular elements of that activity should be separately specified as, for example, seismic exploration or core drilling.

House Report No. 97–228, at 13 (1981). Congress intended for NMFS to articulate specified activities with particularity, as this approach would allow NMFS to more carefully analyze the effects of the activity on marine mammals.

With the relevant authorities and the legislative history in mind, I will now consider whether the Makah Tribe could satisfy the threshold requirements for an ITA under section 101(a)(5). I cannot determine in this proceeding whether an ITA for WNP gray whales would be appropriate, as such a determination requires separate procedures, but nothing about the Makah's activities under the waiver would prevent them from satisfying the threshold requirements.

Under section 101(a)(5), there are three threshold requirements that must be met before NMFS can consider issuing an ITA. First, there must be a request from a citizen of the United States. 16 U.S.C. 1371(a)(5)(A), (D). Members of the Makah Tribe are U.S. citizens and could make such a request.

Second, U.S. citizens must be engaged in a "specified activity (other than commercial fishing) within a specified geographical region." 16 U.S.C. 1371(a)(5)(A), (D). The Makah are proposing a ceremonial and subsistence hunt for ENP gray whales, which is a specified activity other than commercial fishing. Activities under the waiver will occur in the coastal portion of the Makah Tribe's U&A, which is a specified geographic region. Hunting and training activities under the waiver

involve a specific set of actions directed at ENP gray whales. The legislative history for section 101(a)(5) suggests that the specified activity should be “narrowly identified.” House Report No. 97–228, at 13 (1981). A “narrowly identified” activity is consistent with the common meaning of the term “specified,” which is the past tense of “specify” and means to “mention or name in a specific or explicit manner: tell or state precisely or in detail.” Webster’s Third New International Dictionary (3rd ed. 1976). Considering hunting and training activities directed at a single stock of marine mammals in an ITA is consistent with the meaning of the term “specified.”

The final threshold requirement is that taking authorized under section 101(a)(5) must be “incidental, but not intentional, taking.” NMFS has defined the phrase “incidental, but not intentional, taking” to mean “an accidental taking.” 50 CFR 216.103. Consistent with legislative history surrounding this exception, “accidental taking . . . does not mean that the taking is unexpected, but rather it includes those takings that are infrequent, unavoidable or accidental.” *Id.*

Here, a highly conservative analysis forecasts at most 18 approaches of WNP gray whales and a small but real risk of an unsuccessful strike attempt over the 10-year waiver period. Tab 61D. To the extent that each approach represents a take, these takes would be infrequent compared to the 3,530 approaches authorized over the waiver period for ENP gray whales. To the extent that a WNP is present in the U&A during hunting or training activities, approaches may be unavoidable because it is difficult to distinguish between the two gray whale stocks visually in a hunt scenario. In light of the differing statuses of the two stocks, Makah hunters would be targeting ENP gray whales, so any taking of a member of the WNP stock would be accidental.

Pursuing the wrong type of animal in a hunt can be an accident. An analogy helps illustrate this. A hunter enters the field to hunt whitetail deer during whitetail deer season. There are whitetail deer and mule deer in the area, but whitetail deer outnumber mule deer 100 to one. The hunter sees an animal with antlers in the distance and stalks it. Unbeknownst to the hunter, the animal is a mule deer. The mule deer catches the scent of the hunter and flees.

Common sense suggests that when the hunter stalked and thereby hunted the mule deer it was an accident. This is because the hunter intended to hunt whitetail deer, was authorized to hunt

whitetail deer, and reasonably thought the mule deer was a whitetail deer based on its general appearance and the fact that mule deer are rare in the area. Likewise, it would be an accident if Makah whalers approach or throw a harpoon near a WNP gray whale during the course of their hunting and training activities directed at ENP gray whales.

Nevertheless, AWI and some other commenters argue that hunting is always intentional and cannot qualify for an ITA. This argument is not consistent with the text of the MMPA. Under section 101(a)(5), an ITA is available for “incidental, but not intentional, taking.” Taking is the present participle of take, which means “to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal.” 16 U.S.C. 1362(13). If the statutory criteria are met, NMFS is required to allow citizens to incidentally, but not intentionally “harass, hunt, capture, or kill . . . any marine mammal” when engaged in specified activities. *Id.* If Congress had only intended for an ITA to be available for harassing, capturing, or killing—but not hunting—it would not have used the term “taking” in section 101(a)(5).

For all these reasons, if necessary Makah whalers can apply for an ITA under section 101(a)(5) to cover any incidental take of WNP gray whales that is anticipated during the winter/spring hunt.

Comment 23: The MMC comments that it agrees with the statement in the Recommended Decision that the “best available scientific evidence shows that removal of a WNP whale would be detrimental to the stock.” RD at 19. MMC asserts that this statement would preclude NMFS from making the negligible impact determination necessary to authorize the incidental killing of a WNP gray whale under section 101(a)(5).

Response: If the Makah apply for an ITA under section 101(a)(5)(A), NMFS will evaluate their application along with the best available science. I have not affirmed the statement the MMC references from the Recommended Decision related to WNP gray whales since it is premature to speculate on what a potential future analysis would show.

Comment 24: AWI’s comments on the Recommended Decision contend that the taking of WNP gray whales is a certainty under NMFS’s own risk analysis and therefore the Recommended Decision “must be rejected because it will result in the illegal take of WNP gray whales.” Referring to WNP gray whales, AWI further comments that “[t]he

Recommended Decision unlawfully authorizes the directed take of a depleted marine mammal stock” citing guidance from NMFS’s Permits and Conservation Division within the Office of Protected Resources that references two categories: authorizations for incidental take of marine mammals under the MMPA and permits for directed take of species protected under the MMPA and/or ESA.

Response: AWI points to the 18 approaches forecasted in the 2019 Moore and Weller analysis (see Tab 61D) to support their argument that take of WNP gray whales is a certainty. However, this analysis unrealistically assumes that all approaches (hunting and training) occur during the winter/spring period when WNP whales may be present, even though a substantial number of approaches will likely occur outside this period during the summer/fall season when ocean conditions are more favorable for hunting. The Moore and Weller analysis shows that there is a potential risk to WNP gray whales, not that take is inevitable. The risk identified in the Moore and Weller analysis calls for management, not denial of the waiver.

The regulations I adopt in this document include significant protections for WNP gray whales. Before issuing a hunt permit for ENP gray whales, NMFS is required to determine, based on the best available science, whether the activities described in the Makah Tribe’s hunt permit application would result in the take of WNP gray whales. If the activities would result in the take of WNP gray whales, the Makah must have separate authorization for takes of WNP gray whales to hunt or train during the winter/spring season.

The Makah Tribe has at least three options to address concerns related to WNP gray whales; none of which would result in the illegal take of WNP gray whales. First, the Makah may choose not to hunt or train during the winter/spring. Second, the Tribe may propose additional restrictions in their application for a hunt permit that would lead NMFS to conclude take of WNP gray whales is not anticipated during the winter/spring season. Finally, the Makah could obtain an ITA under section 101(a)(5) to cover the take of WNP gray whales.

Regarding AWI’s comment about “directed take,” many of the permits NMFS issues for protected species fall within the incidental or directed take categories, but this proceeding presents a unique permitting scenario, and the definition of “directed take” on the portion of NMFS’s website referenced by the commenter has no bearing on

whether an incidental take authorization could be issued under section 101(a)(5) for WNP gray whales.

Comment 25: AWI comments that the Recommended Decision will result in the hunting of WNP gray whales, which is a violation of the MMPA because this stock is depleted.

Response: Although section 101(a)(3)(B) of the MMPA generally prevents NMFS from issuing permits for the take of WNP gray whales because the stock is depleted, an exception allows NMFS to issue ITAs for animals from depleted stocks. The final regulations and the waiver authorize hunting only ENP gray whales. If NMFS anticipates the hunting of ENP gray whales may result in the take of WNP gray whales, under the final regulations the agency would need to authorize this take separately. As explained in response to comment 22, characterizing the take of WNP gray whales as “hunting,” does not preclude issuance of an ITA under section 101(a)(5) of the MMPA.

Comment 26: AWI comments that the definition of hunt in the proposed regulations, which does not include non-lethal activities, is inconsistent with the plain meaning of the term and has enormous legal significance.

Response: The tribunal addressed this argument in section VII.B.3.b of the Recommended Decision. I agree with that analysis. As the tribunal explained:

I find AWI's reading of the regulations overly formalistic. Moreover, it would likely cause confusion, as it is unclear what other terminology NMFS could use to convey the different limitations on non-lethal training activities and potentially lethal hunting activities. Therefore, I see no need to amend the definition of “hunt” or of the related training activities.

RD at 146. WNP gray whales are designated as “depleted” under the MMPA in addition to their “endangered” status under the ESA, and the moratorium has not been waived for the WNP stock. Under these circumstances, permits cannot be issued for the take of WNP gray whales, except for scientific research, photography, enhancement or incidental take under section 101(a)(5) of the MMPA. 16 U.S.C. 1371(a)(3)(B). As discussed in response to comment 22, characterizing the activities associated with the waiver as hunting WNP gray whales does not preclude issuance of an ITA for this stock, if needed.

Comment 27: AWI comments that the Recommended Decision authorizes harassment of WNP gray whales in violation of the MMPA.

Response: In light of the potential for activities authorized by the waiver and

final regulations to result in the take of WNP gray whales, I have adopted final regulations that manage this risk by ensuring hunting and training does not occur during the winter/spring season without an ITA if the agency determines during the permitting process that take of WNP gray whales is anticipated. Although the Makah are eligible to apply for an ITA, issuance of an ITA is not guaranteed and will be evaluated pursuant to the applicable statutory and regulatory requirements should the Makah choose to apply.

Comment 28: AWI comments that training activities are inconsistent with the purposes and policies of the MMPA and should not be authorized under the waiver.

Response: The Makah have sought a waiver to hunt ENP gray whales and train for that hunt. I have applied the criteria set forth in the MMPA for evaluating the waiver request and implementing regulations and have determined that the training activities authorized in the final rule are consistent with the MMPA. Training is critical to ensure the hunt is safe and humane. NMFS will address issues related to safety and the humaneness of the hunt more specifically during the permitting process. To the extent that training activities authorized under a hunt permit are anticipated to result in take of WNP gray whales, such takes can be authorized and managed in accordance with section 101(a)(5) of the MMPA.

Comment 29: AWI and another commenter argue that *Kokechik Fishermen's Ass'n v. Sec'y of Com.*, 839 F.2d 795 (D.C. Cir. 1988) prohibits issuance of a waiver because the waiver will result in the take of WNP gray whales. WCR, MMC, and the Makah Tribe disagree.

Response: In *Kokechik*, NMFS granted a waiver under section 101(a)(3)(A), adopted regulations under section 103, and issued a permit pursuant to sections 101(a)(2) and 104 authorizing the incidental take of Dall's porpoise in the Bering Sea by the Federation of Japan Salmon Fisheries Cooperative Association (Federation). 839 F.2d at 797–801. NMFS issued the permit in *Kokechik* knowing the Federation would incidentally kill other marine mammal species for which OSP had not been determined. *Kokechik*, 839 F.2d at 799–800. NMFS did not authorize those other takes and limited the authorization to the take of Dall's porpoise. *Id.* Consequently, the take of other marine mammals would have inevitably occurred without authorization under the MMPA. *Id.* at 801. The court held “that the permit, as

granted to the Federation, is contrary to the requirements of the MMPA in that it allowed incidental taking of various species of protected marine mammals without first ascertaining as to each such species whether or not the population of that species was at the OSP level.” *Kokechik*, 839 F.2d at 802.

Kokechik is distinguishable from the present case for at least three reasons. First, *Kokechik* involved section 101(a)(2) of the MMPA, which provides that “it shall be the immediate goal that the incidental kill or incidental serious injury of marine mammals permitted in the course of commercial fishing operations be reduced to insignificant levels approaching a zero mortality and serious injury rate.” The court in *Kokechik* relied on the zero mortality and serious injury rate goal to reach its holding, quoting it twice. 839 F.2d at 801–02. Since that provision is not applicable in the present case, which does not involve commercial fishing, *Kokechik* is distinguishable.

Second, *Kokechik* involved the unauthorized serious injury or mortality of marine mammals that was “not merely a remote possibility but a certainty.” *Kokechik*, 839 F.2d 801–02. For example, the ALJ in *Kokechik* anticipated and recommended that NMFS allow the Federation to kill or seriously injure 45 Northern fur seals from the Commander Island stock. 52 FR 19874, 19877, May 28, 1987. Conversely, the tribunal in this case recognized, and I agree, that the risk of a lethal strike on a WNP is quite low. RD at 135–136. NMFS has produced an extremely precautionary risk analysis that shows a remote risk that a WNP gray whale could be killed or seriously injured. As explained by the tribunal:

The modeling suggests, if the Makah Tribe utilizes every available strike during the 10-year waiver period, there is a 5.8% chance of striking at least one WNP whale and a 30% chance of an unsuccessful strike attempt on a WNP whale. If the hunt continued into perpetuity, using the existing hunt management scheme and other variables, a WNP whale would be struck approximately once every 135 years. (Tab 61 at ¶ 8).

RD at 111. In *Kokechik*, the court suggested several times that the case might have been decided differently if the takes at issue were a “remote possibility.” *Kokechik*, 839 F.2d 801–02. A chance of striking a whale and causing a lethal take once every 135 years (RD at 111) is a remote possibility.

Third, *Kokechik* is distinguishable because the Federation was not eligible to apply for a separate ITA for anticipated takes. In *Kokechik*, it was “foreseeable that takes of northern fur seals, northern sea lions, harbor

porpoises, Pacific white-sided dolphins, and killer whales will occur,” but only the take of Dall’s porpoise was authorized. 839 F.2d at 800. Because the taking of any of “these other marine mammals without a permit is absolutely prohibited by the MMPA,” the court called the legitimacy of the permit for Dall’s porpoise into question. *Id.* In *Kokechik*, the take of northern fur seals, northern sea lions, harbor porpoises, Pacific white-sided dolphins, and killer whales by the Japanese Federation incidental to their commercial fishing operation was “absolutely prohibited,” meaning there was not a separate legal pathway for the Japanese Federation to seek authorization for the incidental take of these animals. This is because the members of the Japanese Federation were not U.S. citizens. The court cited section 101(a)(4) of the MMPA, which (at the time) set a separate “narrow exception for incidental, but not intentional, takings having a negligible impact on the species involved ‘by citizens of the United States while engaging in commercial fishing operations’” and explained this exception did not apply to the Japanese Federation. *Kokechik*, 839 F.2d at 802. Unlike members of the Japanese Federation, as U.S. citizens seeking to pursue a “specified activity (other than commercial fishing) within a specified geographical region,” 16 U.S.C. 1371(a)(5)(A), (D), members of the Makah Tribe can seek separate authorizations for incidental take of WNP gray whales under the incidental take exception in section 101(a)(5), if needed. This option, which does not require an assessment of OSP, was not available to the Japanese Federation in *Kokechik*.

For all these reasons, the holding in *Kokechik* is largely limited to the facts of that case in that NMFS authorized the taking of one species of marine mammal knowing that another species would be killed in violation of the law. The regulations I adopt in this document, by contrast, involve an extremely remote risk of lethal take and require legally-available authorization for any takes of WNP gray whales anticipated during the permitting process.

Comment 30: AWI comments that the Assistant Administrator must determine whether the take of a WNP gray whale can be authorized prior to issuing the waiver.

Response: The take of WNP gray whales cannot be authorized in this proceeding, but the take of WNP gray whales may be authorized under other provisions of the MMPA. To the extent that AWI contends that I must consider effects on WNP gray whales, I have done

so in accordance with section 103(b) of the MMPA. In conjunction with this review, I have concluded that the Makah are not prohibited from applying for an ITA under section 101(a)(5) of the MMPA for the incidental take of WNP gray whales, if necessary.

Comment 31: AWI comments that NMFS cannot rely on the subjective intent of the Tribal hunters to transform deliberate take into incidental take and that doing so would impose a *mens rea* or mental state requirement in the statute that does not exist.

Response: As explained in response to comment 22, there are exceptions in section 101(a)(5) for “incidental, but not intentional taking” that meets certain criteria and has been authorized by NMFS. The statute uses the phrase “not intentional” in these exceptions. The intent of Makah whalers is most certainly relevant to whether their actions are “not intentional.”

That mental state is not an element of civil violations of the take provision has no bearing on whether the exceptions for “incidental, but not intentional, taking” in section 101(a)(5) of the MMPA apply. Mental state is relevant to the exceptions for “incidental, but not intentional, taking,” but need not be proven to establish a *prima facie* violation of the take prohibition. AWI’s comment conflates the distinction between the elements of a civil violation of the take prohibition and the requirements associated with certain exceptions.

Comment 32: AWI cites two decisions, *Black v. Pritzker*, 121 F.Supp.3d 63 (D.D.C. 2015) and *Pacific Ranger v. Pritzker*, 211 F.Supp.3d. 196 (D.D.C. 2016), from the U.S. District Court for the District of Columbia involving NOAA enforcement actions against purse seine fishing vessels that were unlawfully taking marine mammals and comments that NMFS’s position regarding the incidental take of WNP gray whales is inconsistent with its position in those cases.

Response: NMFS’s position with respect to the Makah waiver and implementing regulations differs from the positions it took in *Black* and *Pacific Ranger* because those cases involved facts and law that are very different from the circumstances here. Both cases involved respondents in NOAA civil administrative penalty cases who appealed to the district court after an ALJ found they intentionally encircled marine mammals with purse seine nets while tuna fishing. *Pacific Ranger*, 211 F. Supp. 3d at 221; *Black*, 121 F. Supp. 3d at 101–102. In both cases, the court rejected the respondents’ arguments that the exception in section 118 of the

MMPA for incidental take of marine mammals during commercial fishing operations authorized their conduct. *Pacific Ranger*, 211 F. Supp. 3d at 221; *Black*, 121 F. Supp. 3d at 87–88, 101–102.

Makah whaling is not commercial fishing and does not involve the exception to the MMPA’s take prohibition that was at issue in *Black* and *Pacific Ranger*. Hunting and training activities under the final waiver and regulations involve the exception in section 101(a)(3)(A) that allows NMFS to waive the moratorium and authorize intentional take of ENP gray whales. NMFS may also utilize the exception in section 101(a)(5) for specified activities other than commercial fishing for “incidental, but not intentional, taking” to authorize the incidental take of WNP gray whales, if needed.

If a hunt permit is issued, the Makah will be authorized to hunt ENP gray whales and intentionally take these animals. Depending upon what activities are authorized under a hunt permit, the Makah may accidentally pursue the wrong type of whale (WNP gray whales, as opposed to ENP gray whales) during the course of authorized hunting and training. Such accidental take would be “incidental, but not intentional, taking” of WNP gray whales and could be authorized under section 101(a)(5).

Black and *Pacific Ranger* did not involve a situation where the purse seiners were authorized to encircle one type of marine mammal and accidentally encircled the wrong type. The respondents in *Black* and *Pacific Ranger* were not authorized to intentionally encircle any marine mammal. When they did, NMFS’s position remains that they violated the MMPA and could not avail themselves to the incidental take exception for commercial fishing under section 118 of the MMPA. Makah whaling involves different circumstances and separate exceptions under the MMPA.

Comment 33: AWI comments that the disadvantage test is inapplicable to the take of WNP gray whales. They contend that the relevant inquiry is whether take of WNP gray whales can be authorized under one of the MMPA’s exceptions to the take moratorium.

Response: I agree that the disadvantage test does not apply to WNP gray whales in this proceeding. The plain language of section 103(a) makes clear that the disadvantage test only applies to take regulated under section 103(a). Section 103(a) confers authority on NMFS to regulate taking at the species level or the stock level. NMFS must then “insure that such

taking will not be to the disadvantage of those species and population stocks.” 16 U.S.C. 1373(a). This means that if the takings are regulated at the stock level, then the take must not disadvantage the stock. Conversely, if takes are regulated at the species level, the takes must not disadvantage the species. Here, NMFS has prescribed regulations at the stock level governing the take of ENP gray whales. Therefore, the disadvantage test applies to this stock only. The mere fact that other takes are considered, pursuant to NMFS’s obligations under section 103(b), does not subject these takes to the disadvantage test or the other requirements associated with waiving the moratorium.

Hunt and Training Activities

Comment 34: Several comments were received on the recommendation that the regulations prohibit an approach on a calf or an adult accompanying the calf, including concerns related to identifying a calf or cow-calf pair from a whaling canoe, impairing training activities, risk of inadvertent non-compliance, and the effects of an approach.

Response: I have adopted the recommended provision with modifications to prohibit approaches on calves or adult gray whales accompanying calves *only after* a calf or adult accompanying a calf has been identified. This will maintain the intent of the modification while ensuring the regulations do not set unrealistic expectations and result in inadvertent non-compliance.

Comment 35: Several commenters expressed concern about safety risks associated with the hunt.

Response: Safety concerns are thoroughly addressed in the FEIS and will be further evaluated at the hunt permit stage.

Comment 36: A number of comments were received on the humaneness of the hunt.

Response: Section 3(4) of the MMPA defines “humane” as “that method of taking which involves the least possible degree of pain and suffering practicable to the mammal involved.” Section 104(b)(2)(B) of the MMPA then provides that, before issuing a permit, NMFS must determine that the hunting method is “humane.” Issues related to the humaneness of the hunt will be addressed at the permitting stage.

Comment 37: AWI contends that the tribunal recommended, and AWI supports, that the regulations be amended to provide that hunt permits be issued on a yearly basis, citing RD at 147

Response: This comment mischaracterizes the tribunal’s Recommended Decision, which states:

NMFS proposes to limit the duration of an initial hunt permit to no more than three years, and the duration of any subsequent permit to no more than five years. § 216.113(a)(1). However, a permit can be granted for as little as one year. This will allow for adaptive hunt management, since NMFS would take into account the results of previous hunts when determining whether to issue subsequent permits. This proposal is reasonable and clearly in accordance with the conservation objectives of the MMPA.

RD at 147. While the Recommended Decision notes that permits can be issued for a duration of 1 year, the tribunal did not recommend that the regulations be amended. Rather, the tribunal supported the structure proposed by NMFS, as the regulations recommended in Appendix B to the Recommended Decision maintain the structure proposed by NMFS. Tab 121B.

Comment 38: AWI suggests including requirements for determining the proportion of WNP gray whales in the hunt area presumed to be WNP whales for the purposes of accounting for takes of gray whales under the hunt management requirements and restrictions.

Response: If takes of WNP gray whales are anticipated, the Tribe may apply for an ITA under the MMPA. An ITA application must include specific information, including “the suggested means of accomplishing the necessary monitoring and reporting” 50 CFR 216.104. Under section 101(a)(5) of the MMPA, NMFS must set forth requirements pertaining to the monitoring and reporting of any take. The nature of those requirements, including whether or how to account for the proportion of WNPs present in the hunt area, would be determined as part of the ITA process.

Comment 39: Some commenters suggest that only traditional hunting methods should be permitted.

Response: The Makah Tribe proposes to use both traditional and modern methods for hunting whales to balance the preservation of traditional cultural methods with safety and the need for increased hunting efficiency. Section 104 of the MMPA requires that if the take moratorium is waived and animals are killed, the method of killing must be “humane,” which the MMPA defines as “that method of take which involves the least possible degree of pain and suffering practicable to the mammal involved.” 16 U.S.C. 1362(4). The use of modern technologies (e.g., support vessel, rifle) will help ensure that the

hunt is humane by reducing the time to death over using traditional measures.

Ecosystem and Cumulative Effects

Comment 40: One commenter suggests that the effects of the action should have been considered at a different ecosystem scale.

Response: As noted in the Recommended Decision, NMFS considered ecosystem impacts at several levels, and it was “reasonable for NMFS to conclude that the health and stability of the ecosystems in which gray whales function will not be adversely affected by the proposed waiver and regulations.” RD at 116.

Comment 41: Several commenters comment on the range of anthropogenic threats that gray whales face and the importance that these threats be considered in combination.

Response: Gray whales face many threats, including entanglement, marine debris, vessel strike, whale watching disturbance, ocean noise, and climate change. NMFS is working to address threats to gray whales and other marine mammals. While a cumulative effects analysis is not an express requirement for the MMPA waiver process, NMFS considered the cumulative effects of natural mortality and anthropogenic effects to whales as part of the NEPA analysis.

Comment 42: MMC commented that in considering cumulative impacts, the tribunal’s Recommended Decision took an overly narrow reading of the statutory requirements of section 103 of the MMPA in finding that “the MMPA does not mandate separate consideration of these factors during formal rulemaking proceeding.”

Response: Hunting cannot be authorized or occur if the ENP gray whale stock is below its OSP. This provision ensures hunting in combination with other threats to ENP gray whales will not disadvantage the stock.

Comment 43: A number of comments describe the role that whales play in the ecosystem; the interdependency of animal, human, and environmental health; and the importance to ensure the health and stability of the ecosystem.

Response: Maintaining marine mammal stocks as a significant functioning element in the ecosystem of which they are a part and maintaining the health and stability of the marine ecosystem is a purpose and goal of the MMPA. The effects of a limited hunt of 25 whales over a 10-year period have been fully evaluated, and ENP gray whales are expected to continue to be a significant and functioning element of the ecosystem. The health and stability

of the ecosystem will be maintained under the final waiver and regulations.

Comment 44: One commenter suggests that all reports on waiver activities should be made available for public review.

Response: Per the regulations, the hunt report, annual approach report, and annual handicraft report will be maintained and made available for public review by NMFS. Other documentation may be available in accordance with the Freedom of Information Act and other Federal law.

The Treaty of Neah Bay of 1855

Comment 45: Several groups, government agencies, and private citizens commented on the Recommended Decision supporting the Makah's treaty right to whale. Commenters note that the tribunal's Recommended Decision is consistent with the Federal trust responsibility. Others wrongly claimed that the Treaty is obsolete or irrelevant.

Response: I support the Makah's treaty right and am adopting a final waiver and regulations that will allow the Tribe to exercise their right, in accordance with the MMPA.

Comment 46: The Tribe notes their disagreement with the Recommended Decision's discussion of the Treaty of Neah Bay of 1855, which contends that the application of the Treaty is merely academic and not the controlling law. The Makah maintain that the "because the MMPA did not abrogate the Treaty, the MMPA and Treaty must be harmonized in evaluating whether the hunt may proceed."

Response: I have not adopted the parts of the Recommended Decision that found the Treaty of Neah Bay of 1855 is not relevant. This waiver and accompanying regulations enable the Tribe to exercise their treaty right in full compliance with the MMPA. To the extent the Tribe concludes that the regulations are not in accord with their treaty right, I have provided a process through which the Tribe may request a modification to the final regulations. Modifying the regulations through informal rulemaking may be possible and could be carried out in conjunction with permitting to streamline the process.

Comment 47: Several commenters suggested that the Makah should not be permitted to use modern equipment when whaling.

Response: The Treaty of Neah Bay does not prescribe particular whaling methods. In similar situations, courts have recognized that Tribes may use modern technology when exercising their treaty rights. *See, e.g., United*

States v. Washington, 384 F. Supp. 312, 407 (W.D. Wash. 1974). Allowing modern hunting techniques will also promote a safe and humane hunt.

Procedural Comments

Comment 48: AWI and others comment that the tribunal's decision to issue the Recommended Decision before NMFS issued the SDEIS deprived them of their right to conduct cross-examination and submit rebuttal evidence.

Response: To fulfill its obligations under NEPA, NMFS developed an SDEIS, which was completed after the tribunal issued the Recommended Decision. The prospect that additional information on gray whales may be generated after the hearing did not deny any rights under the APA to conduct cross-examination or submit rebuttal evidence.

The right to conduct cross-examination under the APA is not absolute. The parties to the hearing were entitled to present their "case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. 556(d). The procedural regulations governing this matter provide: "Any party shall be given an opportunity to appear, either in person or through an authorized counsel or representative, to cross-examine witnesses." 50 CFR 228.18(b). The term "witness" is defined in relevant parts as "any person who submits written direct testimony on the proposed regulations." 50 CFR 228.2(b). AWI had the right and the opportunity to cross-examine every witness that submitted direct testimony during the hearing. No witnesses testified after the hearing. This process allowed for a full and true disclosure of the facts in accordance with NMFS's regulations and the APA.

AWI had an opportunity to submit rebuttal evidence at the hearing. After the hearing, AWI had an opportunity to submit rebuttal evidence multiple times, including during the comment period for the parties from November 27, 2023, to December 20, 2023. AWI submitted their comments after the deadline. I then provided the parties with an opportunity to respond to the comments of the other parties. This response period ran from December 20, 2023, to January 17, 2024, and provided an opportunity to rebut information submitted by the other parties. AWI took advantage of this opportunity. This process afforded AWI ample opportunity to submit rebuttal evidence in accordance with the APA.

Comment 49: AWI comments that NMFS's decision to prepare an SDEIS after the formal rulemaking hearing shows that the tribunal's decision was not based on the best available science.

Response: On February 27, 2020, NMFS explained in its Notice of Intent to prepare an SDEIS that "[b]ecause information concerning the ongoing 2019 UME was presented at the agency hearing but not expressly addressed in the 2015 DEIS, NMFS has determined that it would now benefit both the public and agency decision making to prepare a supplement to the DEIS." 85 FR 11347. Because the 2015 DEIS did not include the subsequent scientific information that was available and presented to the tribunal at the formal rulemaking hearing in 2019, it was prudent for NMFS to prepare an SDEIS with that information. It was also prudent for NMFS to notify the public that the SDEIS would include "additional relevant information and will take into consideration the Administrative Law Judge's recommended decision." *Id.* at 11348. NMFS regularly updates its marine mammal population estimates pursuant to the SAR process. NMFS could not ignore those estimates in the SDEIS and comply with its NEPA obligations. Recognizing that the tribunal's Recommended Decision may require additional analysis to satisfy NEPA obligations, NMFS gave notice that it would also take the Recommended Decision into account in the SDEIS. The tribunal's decision also included a recommendation that NMFS set a low abundance threshold for ENP gray whales. This recommendation warranted additional analysis under NEPA, and so it was appropriate for NMFS to give notice to the public that the SDEIS would consider the tribunal's Recommended Decision.

Comment 50: AWI and another commenter contend that NMFS violated its hearing regulations and the MMPA by not completing the environmental analyses in the SDEIS before the formal rulemaking hearing.

Response: None of the procedural regulations governing this matter expressly reference supplemental draft environmental impact statements or require that this document be a part of the record before a presiding officer issues a recommended decision. The procedural regulations do reference draft environment impact statements in two places. First, NMFS was required to publish a notice of hearing under 50 CFR 228.4. In addition to other statements, the notice must state: "If a draft Environmental Impact Statement is required, the date of publication of the

draft and the place(s) where the draft and comments thereon may be viewed and copied.” 50 CFR 228.4(b)(6). NMFS complied with this requirement on April 5, 2019. 84 FR 13604. Second, under 50 CFR 228.16(b), the tribunal was required to introduce the “the draft Environmental Impact Statement” into the record at the “commencement of the hearing.” 50 CFR 228.16(b). The tribunal did this. Tab 101 at 11–12.

I do not interpret the term “draft Environmental Impact Statement” in 50 CFR 228.16(b) and 228.4(b)(6) to apply to any document other than a “draft Environmental Impact Statement.” The DEIS and SDEIS are separate documents. The DEIS was issued on March 13, 2015. 80 FR 13373. The SDEIS was issued on July 1, 2022. 87 FR 39517. That the title of the SDEIS includes the term “draft” does not mean the SDEIS and the DEIS are one and the same for the purposes of the hearing. Indeed, NEPA’s implementing regulations describe draft, final, and supplemental environmental impact statements separately. 40 CFR 1502.9. Since an SDEIS is not the same as a DEIS, the tribunal was not required to make this document a part of the record before rendering the Recommended Decision.

Furthermore, the commenters’ argument is not consistent with the structure of the procedural regulations. Sections 228.16(b) and 228.4(b)(6) of the procedural regulations apply at specific junctures in the waiver process. These provisions do not impose an ongoing obligation on NMFS to remand a case whenever NMFS supplements its environmental analyses in accordance with NEPA.

Section 103(d) of the MMPA is similar and only applies at a specific juncture in the waiver process. This section requires NMFS to “publish and make available to the public” certain scientific statements and studies “either before or concurrent with the publication of notice in the **Federal Register** of his intention to prescribe regulations under this section.” 16 U.S.C. 1373(d). Section 103(d) does not impose additional publication requirements on NMFS after the notice in the **Federal Register** announcing proposed regulations. NMFS complied with the requirements in section 103(d), by issuing a **Federal Register** notification on April 5, 2019. 84 FR 13604. This **Federal Register** notification also included the statements required by section 103(d). Nothing further is required.

The commenters are misconstruing specific procedural requirements that do not apply at this stage in the process

with the question of whether a remand is warranted. I explain why a remand is not warranted in section IX of this Final Decision.

Comment 51: Citing 40 CFR 1502.9(c)(4) (1978), one commenter contends that NEPA regulations required NMFS to publish an SDEIS before the hearing.

Response: The 1978 NEPA regulations provide that agencies shall “shall prepare, circulate, and file a supplement to a statement in the same fashion (exclusive of scoping) as a draft and final statement unless alternative procedures are approved by the Council.” 40 CFR 1502.9(c)(4). This language means that the same NEPA procedures applied to the development of the SDEIS as applied to the development of the DEIS. In accordance with this requirement, NMFS prepared an SDEIS, filed the SDEIS with the EPA, published the SDEIS, and sought public comment on the SDEIS. 87 FR 39517, July 1, 2022; 87 FR 39804, July 5, 2022.

Comment 52: AWI comments that the “Assistant Administrator cannot unilaterally consider extra record evidence in making her waiver decision that was not subject to rebuttal or cross examination at a formal hearing before the presiding officer.”

Response: All evidence forming the basis for my decision was on the record as provided by the governing APA provisions and implementing regulations. I explained how AWI’s rights to submit rebuttal evidence and conduct cross examination under the APA were vindicated in response to comment 48. NMFS published additional documents related to this rulemaking after the hearing was held pursuant to obligations under NEPA, the ESA, and other Federal law and provided opportunities for comment. AWI has taken advantage of all the opportunities for comment that were available after the hearing, and I have taken their comments into consideration.

Comment 53: AWI comments that in “the interest of a fair and impartial hearing process,” the Assistant Administrator should have remanded the Recommended Decision to the tribunal until the SDEIS was completed “and reopen the record for further factual development in accordance with the MMPA and APA.”

Response: As explained in section IX of this Final Decision, I considered whether a remand was warranted and have decided not to remand the case because the additional information developed after the hearing is not significant enough to compel different conclusions than those I have reached

based on the evidence in the record assembled by the tribunal.

Comment 54: One commenter suggests that the Recommended Decision is at odds with the fundamental requirement of NEPA to lead to informed decision because it was not rendered based on the information in the SDEIS.

Response: As explained in my responses to comments 50 and 51, the SDEIS was not required to be part of the record before the tribunal. As noted in section IX of this Final Decision, the SDEIS and FEIS informed my decision on whether a remand was warranted. Using the SDEIS and FEIS in this way is consistent with NEPA.

Comment 55: Citing sections 101(a)(3)(A) and 103(d), one commenter suggests that the parties are entitled to request a hearing to consider the new evidence in the SDEIS.

Response: Nothing in these sections of the MMPA specifically address rehearings or remands for additional evidence. For the reasons I explain in section IX of this Final Decision, a remand is not warranted.

Comments on the Implementing Regulations

Comment 56: A number of comments were received on specific changes to the proposed regulations. This included, among others, comments on restructuring and clarifying the regulations, an abundance threshold for ENP gray whales, data availability, prohibitions, and hunt management.

Response: I have addressed changes to the regulations in section VII of this Final Decision. A low abundance threshold for ENP gray whales is addressed in comment 12. Comments not specifically addressed in section VII of this Final Decision are addressed in this section.

Comment 57: Commenters expressed concern that the Makah Tribe would commercialize the hunt, noting there is a market for whale meat. Another comment indicated that the Recommended Decision’s provisions on the use of edible and non-edible parts clearly identify how gray whale products can be used and by whom.

Response: The regulations issued in this document prohibit selling, offering for sale, or purchasing any gray whale products, except Makah Indian handicrafts that have been marked and certified.

Comment 58: One commenter suggests a clause requiring that the United States and Canadian management teams communicate gray whale data to ensure an accurate gray whale count. Another commenter noted

the tribunal's Recommended Decision does not acknowledge that ENP gray whales are transboundary, is written as if the United States has unilateral authority over the management of gray whales, and disregards the assessment by COSEWIC.

Response: NMFS works closely with our international partners on marine mammal management and science to help ensure the best scientific data are available. This close collaboration obviates the need for a requirement to communicate in these regulations. The Recommended Decision acknowledges that gray whales are transboundary stock within multiple management jurisdictions (see, for example, RD at IV.D.1.b, VI.A.2), and it reflects the assessment by COSEWIC (see RD at 62–67).

Comment 59: AWI recommends that the Assistant Administrator consider imposing geographic restrictions on where consumption is allowed and ensure that law enforcement jurisdictions are properly educated on the regulations. AWI recommends NMFS consider limiting the geographic scope to Washington State given the Recommended Decision accepted NMFS's assertion that NOAA Office of Law Enforcement agents or Washington Department of Fish and Wildlife officers would be available to enforce these provisions.

Response: I disagree that further restrictions are needed to facilitate enforcement. The NOAA Office of Law Enforcement has jurisdiction beyond Washington State and works closely with states through joint enforcement agreements throughout the country to help ensure compliance with laws administered by NMFS.

Comment 60: AWI suggests amending § 216.116 to specify that the 2 pound per person limit applies to all circumstances in which edible whale products may be consumed outside of reservation boundaries.

Response: There is no 2-pound limit at Tribal members' residences to accommodate storage of edible gray whale products.

Comment 61: AWI suggests that § 216.113 should specify that if the Tribe has not complied fully with the regulations and all prior permit terms and conditions, a hunt permit should not be issued.

Response: The regulations specify the "Regional Administrator must determine that the Makah Indian Tribe has complied with the requirements of these regulations and all prior permit terms and conditions, or if the Makah Indian Tribe has not fully complied, that it has adopted measures to ensure

compliance." The appropriate response to non-compliance depends on the nature of the infraction and will be addressed if an infraction occurs.

Comment 62: AWI suggests adding "will be reported as an infraction to the International Whaling Commission" to § 216.115(b)(4) Unauthorized strikes.

Response: I disagree that this language is necessary. NMFS will comply with all reporting requirements of the IWC should an unauthorized strike occur.

Comment 63: One commenter suggests that § 216.118(a)(1) be amended to specify "For every whale struck, the tribal hunt observer must make every reasonable attempt to collect samples for genetic sampling as quickly as possible without compromising the safety of the hunt."

Response: As described in section VII of this Final Decision, I have clarified that individuals authorized to collect biological samples for identification must make every reasonable attempt to do so without compromising the safety of the hunt.

Other Comments

Comment 64: Several commenters suggest that the Tribe does not have a cultural or subsistence need for whale products and non-lethal alternatives should be considered to maintain the cultural connection to marine mammals. Other commenters recognize the relationship between the Tribe and whales, their cultural traditions, and the importance of resuming a whale hunt.

Response: I defer to the Tribe on their cultural and subsistence needs. Although whaling may seem outdated to some people, the Makah Tribe, as a sovereign nation, decides which cultural traditions it pursues, within the bounds of applicable law. In the Treaty of Neah Bay of 1855, the Makah Indian Tribe secured the right to hunt whales. Treaties with Indian Tribes are Federal law, coequal with all other Federal law. Pursuant to obligations under NEPA, NMFS considered non-lethal alternatives in the FEIS and, for the reasons described therein, rejected those alternatives.

Comment 65: Some commenters suggest that the issuance of a waiver will affect international relations and potentially have precedential effects on whaling in the United States and worldwide.

Response: The decision to waive the take moratorium is specific to the request submitted by the Makah Tribe and is consistent with the approval they already received from the IWC, first approved in 1997, to hunt ENP gray whales. For roughly 20 years, the Makah Tribe has not been able to use their

portion of the IWC quota due to the need to comply with MMPA procedures, and as a result, the Makah's quota was temporarily provided to Chukotkan Natives in the Russian Federation. Section 103(b)(2) requires NMFS to consider international treaties and agreements, not international relations, in making a determination to waive the moratorium on take. NMFS did examine the potential for authorization of a gray whale hunt to have precedential effects on hunts for marine mammals in the United States and whaling worldwide in the DEIS. Tab 90F at 4:260–273.

Comment 66: Several commenters express concern about the safety of consuming whale meat and the danger consumption poses to public health.

Response: The FEIS presents the available information regarding the nutrients and contaminants found in gray whale products. This information is available to the Makah Tribe for consideration when assessing the potential risks of consuming gray whale blubber.

Comment 67: PCPW comments that the WNP and PCFG are similar "whale stocks" (e.g., small population size, different migratory patterns and feeding habits, genetic differences) but are viewed and managed differently.

Response: WNP gray whales are a depleted stock under the MMPA and listed as endangered under the ESA; PCFG gray whales are a feeding aggregation within the more abundant ENP stock (see RD at IV.D). While both the WNP and PCFG populations are small relative to the overall abundance of ENP gray whales, there are a number of differences that warrant different management.

Comment 68: One commenter notes that the phrase "best available science" is used repeatedly throughout the tribunal's Recommended Decision, that the term needs to be defined, and the term "independent" should perhaps be part of that.

Response: Sections 101(a)(3)(A) and 103(a) of the MMPA require the use of the best scientific evidence available in this proceeding. The Recommended Decision describes this standard, the available scientific information, and how it was considered (see RD IV.B.). I agree with the discussion of these issues in section IV.B of the Recommended Decision.

Comment 69: PCPW references a United Nations' report that recognized the importance of animal culture in conservation, indicating that the report finds that different social groups within a species deserve special protection. PCPW suggest that the PCFG are more

than a feeding group and are a cultural group.

Response: It is not clear what report PCPW is referencing, and no report was provided. Under the MMPA, the PCFG are a feeding aggregation within the ENP stock of gray whales. The regulations include a number of measures to minimize impacts to the PCFG.

Comment 70: PCPW comments that NMFS “speculates” on the behavior of whales in different locations, and conditions, and questions the evidence used to support the conclusions drawn.

Response: NMFS has drawn reasonable conclusions and adopted a conservative management framework for the Makah hunt based on the best available scientific evidence. The parties opposing the hunt have had numerous opportunities to rebut the evidence NMFS relied on in support of the waiver and implementing regulations but have failed to provide better scientific information that undermines the data and analysis on which NMFS relies.

Comment 71: A number of individual commenters expressed general disagreement with the Recommended Decision. PCPW and AWI are generally opposed to the Recommended Decision.

Response: I have largely affirmed the Recommended Decision. Sections VII through VIII of this Final Decision describe where I have/have not affirmed the Recommended Decision.

Comment 72: A number of commenters noted that the requirements for a waiver have been satisfied, expressed general support for the Recommended Decision, and commented that it was based on the best available science. WCR, MMC, and the Makah Tribe generally support the Recommended Decision.

Response: I have generally affirmed the Recommended Decision and adopted it as part of this Final Decision, except as explained herein.

Comment 73: Commenters note that more recent information has been published (e.g., ENP abundance) since the Recommended Decision. Another commenter notes that estimates of the OSP range may have changed.

Response: Additional scientific information and analysis developed following the Recommended Decision is discussed in section IX of this Final Decision.

VI. Measures in the Final Regulations

This section provides a general overview of the regulations governing the hunt. As described in Section II of this Final Decision, two key management goals shaped many of the provisions in the proposed and final

regulations: (1) ensuring that hunting does not reduce the ENP gray whales' PCFG abundance below recent stable levels and (2) limiting the likelihood that Tribal hunters would strike or otherwise harm a WNP gray whale.

Management measures in the final regulations include:

- *Alternating Hunt Seasons:* Winter/spring hunts would occur during the migration season (December 1 through May 31) to reduce risk to PCFG whales, which are more prevalent in the U&A in the summer and fall during their feeding season. Summer/fall hunts would occur during the feeding season (July 1 through October 31) to reduce risk to WNP whales, which are only known to occur in the U&A during the migratory season. There would be a 1-month gap after a summer/fall hunt and a 13-month gap after a winter/spring hunt.

- *Maximum Annual Strike Limits:* A maximum of three strikes may be authorized during winter/spring hunts and two during summer/fall hunts. Thus, up to 25 whales may be struck or struck and lost over the 10-year waiver. Unsuccessful strikes are not counted against this limit.

- *Maximum Struck and Lost Limits:* A hunt permit may authorize no more than three gray whales to be struck and lost in any calendar year.

- *Maximum PCFG Mortality Limits:* Over the 10-year waiver period, no more than 16 PCFG whales may be struck. Of these, no more than 8 may be female PCFGs. NMFS will, taking into account the abundance of PCFG whales, notify the Tribe prior to the beginning of a hunt season of the maximum number of PCFG whales, including females, that may be struck during the upcoming hunting season.

- *Maximum Annual Landing Limits:* A hunt permit may authorize landing (i.e., bringing a gray whale or any products thereof onto the land) no more than three whales during winter/spring hunts and one whale during summer/fall hunts. That is, no more than 20 whales can be landed over the waiver period.

- *Maximum Annual Limits on Unsuccessful Strike Attempts:* Unsuccessful strike attempts are any attempt, including training harpoon throws, to strike a gray whale while hunting that does not result in a strike. A hunt permit may authorize no more than 18 unsuccessful strike attempts during winter/spring hunt and no more than 12 unsuccessful strike attempts during summer/fall hunts.

- *Maximum Annual Approach Limits:* A hunt permit may authorize no more than 353 approaches, including both hunting and training approaches,

each calendar year, of which no more than 142 may be on PCFG whales.

- *PCFG Abundance Trigger:* No hunting will be authorized for an upcoming season if the most recent PCFG population estimate or the projected estimate for the upcoming hunt season is less than 192 whales or the most recent or projected minimum abundance estimate is less than 171 whales.

- *ENP Low Abundance Thresholds:* Hunting ceases if the ENP abundance falls below the stock's OSP.

- *Take of WNP whales:* Prior to permitting hunt activities in the winter/spring hunt season, NMFS must determine if take of WNP whales is anticipated and, if so, must include a condition in the permit requiring separate take authorization for WNP gray whales during the winter/spring hunt. If a WNP whale is accidentally killed during a hunt, hunting must cease until measures are put in place to prevent any further activity that could result in another lethal take of a WNP gray whale.

- *Accounting and Identification of Gray whales:* The final regulations establish procedures to determine whether a gray whale approached or struck is a WNP, PCFG, or non-PCFG gray whale, or cannot be identified. If a gray whale cannot be identified, the regulations include measures for presuming the whale to be a PCFG whale.

- *Management of Handicrafts:* The final regulations include marking and certification requirements for handicrafts as well as measures to regulate when handicrafts may be shared, bartered, traded, or sold.

- *Monitoring, Reporting, and Recordkeeping:* Certified Tribal hunt observers must accompany each hunt and maintain hunt logs, including information on approaches, attempted strikes, and strikes. The Tribe is required to submit an incident report within 48 hours of a gray whale being struck, a hunt report at the end of each season, an annual approach report, and an annual handicraft report. After receiving an incident report documenting that eight gray whales have been struck, NMFS will evaluate the photo-identification and notification requirements and the humaneness of the hunt.

VII. Changes to Final Regulations

The tribunal recommended changes to the proposed regulations, which are described in the Recommended Decision and Appendix B to the Recommended Decision. Changes made to the regulations described in

Appendix B to the Recommended Decision are described in this section of this Final Decision.

In sections V.II.B to C of the Recommended Decision, the tribunal recommended certain modifications to the proposed regulations and addressed an unopposed motion to amend the regulations to clarify the definition of strike and expand certain off-reservation use of edible gray whale products. I agree with and affirm the recommendations in sections V.II.B to C of the Recommended Decision as part of this Final Decision, with the exceptions noted below.

Section 216.112 Definitions

I redefined the odd-year hunt as the summer/fall hunt and the even-year hunt as the winter/spring hunt. This change was made to allow the initial hunt permit to start in either season regardless of whether the permit was issued in an odd or an even year, providing flexibility in the timing of the initial hunt season. Use of the “odd-year”/“even-year” language might inadvertently and unnecessarily restrict the time that a hunt could commence upon receipt of all necessary authorizations. This change maintains the alternating year structure of the regulations but allows for a hunt permit to be issued at the earliest possible time. This change does not affect the hunt structure (e.g., number of hunts that may be permitted, months in which hunting can occur, and the gap between hunt seasons) and, therefore, has no impact beyond what was considered in the proceedings. This is also consistent with the tribunal’s recommendation that the odd-year (summer/fall) hunts be allowed to commence at the soonest appropriate time. RD at 148.

I slightly modified the definitions of “strike” and “struck” for clarity. Prior to the hearing, WCR filed a motion to clarify, in response to AWI’s argument that the definition was ambiguous, that multiple strikes on the same whale would count as a single strike. Tab 86. The tribunal recommended that the regulations adopt WCR’s amendments and also specify “Once a whale is struck, subsequent penetrations of the same whale’s skin during the hunt for the purpose of killing or landing that whale are considered to be part of the initial strike.” RD at 141. I have adopted this recommendation with a slight modification. In their comments on the Recommended Decision, the Makah Tribe questioned whether this additional sentence may create confusion, and they believe it is unnecessary. They noted that it is unclear whether subsequent harpoon

strikes to attach floats to keep the whale at surface would be “for the purpose of killing or landing the whale.” The Tribe recommended the language be simpler, such as “Multiple strikes on the same whale are considered a single strike.” I agree with the Makah Tribe and have adopted their recommendation.

I have added definitions of “export” and “share.” The regulations recommended by the tribunal include provisions related to export of and sharing of gray whale products; therefore, I added a definition of export and share to provide clarity. “Export” in the regulations mean “the act of sending goods from one country to another.” The definition of share includes “gift” and is similar to how gift was defined in the preamble to the proposed regulations (i.e., voluntarily transfer to another person without compensation). 84 FR 13604, April 5, 2019. Therefore, I changed instances of the term “gift” to “share” in the final regulations for consistency.

Section 216.113 Issuance and Duration of Permits

I have added a requirement at § 216.113(a) that the Makah Tribe specify the proposed duration of the permit in its application. The duration of the initial permit and subsequent permits can be up to 3 years and 5 years, respectively. This addition will provide clarity on the permit duration sought by the Tribe. I have also added requirements that the Makah Tribe, in its application for a hunt permit, must include any permit conditions they propose and a justification for the proposed conditions. In addition, if the Tribe is seeking a modification from any of these regulations, the Tribe must specify the modification and the justification for that modification. Modifying the regulations through informal rulemaking may be possible and could be carried out in conjunction with permitting.

I have specified at § 216.113(b)(2) that the Regional Administrator may not authorize hunting, hunting approaches, training approaches, or training harpoon throws from December 1 through May 31 unless: (1) the Tribe has obtained separate authorization under the MMPA or (2) the Regional Administrator, in consultation with the Office of Protected Resources, has determined take of WNP gray whales is not anticipated. My rationale for adding this provision is described in section VIII of this Final Decision. The tribunal recommended that the final regulations include provisions that require that the Tribe obtain an ITA prior to authorizing hunt activities when WNP gray whales may

be present. RD at 136–137. However, the Tribe may include in their permit application a hunt plan that avoids the take of WNP whales, in which case an ITA is not necessary. This change provides flexibility for NMFS to evaluate the Tribe’s permit application and make the determination whether or not an ITA is needed based on the best available science at the time, rather than the information presented during the formal rulemaking hearing in 2019.

The tribunal concluded that the evidence weighs in favor of an overall abundance threshold and recommended the Secretary consider setting one in the final regulations. RD at 150–151. I have included an abundance threshold at § 216.113(b)(3) prohibiting lethal hunting unless the stock is within its OSP and requiring the Regional Administrator to ensure the stock is within OSP before issuing a hunt permit. The Regional Administrator is also required to ensure that the level of hunting authorized under the permit will not cause the stock to fall below its OSP.

Section 216.114 Hunt Management Requirements and Restrictions

Where appropriate, I have added “ENP” before gray whales to clarify that the hunt permit may only authorize take of ENP gray whales. The two hunt seasons (described as odd- and even-year hunts in the proposed rule and the Recommended Decision) are carried over into the final rule and have been renamed to summer/fall and winter/spring. I have provided additional clarity on the alternating hunt structure under § 216.114(a) by articulating when hunts may be authorized based on whether the initial hunt season permitted is a summer/fall or winter/spring.

Unsuccessful strike attempt limits at § 216.114(b) are carried over from the proposed rule and Recommended Decision, and training harpoon throws continue to count against the unsuccessful strike attempt limits. Under the Recommended Decision, training harpoon throws could be authorized between July 1 and October 31 in odd-number years and in any month in even-number years. The final regulations maintain the alternating pattern but decouple it from the even and odd year framework.

The final regulations specify that training harpoon throws may be authorized between July 1 and October 31 in years of summer/fall (previously odd-year) hunts and at any time during winter/spring hunts as well as the subsequent 7 months of the calendar year in which those winter/spring

(previously even-year) hunts occur. Under the proposed regulations, as an artifact of the even/odd year structure, training harpoon throws could not be authorized in December of the winter/spring hunt. There could be unsuccessful strike attempts in December, but those unsuccessful strike attempts could not be training throws. The final regulations allow training throws to be included within the unsuccessful strike attempts in December without changing the unsuccessful strike attempt limits. Unsuccessful strike attempts could occur in December of winter/spring hunts under the Recommended Decision, so this change does not change the impacts to gray whales or other ecosystem components. Rather, these changes provide flexibility when authorizing hunt seasons and training harpoon throws while maintaining the intent of the structure of the Recommended Decision.

I have also added a requirement, specified at § 216.114(d), that hunting must cease when the Makah Tribe is notified in writing that the ENP gray whale stock has fallen below its OSP. Hunting may not resume until the Tribe is notified in writing that the stock has obtained OSP. This provision is consistent with the tribunal's recommendation to specify a low abundance threshold below which hunting would cease. RD at 150–151.

Section 216.115 Accounting and Identification of Gray Whales

AWI commented on the importance of identifying gray whales subjected to hunt activities and suggested adding a provision that every reasonable effort should be made to collect genetic samples. Accounting and identification of gray whales are important to monitoring the hunt and, as such, the WCR included requirements for accounting and identification of gray whales in the proposed rule. As specified in § 216.115(b), genetic data may be used in the identification and accounting of gray whales. Thus, I have specified in § 216.115(a) that personnel authorized by NMFS to collect biological samples must make every reasonable attempt to collect samples for genetic testing from struck whales without compromising the safety of the hunt. This addition makes clear that such personnel should make every reasonable effort to collect biological samples but should not put themselves or the Tribal hunters in an unsafe situation.

Section 216.116 Use of Edible and Non-edible Whale Products

I added “shared for” before “consumption” in § 216.116(a)(1)(ii)(A) to clarify this requirement. I added “transport” to § 216.116(a)(1)(iii) as this omission was an oversight and the change aligns the authorization with the corresponding prohibitions in § 216.117.

Section 216.117 Prohibited Acts

The tribunal recommended prohibiting approaches on gray whale calves or adult gray whales accompanying calves, in addition to the proposed prohibitions on strikes and training throws. RD at 154. Accurately identifying a calf at 100 yards (91.5 m) can be complicated by the whale's behavior, the observer's experience, and the environmental conditions. The Makah Tribe commented, in part, that this recommendation, if adopted, could lead to an inadvertent violation of regulations. To address this recommendation while ensuring the regulations do not set unrealistic expectations on the whaling crew or result in inadvertent noncompliance, I have amended the regulations at § 216.117(a)(6) and (7) to prohibit approaches on calves or adult gray whales accompanying calves only after a member of the whaling crew has identified a calf or adult accompanying a calf.

I have also added a prohibition at § 216.117(a)(14) on hunting after notification by the Regional Administrator that the ENP gray whale population has fallen below OSP. This addition aligns the requirements under § 216.113(b)(3) and is consistent with the tribunal's recommendation to include a low abundance threshold. RD at 150–151.

To the exceptions on prohibited use at § 216.117(a)(19)(ii), I clarified that “a product that has been fashioned into a Makah Indian handicraft” includes both products that have been marked and certificated per the regulation and those that have not. I clarified the language in § 216.117 related to the use of edible and non-edible gray whale parts. I changed “gift” to “share” for consistency.

I added “consume” to § 216.117(b)(2) as this omission was an oversight and the change aligns the prohibition with the corresponding authorization in § 216.116(a)(3). In § 216.117(b)(6), I clarified the exception by referring to § 216.116(a)(2)(iii) and (iv), which corresponds to the use authorizations for handicrafts for any person who is not an enrolled member of the Makah Indian Tribe.

I have clarified § 216.117(b)(6) by removing the text “unless the product has been fashioned into a Makah Indian handicraft and was shared by or with, or bartered from or to, an enrolled member of the Makah Indian Tribe” and, instead referencing § 216.116(a)(2)(iv).

Section 216.118 Requirements for Monitoring, Reporting, and Recordkeeping

I amended § 216.118(a)(1) to clarify that the certified Tribal hunt observer *must make every reasonable attempt* to collect digital photographs of every whale approached in response to comments on the Recommended Decision. This change makes clear that hunt observers are not required to put themselves or the Tribal hunters in an unsafe situation to collect digital photographs.

Section 216.119 Expiration and Amendment

I clarified that the waiver period begins the first day of the first season after issuance of the initial hunt permit. I also added a provision to allow for a split hunt season. If the initial hunt season is not authorized for the full duration (either December 1 through May 31 if a winter/spring hunt or July 1 through October 31 if a summer/fall hunt), the remainder of the season may be authorized during the final year of the waiver period. This provision will allow flexibility if the initial permit is issued part way through a hunt season.

VIII. Application of the Statutory Criteria to the Final Waiver and Regulations

The final regulations and waiver maintain the core elements included in the proposed regulations (84 FR 13604, April 5, 2019) and Recommended Decision. These include the alternating hunt season to minimize impacts to WNP and PCFG gray whales; limits on the number of whales harvested, struck, and struck and lost; additional limits on harvest and mortality of PCFG whales; a hunt permit structure that allows for adaptive hunt management; limiting the waiver to only 10 years; and numerous monitoring requirements. The Recommended Decision suggested several modifications to the proposed regulations. The most significant suggestions included specifying an abundance threshold for ENP gray whales below which hunting would not be permitted and requiring that the Tribe obtain an ITA for WNP gray whales prior to permitting winter/spring hunt activities. Other recommendations included reorganizing the structure of

the regulations, clarifying definitions, and explicitly prohibiting approaches on gray whale calves or adult gray whales accompanying calves.

The final regulations maintain the core elements from the proposed waiver and regulations and the Recommended Decision and adopt the tribunal's recommendation regarding a low abundance threshold for ENP gray whales. Based on the tribunal recommendations, the final regulations also include protections for gray whale calves and adults accompanying calves and provisions to ensure that take of WNP whales, if it is anticipated during the permitting process, is separately authorized. The specific changes from the proposed regulations are described in detail in section VII of this Final Decision.

The Final Decision on the waiver and implementing regulations “may affirm, modify, or set aside, in whole or in part, the recommended findings, conclusions and decision of the presiding officer” and must include “[f]indings on the issues of fact with the reasons therefor; and [r]ulings on issues of law.” 50 CFR 228.21(a) and (b). The final waiver and regulations are largely consistent with the proposed regulations and the Recommended Decision. Therefore, I affirm the findings on issues of fact and rulings on issues of law described in the Recommended Decision as part of this Final Decision, except as set forth herein.

Threshold Determinations

As part of the Recommended Decision, the tribunal made findings and rulings regarding the best scientific evidence available standard, the credibility and utility of the scientific evidence in the record, consultation with the MMC, and gray whale stock structure. The tribunal also summarized the parties' arguments and public comments. I agree with the Recommended Decision's treatment of these issues in section IV.B through D and section V. Accordingly, I affirm these sections of the Recommended Decision for the reasons explained therein as part of this Final Decision. I also find that additional consultation with the MMC occurred through the public comment period on the Recommended Decision, which ran from September 29 to November 31, 2021, and the additional comment and response period for the parties from November 27, 2023, to January 17, 2024.

I am not affirming sections I through III, the beginning of section IV (pages 25–27), or section VI.A of the Recommended Decision. Sections I and II of the Recommended Decision

provide a Statement of the Proceeding, Background, and Procedural History. I have addressed these issues in sections I and II of this Final Decision. Section III of the Recommended Decision is a summation of findings included in sections IV through VIII of the Recommended Decision. I have not adopted the summations in section III; rather I have adopted the actual findings in sections IV through VIII of the Recommended Decision as appropriate.

I am not affirming the beginning of section IV, which provides an overview of MMPA requirements, because this Final Decision explains the relevant requirements. I am also not adopting section IV.A of the Recommended Decision because it discusses the tribunal's jurisdiction in rendering the Recommended Decision. Although I agree with the tribunal's assessment of its jurisdiction, it is different from my jurisdiction in rendering this Final Decision. Finally, I am not adopting the Recommended Decision's statements (quoted above at the end of section IV) suggesting that the Treaty of Neah Bay of 1855 has no bearing on this proceeding.

Due Regard for the Biological Factors

Section 101(a)(3)(A) of the MMPA requires NMFS to give due regard to the “distribution, abundance, breeding habits, and times and lines of migratory movements” of the stock under consideration—here, ENP gray whales. The tribunal concluded that NMFS satisfied that requirement, and I agree.

Distribution

The tribunal determined the distribution for ENP and PCFG gray whales would not be affected by the waiver and proposed regulations. RD at 88–93. It found the hunt will not have a significant, lasting, or detrimental effect on the distribution of PCFG whales. RD at 93. It based that determination, in part, on the facts that the hunt area comprises approximately 1 percent of the lineal distance of the whole ENP range; approximately 4 percent of the lineal range of the designated PCFG range; that there is no evidence that the hunt activities will prevent the ENP stock from maintaining its distribution, including during migration; and that the majority of ENP individuals may never encounter a Makah hunter. *Id.* at 91. I agree with section VI.A.1 of the Recommended Decision and affirm it as part of this Final Decision with one minor exception. On page 85 of the Recommended Decision, the month of April should be substituted with the month June and the term “consecutive”

should be deleted for the following statement to be accurate: “In order for a whale to be designated as part of the PCFG, it must be identified as being in the PCFG range between April 1 and November 30 of two consecutive years.”

Abundance

The tribunal analyzed the impact of the hunt on the abundance of ENP and PCFG gray whales. RD at 103–105. The Recommended Decision explains: “A successful hunt will inevitably reduce the number of living gray whales. However, at a population level, the removal of approximately 2.5 whales per year (assuming the Makah Tribe takes the full number of whales allowed) would not significantly affect the ENP stock.” *Id.* at 103. Regarding the effect of the Chukotkan hunt, the tribunal explained:

Under the most recent IWC quota for aboriginal subsistence hunting, 980 gray whales may be taken by Russia and the United States over seven years, which equates to 140 whales per year. Either country may yield their share of the quota to the other if it is unused. (*Id.* at 92:18–24). Consequently, regardless of whether the Makah hunt goes forward, the overall number of ENP whales taken under the IWC catch allowance is unlikely to be significantly affected.

Id. at 95. Addressing the effects of the UME, the tribunal concluded: “the best available scientific evidence is the UME should not preclude issuance of a waiver,” but also found “the regulations may warrant modification to further limit hunting activities during an active UME or if the stock does not rapidly recover from a UME.” *Id.* at 103.

I agree with section VI.A.2 of the Recommended Decision for the reason explained therein and affirm it as part of this Final Decision. However, I will expand on and clarify the role of some of the findings in my Final Decision. In the Recommended Decision, the tribunal found:

The 2018 SAR estimated the population of ENP gray whales to be 26,960. (Tab 54D at 3; *see also* Tab 101 at 90:20–21; Tab 1H at 13). While the population estimates are subject to a certain level of uncertainty, researchers believe with 95% certainty that the true abundance in 2015/2016 was between 24,000 and 30,000 whales. Most recently, the ENP stock is estimated at 85% of carrying capacity, with an 88% likelihood that the stock is above its MNPL (*Id.*). The PBR for the ENP stock is 801 animals, and in 2018 the number of human-caused mortalities among the stock was estimated at 139 animals. (Tab 101 at 91:9–11).

RD at 95. These findings clearly show that the ENP gray whales population is capable of attaining OSP. Looking at the population trends since 1994, it is also

clear that the population is subject to significant periodic declines in its abundance and has experienced two UMEs. Tab 1H at 15; Tab 117 at 5–6.

In giving due regard to abundance, I have focused on the stock's long-term population dynamics, rather than the specific abundance estimate in any given year. Since 1967, NOAA has conducted surveys of the ENP gray whale populations. Tab 3 at 11. These surveys show the ENP gray whale population experiences periods of significant decline followed by population growth. Significant declines occurred in the late 1980s, and multi-year UMEs were declared in 1999 and 2019 due to increased strandings. Tab 1H at 15; RD at 98. The population also experiences periods of growth, including rebounds in the population following each of the prior declines. For example, the abundance estimate of 26,960 in 2015/16 represents a 22 percent (5970 whales) increase in the 5 years since the 2010/11 estimate of 20,990. Tab 1H at 15. Overall, the population nearly doubled in size over the first 20 years of monitoring and has fluctuated for more than 30 years. Tab 62B at 163.

I agree with the tribunal that the removal of 2.5 ENP gray whales, on average, would not significantly affect the population. RD at 103. It is improbable that the removal of such a small fraction of a percentage of the stock's abundance would have an appreciable effect on the ENP gray whales abundance or rate of growth. This level of removals would have no effect on the ENP gray whale abundance related to OSP. Furthermore, it is likely that the net effect to ENP gray whale abundance is the same with or without a Makah Tribal hunt. It is important to remember that under a bilateral agreement with the Russian Federation, the United States has routinely transferred its unused IWC quota for ENP gray whales to the Russian Federation. Tab 3 at 5. Chukotkan hunters have used and, at times, exceeded the IWC quota. Tab 60 at 6. While it cannot be known with certainty that the Chukotkan Natives would harvest the entire quota of 140 ENP gray whales per year, they have harvested as many as 143 whales in a year. Tab 60 at 6–7. With this waiver, the Makah Tribe can use their allotment for ENP gray whales rather than transfer it to the Russian Federation, and there will be no change in the number of ENP whales that can be harvested under the quota authorized by the IWC.

Breeding Habits

The tribunal determined the breeding habits for ENP and PCFG gray whales would not be meaningfully disrupted by the waiver and proposed regulations. RD at 132. The tribunal found no evidence to suggest that the hunt will prevent whales from breeding. *Id.* at 106–107. It noted any disruptions to whales “would be limited in scope” due to the relatively small area the U&A encompasses and that “there was no evidence to suggest approaches or training harpoon throws would prevent whales from mating.” *Id.* I agree with section VI.A.3 of the Recommended Decision and affirm it as part of this Final Decision.

Time and Lines of Migratory Movements

The tribunal determined that the times and lines of migratory movement for ENP and PCFG gray whales would not be meaningfully affected by the waiver and proposed regulations. RD at 132. It based that determination on the facts that “only a few migrating whales would encounter Makah hunters on any given day” during their southbound migration and that “there is no credible evidence that the whales encountered during a hunt will cease migration or change their migratory path in future years to avoid the hunt.” RD at 111–112. The tribunal found that northbound whales may be more likely to encounter Makah hunters for several reasons, but the evidence does not show that the hunt will cause northbound non-PCFG ENP whales to slow, halt, or otherwise vary their migration. *Id.* at 112. The tribunal further explained: “There is also no evidence gray whales will desert the Makah U&A entirely as a result of the hunt, particularly bearing in mind that it will only occur during the feeding season in alternate years.” *Id.* at 112. I agree with section VI.A.4 of the Recommended Decision and affirm this section as part of this Final Decision.

Conclusion on Biological Factors

The tribunal concluded that NMFS has complied with its duties under the MMPA to consider the hunt's effects on the ENP stock's distribution, abundance, breeding, and times and lines of migratory movement and relied on the best available scientific evidence. RD at 112. I agree with and affirm section VI.A.5 of the Recommended Decision as part of this Final Decision.

Required Assurances

In addition to giving due regard to the enumerated biological factors, I must also be “assured” that the taking of ENP gray whales under the final waiver and regulations “is in accord with sound

principles of resource protection and conservation as provided in the purposes and policies of this chapter.” 16 U.S.C. 1371(a)(3)(A). Section 2 of the MMPA describes purposes and policies of the Act. These include maintaining marine mammal stocks as a significant functioning element in the ecosystem of which they are a part, maintaining the health and stability of the marine ecosystem, and obtaining and maintaining an optimum sustainable population for marine mammal stocks keeping in mind the carrying capacity of the habitat. 16 U.S.C. 1361.

The Marine Ecosystem

For the reasons explained in section VI.B of the Recommended Decision, I am assured and find that ENP gray whales will continue to be a significant and functioning element of the ecosystem and that the health and stability of the ecosystem will be maintained under the final waiver and regulations. As the tribunal noted, NMFS has considered impacts at several levels including the California Current ecosystem, the northern California Current ecosystem, and the local environment. RD at 115–116. The tribunal concluded that the waiver will not result in gray whales ceasing to be a significant functioning element of the northern California Current ecosystem or the environment of the northern Washington coast given that these habitats are shaped by dynamic, highly energetic, large-scale processes, that the role of ENP gray whales in structuring these habitats is limited, and that the waiver and regulations are unlikely to result in an appreciable decrease in the numbers of gray whales present in the northern California Current ecosystem or the northern Washington coastal environment. *Id.* at 113–116. I agree with section VI.B of the Recommended Decision and affirm this section as part of this Final Decision.

OSP

I am assured and find that the final waiver and regulations are in accord with sound principles of resource protection and conservation related to obtaining and maintaining OSP for ENP gray whales. This is because the level of hunting authorized under the final waiver is so low that it will not have an appreciable effect on the overall population dynamics of ENP gray whales. Therefore, it will not affect the ability of the stock to obtain and maintain OSP. The waiver and final regulations could result in the death of a maximum of two whales in the summer/fall season and three whales in the winter/spring season, followed by a

13-month gap in hunting. Thus, the highest number of whales that could be killed, on average each year, over the 10-year waiver is 2.5. Under this structure, no more than 25 gray whales could be killed during the 10-year waiver period.

In evaluating a waiver application, it is appropriate to look at the abundance of the stock over time, including its lowest levels of abundance. Abundance surveys have been conducted since the late 1960s. Tab 3 at 11. During this time series, the lowest abundance estimate for ENP gray whales was roughly 11,000 animals in 1971/1972. Tab 1H at 15. Even if the stock drops to around 11,000 animals, hunting could still occur without affecting the ability of the stock to maintain OSP. If the stock were to drop to 11,000, the loss of 2.5 whales per year from the ENP stock would represent an average annual reduction of 0.02 percent. Twenty-five whales represent less than 0.3 percent of the population at 11,000. This level of mortality is a very small fraction of the annual variability of the stock's abundance (approximately 16,000 to 27,000 between the mid-1990s and 2019). Tab 3 at 19.

Under the MMPA, PBR is a key management measure that is useful in evaluating the effect of the hunt on OSP. PBR is "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." 16 U.S.C. 1362(20). The formula for PBR is set forth in the MMPA as the product of the following factors: "(A) The minimum population estimate of the stock. (B) One-half the maximum theoretical or estimated net productivity rate of the stock at a small population size [R_{max}]. (C) A recovery factor of between 0.1 and 1.0 [F_r]." *Id.*

Using the lowest abundance in the time-series (11,079 animals), an R_{max} of 0.062 and an F_r of 1, PBR would be 343. At an abundance of 11,000, PBR would be 341. However, there is uncertainty around the estimate of 11,079 from Laake *et al.* (2012). Tab 23LL at 15; Tab 1H at 15. The formula for the minimum population estimate in the GAMMs (see Tab 23TT) was used to account for this uncertainty, providing a more conservative estimate of the minimum population size. Laake *et al.* (2012) estimated the abundance of gray whales to be 11,079 animals (CV=0.093) in the 1971/72 season. Using this information and the formula for calculating the minimum population size in the GAMMs, the minimum population would be 10,246, and PBR would be

318. In both cases (*i.e.*, using the lowest abundance in the time series and then accounting for uncertainty in that value), the annual average mortality estimated from the Makah Tribe's hunt (2.5 individuals) is well below the number of animals that may be removed while allowing that stock to reach or maintain its OSP. The IWC quota shared between the United States and the Russian Federation (140 animals) is also significantly lower than PBR even at an abundance of 11,000.

Levels of human-caused mortality remain low relative to PBR. Estimates of human-caused mortality and serious injury, based on data from 2006–2018 and as reported in the SARs, averaged 127 to 139 ENP gray whales per year. Greater than 90 percent of the mortalities were from the Chukotkan hunt. Tabs 2F at 1; 2G at 14; 21M–0064 at 8; 54D at 163. PBR ranged from 558 to 801. Tabs 2F at 6; 2G at 10; 21M–0064 at 4; 54D at 160. That is, the number of human-caused mortalities and serious injuries are substantially less than the number that may be removed from the stock while allowing that stock to reach or maintain OSP.

Furthermore, the Russian Federation and the United States share the IWC quota for ENP gray whales, meaning any whales the Makah do not harvest will likely be harvested by Chukotkan Natives. Whether ENP gray whales are taken by the Makah or the Chukotka has no effect on the ability of the stock to attain and maintain OSP. The Russian Federation and the United States have submitted joint proposals to the IWC for an aboriginal subsistence whaling catch limit for ENP gray whales for the Chukotkan and the Makah since 1997, and the IWC has repeatedly established catch limits. Tab 90F at section 1.4.1.2.2; Tab 3 at 5. In September of 2018, the IWC approved the latest catch limit of 980 ENP gray whales for the period 2019–2025 with an annual cap of 140 whales. Tab 3 at 5. A separate bilateral agreement between the United States and Russian Federation sets overall and annual limits for the two countries. *Id.* The Makah Tribe are entitled to harvest no more than 5 whales per year under the agreement with the Russian Federation. This agreement also specifies that any country's unused quota may be transferred to the other. In past years, the United States has transferred its entire quota to the Russian Federation while NMFS completes the necessary steps under domestic law to consider the Makah Tribe's request for a waiver. *Id.* at 5–6. This practice would likely continue if the Makah do not harvest the whales set aside for them. For these

reasons, if ENP gray whales are not harvested by the Makah Tribe, they will most likely be harvested by Chukotkan Natives, meaning the hunt authorized under the waiver and final regulations will have likely no effect on the overall population of ENP gray whales and therefore no effect on the ability of the stock to obtain and maintain OSP.

The ENP stock has also proven highly resilient to sustained hunting. RD at 104, 116. The IWC reports 3,787 gray whales harvested from annual aboriginal subsistence hunts from 1985 to 2016, which includes struck and lost whales. The estimated population size of ENP gray whales increased during this same period. Tab 59B at 7. From 2012–2016, Chukotkan hunters harvested an average of 128 gray whales annually. Tab 81B at 162. This is approximately 51 times the projected average annual harvest of 2.5 whales that will occur under the Makah Tribe's hunt. The ENP gray whale population has already demonstrated resilience to decades of hunting by Chukotkan Natives, growing to approximately 27,000 individuals in 2016. Tab 3 at 11. This reinforces the determination that a Makah Tribal hunt, even when viewed in combination with the Chukotkan Native hunt, will not impact the ability of the ENP gray whale stock to attain and maintain OSP.

I have not adopted the tribunal's analysis in section VI.C of the Recommended Decision to provide the necessary assurance that the waiver is consistent with the purposes and policies of the MMPA related to attaining and maintaining OSP, except I agree with the statement that "the ENP have attained OSP and are likely to maintain it even if a limited number of whales are removed due to the Makah Tribe's hunt." RD at 116. The remainder of section VI.C of the Recommended Decision addresses issues related to WNP gray whales and PCFG gray whales. For the reasons explained in response to comment 1, an OSP analysis is not required for WNP gray whales to satisfy the statutory factors under section 101(a)(3)(A) of the MMPA. Nevertheless, I agree with certain aspects of the discussion in section VI.C of the Recommended Decision related to WNP gray whales and will adopt some of the findings to satisfy other statutory criteria, as set forth below in section VIII (*Risk to WNP Gray Whales*) of this Final Decision. Although issues related to PCFG gray whales are relevant under certain provisions of section 101(a)(3)(A) of the MMPA when evaluating a waiver application, an OSP analysis is not required for the PCFG in order to obtain the necessary assurance

that the waiver is in accord with the purposes and policies of the MMPA related to obtaining and maintaining OSP for marine mammal stocks because the PCFG is not a stock.

For the reasons explained in this section of the Final Decision, I am assured that the taking authorized under the final waiver and regulations will not affect the ability of the ENP gray whale stock to obtain and maintain OSP. Therefore, I am assured that the taking under the waiver is in accord with sound principles of resource management and protection in the purposes and policies of the MMPA related to attaining and maintaining OSP.

Consistency With the Section 101(a)(3)(A) of the MMPA

The tribunal addressed other concerns raised by the parties (including the implications of the decision in *Kokechik*, climate change, and impacts on scientific research) before concluding that NMFS has satisfied the statutory factors set forth in section 101(a)(3)(A) and that the waiver should be granted. I agree with sections VI.D–E of the Recommended Decision and affirm the findings and rulings contained therein as part of this Final Decision, except I am not affirming section VI.D.1, which addresses the decision in *Kokechik*. My views on the implications of *Kokechik* in this matter are described in the response to comment 31.

The Final Regulations

The final regulations implementing a waiver must satisfy additional criteria set forth in section 103 of the MMPA. Some of these requirements are quite similar to the requirements related to the waiver determination under section 101(a)(3)(A). For example, both the regulations and waiver require consultation with the MMC, a decision based on the best available scientific evidence, and an evaluation of the purposes and policies in section 2 of the MMPA.

Under section 103(a), I must “insure” regulations implementing taking under a waiver will not disadvantage the ENP stock—a requirement often referred to as the disadvantage test. NMFS’s long-standing interpretation of the disadvantage test is that it relates to the impact of take on OSP. 45 FR 72185, October 31, 1980.

Pursuant to section 103(b), I must also give full consideration to all factors that may affect the extent to which the ENP stock may be taken. This includes five enumerated considerations: (1) existing and future levels of marine mammal species and population stocks; (2)

existing international treaty and agreement obligations of the United States; (3) the marine ecosystem and related environmental considerations; (4) the conservation, development, and utilization of fishery resources; and (5) the economic and technological feasibility of implementation. 16 U.S.C. 1373(b). Section 103(b) also requires an assessment of impacts to WNP gray whales in this case, given the remote risk to WNP gray whales associated with the regulated taking of ENP gray whales under the final waiver and regulations.

Disadvantage Test

The final regulations will not disadvantage the ENP stock because no lethal hunting can occur unless the stock is within its OSP and NMFS determines that the level of hunting authorized by permit will not cause the stock to dip below its OSP. This insures that ENP whales are only removed from the population when the stock is within a population range representing the “the maximum productivity of the population . . . keeping in mind the carrying capacity of the habitat and the health of the ecosystem” and insures the taking under the waiver will not disadvantage the ENP stock. 16 U.S.C. 1362(9).

Consistency With the Purposes and Policies of the MMPA

Section VIII of this Final Decision discusses the Marine Ecosystem, OSP, and the Disadvantage Test and explains how the final regulations insure the taking authorized under the waiver is consistent with the purposes and policies of the MMPA.

Existing and Future Levels of Marine Mammal Species and Population Stocks

In the first paragraph of section VII.A.1, the tribunal concluded that NMFS thoroughly considered both the existing and future abundance levels for the ENP, including the PCFG, and WNP stocks; that the methodology was robust; and that no credible evidence was presented that the analysis relied on incorrect assumptions or reached implausible results. RD at 135. I concur and affirm the first paragraph of section VII.A.1 as part of this Final Decision. The remainder of section VII.A.1 discusses issues related to WNP gray whales and the *Kokechik* decision. I address issues related to *Kokechik* in response to comment 29 and issues related to WNP gray whales later in section VIII of this Final Decision (*Risk to WNP Gray Whales*).

Existing International Treaty and Agreement Obligations of the United States

I agree with the tribunal’s analyses in the first paragraph of section VII.A.2 of the Recommended Decision and affirm this paragraph as part of this Final Decision. The tribunal concluded, and I agree, that the main international agreement relevant to this waiver determination is the International Convention for the Regulation of Whaling. RD at 137.

I set aside the remainder of section VII.A.2, which discusses the Treaty of Neah Bay of 1855 and some of the parties’ arguments suggesting that the waiver may have impacts on international relations. Section 103(b)(2) of the MMPA requires NMFS to consider international treaties and agreements, not international relations. Accordingly, the discussion in the last paragraph of section VII.A.2 is not necessary and is set aside. Although the Treaty of Neah Bay is relevant to this proceeding, it is not relevant to the analysis under section 103(b)(2) because it is not an international treaty or international agreement. I address the implications of the Treaty of Neah Bay in response to comments 45 and 46.

The Marine Ecosystem and Related Environmental Conditions

I agree with the tribunal’s analyses in section VII.A.3 of the Recommended Decision and affirm this section as part of this Final Decision. The record contains ample evidence that in prescribing these regulations, NMFS has fully considered the effect of the regulations on the marine ecosystem and environmental considerations.

The Conservation, Development, and Utilization of Fishery Resources

I agree with the tribunal’s analyses in section VII.A.4 of the Recommended Decision and affirm this section as part of this Final Decision, with one exception. The tribunal determined that the proposed regulations would have no effect on the conservation, development, or utilization of fishery resources. I agree but do not believe that impacts to whale watching should be analyzed under this factor. The MMPA defines “fishery” to mean: “(A) one or more stocks of fish which can be treated as a unit for purposes of conservation and management and which are identified on the basis of geographical, scientific, technical, recreational, and economic characteristics; and (B) any fishing for such stocks.” 16 U.S.C. 1362(16). Section 103(b)(4) of the MMPA concerns fish stocks, not marine mammals and,

therefore, does not contemplate consideration of effects to whales or the whale watching industry. Therefore, I affirm the tribunal's ultimate conclusion in section VII.A.4 as part of this Final Decision but do not adopt its analysis of impacts due to whale watching.

The Economic and Technological Feasibility of Implementation

I agree with the tribunal's analyses in section VII.A.5 of the Recommended Decision and affirm this section as part of this Final Decision. The only technical concern the tribunal noted was potential minor difficulties in obtaining usable photographs for every approached whale and whether photo-identification for all whales within 24 hours is achievable, noting that the latter seems likely but not certain. RD at 139. The regulations I am issuing in this document include measures to help ensure these challenges can be overcome. For example, the Regional Administrator must determine that there are adequate photo-identification catalogs and processes available to allow for the identification of WNP gray whales and PCFG whales prior to issuing a hunt permit. In addition, NMFS has developed a protocol for identifying gray whales encountered during the hunt. Tab 1J.

Risk to WNP Gray Whales

Section 103 of the MMPA requires consideration of the risk to WNP gray whales in this case. The WNP population is approximately 290 animals, increasing at an annual rate of around 2 to 5 percent. RD. at 117. PBR for the WNP stock is 0.12 per year, or one whale every 8 years. *Id.* WNP gray whales are also protected as an endangered species under the ESA.

Whales from the WNP stock occasionally migrate along with ENP gray whales to the breeding grounds in North America with the best available scientific evidence showing a mixing proportion of at least 0.37. RD 18–19. WNP gray whales have not been documented in the ENP range from June through November. *Id.* at 110. Given that Tribal hunters may encounter a WNP gray whale migrating through the hunt area during the winter/spring season, NMFS conducted an analysis to estimate the risk to WNP gray whales from a Tribal hunt. The Recommended Decision reviewed NMFS's analysis of the risk to gray whales and found that NMFS produced a scientifically sound calculation of the risk. *Id.* at 117. The risk analysis adopted a conservative approach, and the risk to WNP is likely lower. Conservative assumptions included: (1) migrating WNP and ENP

gray whales are evenly mixed; (2) all approaches authorized under the regulations would occur during the winter/spring season; (3) the mixing proportions of ENP and WNP gray whales (*i.e.*, the proportion used in the analysis likely overstates the number of WNP gray whales likely to be present); and (4) all authorized strikes and approaches would be used during the waiver period. RD at 111, 118. However, it is unlikely many of the training activities would occur during the winter months when ocean conditions are unfavorable. *Id.* at 118.

The analysis of risk to WNP gray whales was updated at the beginning of the hearing in 2019. Tab 61D. The risk analysis conducted by Moore and Weller (Tab 61D) analyzed the probability of approaching, unsuccessfully striking, and striking a WNP gray whale during a Tribal hunt. Over the 10-year waiver period, a maximum of 15 whales could be struck in winter/spring hunts that could have some probability of being a WNP gray whale. While Tribal hunters may encounter a WNP gray whale, the likelihood of a strike remains a remote possibility. Moore and Weller (2019) estimate that for an individual strike on a gray whale, the expected probability of it being a WNP whale is 0.5 percent. Tab 61D. If all three strikes are used in a winter/spring hunt, up to 0.015 of those strikes would be on a WNP gray whale. That is, we would expect one WNP whale to be struck every 67 years if the hunt were to continue in perpetuity and using the conservative assumptions in the risk analysis. *Id.* The probability of at least one WNP whale being subject to an unsuccessful strike attempt (which includes those associated with training) over the 10-year waiver period was estimated at 3.7 percent. *Id.*

In estimating the number of approaches, Moore and Weller (2019) assumed that all approaches (hunting and training) would occur during the winter/spring season when WNP gray whales may be present. *Id.* This is a very conservative assumption, as some proportion of approaches are likely to occur in the summer/fall season when environmental conditions are better. RD at 118. Assuming that the maximum number of approaches (353) is achieved every year during the waiver period, up to 18 WNP whales could be approached (0.5 percent times 3,530 approaches). However, it is likely that less than 18 WNP gray whales would be approached given that a substantial number of approaches are expected to occur during summer/fall when conditions are more favorable. Neither approaches nor training harpoon throws are lethal, nor

are they likely to cause more disturbance than approaches or biopsy sampling for research purposes. *Id.* a 123. An approach on a WNP gray whale, the most likely scenario, is not expected to have any effect on the stock's ability to attain and maintain OSP. *Id.* at 120.

The regulations I am issuing in this document contain a number of protections for WNP gray whales to manage the remote risk associated with the hunt. These include: (1) an alternating hunt season to minimize risk to WNP gray whales; (2) requirements that the Tribe obtain separate authorization for WNP gray whales for the winter/spring season if take is anticipated; (3) a limit of one strike within a 24-hour period during a winter/spring hunt as a precaution against striking multiple WNP gray whales that might be traveling together; and (4) measures to insure that the processes are available to allow for the identification of WNP gray whales. In addition, the hunt must cease if NMFS determines that a WNP gray whale is struck during the hunt and no further hunt permits may be issued unless and until measures to prevent any additional strikes on WNP gray whales are implemented.

Although the tribunal determined that an ITA was necessary during the winter/spring hunt, my decision is that the risk to WNP gray whales should be managed in a more adaptive way based on an assessment of the risk to WNP gray whales associated with the hunting authorized under a permit. The actual hunting authorized under a permit will provide a more realistic and accurate picture of the risk to WNP gray whales than the WNP risk assessment published by Moore and Weller (2019) which includes some unrealistic assumptions regarding hunting activity in the winter/spring. Moore and Weller (2019) show that there is a risk to WNP that needs to be managed, but whether an ITA is required should be based on the actual levels of hunting that are authorized. Accordingly, under the final regulations, the Regional Administrator is required to assess, in conjunction with the NOAA Office of Protected Resources, whether take is anticipated based on the hunting proposed in the Makah's permit application. If take of WNP gray whales is anticipated, the permit must include a condition requiring separate authorization for the winter/spring hunt.

This approach is a middle ground between the Recommended Decision and the proposed regulations. Under the Recommended Decision, an ITA is necessarily required to hunt during the winter/spring season, even if the

information available during the permitting process indicates that the actual hunting authorized under the hunt permit will not result in the take of WNP gray whales. The proposed regulations would require the Makah to obtain “relevant incidental take authorization for other marine mammals.” This language does not specifically require any further analysis related to WNP gray whales at the permitting stage, even though the best scientific evidence presented at the hearing shows there is a risk of take. The final regulations I adopt in this document require NMFS to address risks to WNP gray whales by ensuring that any anticipated take of WNP gray whales is separately authorized before a winter/spring hunt.

Based on Moore and Weller (2019), the lethal take of a WNP is a remote possibility under the final waiver and regulations. The sub-lethal accidental takes forecasted in this analysis (which would need to be separately authorized and evaluated) will not impact WNP fitness, as any effects are expected to be minor and temporary—similar to the impacts associated with scientific research activities and whale watching. RD at 120. These sub-lethal takes are not expected to have any impacts on the ecosystem. Finally, although this finding is not required by the MMPA in this case, the sub-lethal takes forecasted by Moore and Weller (2019) are not expected to impact the WNP stock’s ability to obtain or maintain its OSP. *Id.*

Conclusion on the MMPA Statutory Criteria

Based on the proposed waiver and regulations, the Recommended Decision, the record assembled by the tribunal, and the comments of the parties submitted in accordance with 50 CFR 228.20(d), I have determined that a waiver should be granted and implementing regulations should be adopted as set forth herein. I agree with and affirm the tribunal’s conclusion in section VIII of the Recommended Decision as part of this Final Decision, with the following exceptions. Although I agree that NMFS has adequately considered the distribution, abundance, breeding habits, and times and lines of migratory movements of WNP gray whales, these specific determinations are not required for the WNP stock under section 101(a)(3)(A) of the MMPA because the waiver is limited to the ENP stock. I also disagree with the conclusion that an incidental take permit is necessarily required during periods when WNP gray whales might migrate through the Makah U&A.

IX. Scientific Information and Analysis Developed After the Recommended Decision

After the tribunal issued the Recommended Decision, NMFS completed an SDEIS on the Makah Tribe’s Request to Hunt Gray Whales. The SDEIS was issued on July 1, 2022 (88 FR 80300), and, on the same day, NMFS opened a 45-day public comment period, which was subsequently extended until October 14, 2022. 87 FR 50319, August 16, 2022. On November 17, 2023, NMFS issued an FEIS. 88 FR 80300.

As gray whales are well studied, new scientific research is published regularly, and the SDEIS and FEIS include additional scientific evidence and analyses that were not available at the time of the hearing before the tribunal. There is updated information on the abundance of ENP gray whales (Stewart and Weller, 2021a; Eguchi *et al.* 2022a; Eguchi *et al.* 2023a, Eguchi *et al.* 2024), abundance of PCFG gray whales (Harris *et al.* 2022), calf production (Stewart and Weller, 2021b, Eguchi *et al.* 2022b, Eguchi *et al.* 2023b), potential impacts to WNP gray whales (Moore *et al.* 2023), factors affecting the abundance and distribution of ENP whales (Perryman *et al.* 2021; Joyce *et al.* 2022; Stewart *et al.* 2023), carrying capacity (Stewart *et al.* 2023), gray whale morphology (Bierlich *et al.* 2023), and gray whale stock structure (IWC 2021, NMFS 2023; Weller *et al.* 2023). Under NMFS’s procedural regulations, I have discretion to “remand the hearing record to the presiding officer for a fuller development of the record.” 50 CFR 228.21(a). The additional information on gray whales developed after the hearing raises the question of whether a remand is warranted.

Following the issuance of the FEIS, I provided the parties with an opportunity to submit comments. The parties were able to comment on recent scientific information and on whether any additional procedures were necessary in this formal rulemaking. Some parties argued a remand was warranted. Others noted that the comment period provides adequate due process consistent with the procedures in section 556(e) of the APA, which provides that when “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.”

My decision on the waiver and the regulations rests on the material facts in the record assembled by the tribunal in support of the Recommended Decision,

the proposed waiver and regulation, and the comments submitted in accordance with 50 CFR 228.20(d). I considered additional information to evaluate whether that information warranted a remand. In making this assessment, I considered whether the new information would compel changes to my determinations. As described in greater detail below, the new information does not compel changes. The recent scientific information is largely consistent with the information available at the time of the hearing, and the final waiver and regulations include processes to address new information through the permitting process.

ENP Abundance

Since 1967, NMFS has conducted abundance surveys of ENP gray whales and regularly (annually in recent years) updates the estimates of ENP abundance and calf production. In addition, abundance estimates for the PCFG have been updated (Harris *et al.* 2022). It is expected that these estimates will change over time. When the hearing was held in 2019, the abundance of ENP gray whales was estimated to be 26,960 individuals. RD at 14. After the hearing, these estimates were updated (Stewart and Weller 2021a; Eguchi *et al.* 2022a; Eguchi *et al.* 2023a, Eguchi *et al.* 2024) using the same modeling approaches that generated the estimates considered in the Recommended Decision. At the time of the comment and response period, which ran from November 27, 2023, to January 17, 2024, the ENP abundance was estimated at 14,526 whales, a decline of approximately 46 percent from 2016 to 2023 (Eguchi *et al.* 2023a). In March 2024, Eguchi *et al.* (2024) published an estimated abundance of 19,260. This estimate represents a 32.6 percent increase from the 2022/2023 season. This updated estimate is consistent with the previously observed pattern of fluctuating abundance (Eguchi *et al.* 2024). That is, observed declines are followed by an increase in population.

While the ENP population experienced a significant decline in abundance, fluctuations in abundance were anticipated based on the long-term data sets that were included in the record before the tribunal. Tab 1H at 15. The tribunal recommended a low abundance threshold based, in part, on the most recent UME. RD at 151. Large-scale fluctuation in the population abundance occurred from the 1987/1988 abundance surveys to the 1992/1993 abundance surveys (approximately a 40 percent decline) and from the 1997/1998 abundance surveys to 2001/2002 abundance surveys (approximately a 24

percent decline). Tab 1H at 15. UMEs occurred in 1999–2000 and again in 2019–2023. RD at 98.

While the year-over-year decline from 2016 to 2023 represented a novel pattern (Eguchi *et al.* 2023a), the most recent estimate shows an increase in the ENP population, indicating population-level resilience in ENP gray whales (Eguchi *et al.* 2024). I expect the population to continue to rebound from the current decline as it has done following each of the prior declines. Eguchi *et al.* (2023) notes that “despite occasional declines in abundance since the time-series of data began in 1967, the population has recovered.” Eguchi *et al.* (2024) notes that “the population has shown a generally increasing trend since the time-series of data began in 1967.” Even before the latest abundance estimate, there were hints of a turnaround in the most recent decline: strandings decreased, calf counts increased, and the body condition of gray whales in the breeding lagoons improved (Eguchi *et al.* 2023b; LSIESP 2023; NMFS 2023a). Consistent with the tribunal’s recommendation, the final regulations include an abundance threshold to protect the ENP stock if the abundance of the stock falls below OSP. NMFS also plans to closely monitor the population with regular surveys to estimate abundance, calf production and body condition of gray whales (Eguchi *et al.* 2024).

The estimate of PCFG abundance was 232 individuals in 2017. RD at 96; Tab 96 at 33. Harris *et al.* (2022) updated the PCFG abundance using the modeling framework in Calambokidis *et al.* (2019; Tab 96) to maintain continuity with past estimates. As with Calambokidis *et al.* (2019), the researchers evaluated the abundance at three nested spatial scales: (1) NCA–NBC (*i.e.*, the definition of the PCFG range); (2) OR–SVI, which is within the NCA–NBC; and (3) the Makah U&A (MUA), which is within the OR–SVI. Calambokidis *et al.* (2019) estimated 232 whales in NCA–NBC region; 196 in the OR–SVI region, and 117 in the MUA region in 2017. Tab 96. Harris *et al.* (2022) estimated 212 whales in the NCA–NBC region, 199 in the OR–SVI region, and 119 in the MUA region in 2020. These most recent abundance estimates, though declining slightly from an observed peak in abundance in 2015, continue to indicate that the PCFG population has been stable over the last 20 years (Harris *et al.* 2022). Harris *et al.* (2022) found mixing rates for PCFG and non-PCFG individuals between December and May were similar to Calambokidis *et al.* (2019) and recommended referring to Calambokidis *et al.* (2019) for mixing

rates estimates. In addition, the PCFG estimate remains above the abundance thresholds considered in the proposed regulation, and carried over to the final regulations, and the analyses. Thus, the new information on the PCFG abundance is not significantly different from the information considered in the Recommended Decision.

I have determined that the updated information on ENP abundance, including the PCFG abundance, does not warrant a remand. The PCFG population remains stable and the recent decline in the ENP population is similar to previous declines in abundance from which the stock has recovered. All this is consistent with the evidence before the tribunal and does not compel a different result. Rather, the decline shows the wisdom of the tribunal’s recommendation to set an abundance threshold for ENP gray whales as well as the proposed regulations allowing for reductions in PCFG strike limits. I have included both these measures in the final regulations.

Factors Affecting Gray Whale Abundance and Distribution

Several recent studies have examined factors affecting gray whale abundance and distribution on the northern feeding grounds. Gray whales use various feeding techniques including suction feeding on prey that lives on or just above the seafloor and engulfing/skimmed prey in the water column and at the surface. Tab 90F at 22. As described in the DEIS (Tab 90F at 3–98 to 3–99) and FEIS, a number of studies (*e.g.*, Grebmeier *et al.* 2006; Moore *et al.* 2003; Moore 2005; Moore *et al.* 2007; Stafford *et al.* 2007) suggest that gray whales are shifting their foraging areas in the Pacific Arctic where their diet is dominated by benthic amphipods (Moore *et al.* 2022). The food web in the Pacific Arctic is dependent on sea ice, and the Arctic is now characterized by warmer conditions with less sea ice coverage. Tab 90F at 3–99. Sea ice retreat occurs earlier in the season, resulting in increased productivity in the water column but reducing the amount of organic carbon reaching the seafloor (Grebmeier *et al.* 2006). Algae growing on the underside of the sea ice dies and falls to the bottom, fertilizing the benthic sediments that amphipods depend on. In addition, the lack of sea ice increases currents, washing away the fine sediments that are habitat needed for tube-building amphipods. These tube-building amphipods have a high lipid content (Grebmeier *et al.* 2006; Grebmeier *et al.* 2010). While abundance has remained constant, crustacean biomass has decreased. The

decline in biomass is most likely associated with species distribution shifts of benthic amphipods and other crustaceans. The decrease in organic carbon reaching the seafloor and the increased current speed are conditions that favor smaller, less nutritious amphipods (Stewart *et al.* 2023).

Stewart *et al.* (2023) found that the combined effect of sea ice cover and benthic productivity on gray whale population dynamics has driven major boom-bust cycles, including two modern booms in abundance that may have exceeded pre-exploitation levels. They found gray whale population dynamics were strongly linked to prey access and biomass, meaning that in years with low prey biomass and low access to prey (*i.e.*, high ice cover), ENP gray whales experienced major mortality events. While previous work has suggested that early sea ice retreat may benefit gray whales by increasing access to their prey base (Tab 90F at 3–86), Stewart *et al.* (2023) found that changing sea ice extent also affects benthic and pelagic communities in ways that may negatively impact higher trophic species in the Arctic. When low prey biomass coincided with high ice cover, ENP gray whales experienced large-scale declines in abundance.

Joyce *et al.* (2023) found a negative relationship between gray whale counts and ice concentration in the northeast Chukchi Sea, along with absence of gray whales in foraging hot spots during years with delayed ice break-up and during periods of dense ice cover. Further, the authors found that the onset of acoustic detection of gray whales had a strongly positive relationship with ice break-up date, meaning that gray whales arrive later to the foraging grounds when sea ice break-up is later (Joyce *et al.* 2023). In various locations throughout the Bering and Chukchi Seas, Moore *et al.* (2022) found that gray whale calls were associated with winter sea ice retreat, and that gray whale distribution correlated with prey abundance and wind patterns that influence prey abundance.

Perryman *et al.* (2021) noted the high interannual variability in calf production between 1994 and 2016 and found that environmental indices (the Pacific Decadal Oscillation and the North Pacific Index) in combination with ice cover in the Bering and Chukchi Seas during the early phase of gestation are important factors in explaining the observed variability. They concluded that access to prey early in the gestation period is critical to reproductive success in the ENP population (Perryman *et al.* 2021).

In their review of reported climate change effects on gray whales and described in the DEIS and FEIS, Salvadeo *et al.* (2013; see Tab 90F at 3–197) cited a number of likely gray whale responses to global warming. Some of these have been realized in recent years coinciding with the recent UME, including fewer whales in the Gulf of California, reduced number of whales in the breeding lagoons (LSIESP 2023), and shifting occurrence in feeding areas (Moore *et al.* 2022; Joyce *et al.* 2023).

The record assembled by the tribunal considered large-scale fluctuations in abundance with significant declines experienced during three mortality events. Tab 1H at 15. Two of these mortality events were declared UMEs. RD at 98. The recent research supports that gray whales are sensitive to dynamic and changing conditions due to climate change. Stewart *et al.* (2023) suggest that changes in benthic biomass in the future will likely drive changes in the carrying capacity of gray whales. These recent studies provide us with a better understanding of the mechanisms driving the fluctuations in the population. They do not contradict our conclusions that the removal of 25 ENP gray whales over 10 years, an average of 2.5 gray whales per year, would have no appreciable effect on the population or its ability to remain within OSP and be a functioning part of the ecosystem.

Calf Production

Since 1994, counts of female gray whales with calves have been conducted nearly annually from the Piedras Blancas Lighthouse Station in central California. Tab 90F at 3–73. Both the survey methods and the analytical approach used to estimate total annual calf production remained consistent through the 2019 survey (Perryman *et al.* 2021). In 2021, Stewart and Weller introduced a new Bayesian modeling approach to account for uncertainty during unsampled periods (*i.e.*, evenings, weekends, and unworkable weather). In general, scientific models and analyses are refined and updated as new information and improved techniques become available. Stewart and Weller (2021b) describe the advantages to the updated calf production model, including that the updated approach provides a more complete accounting of the uncertainty associated with unobserved periods.

Using this Bayesian modeling approach, Eguchi *et al.* (2022b) and Eguchi *et al.* (2023b) estimated calf production since 1994. While the Bayesian approach generally resulted in greater estimates than the earlier method by Perryman *et al.* (2002), the

trends in calf production were almost identical when compared to estimates under the previous approach (Stewart and Weller 2021b).

Eguchi *et al.* (2022b) found a linear relationship between estimated abundance and estimated calf production, suggesting that the factors driving or mediating rates of ENP gray whale fecundity and mortality may be similar. Coinciding with the onset of the current UME, calf production has been low since 2019 (Stewart and Weller 2021b; Eguchi *et al.* 2022b; Eguchi *et al.* 2023b). While still lower than many estimates in the time series, calf production in 2023 (412 calves) was nearly double the estimate in 2002 (Eguchi *et al.* 2023b).

Based on the long-term data series, periodic declines in calf production are expected to occur. The population experienced decreased production from 1999 to 2001 and from 2007 to 2010. Tab 90F at 3–75. From 2018 to 2022, the population again experienced decreased production (Eguchi *et al.* 2023b). The earlier declines in calf production generally lasted 3–4 years followed by increased production (see Weller and Perryman 2017; Tab 52O). This suggests that the current pattern may be typical of ENP gray whale population dynamics (Stewart and Weller 2021b), and we anticipate that calf production will increase following this most recent decline.

As described above, the trends using the Bayesian modeling approach were almost identical when compared to estimates under the previous modeling approach. Thus, Stewart and Weller (2021b) did not anticipate the updated approach leading to significant reinterpretations of calf estimates for management purposes. I agree and find that the new calf estimates are consistent with the estimates in the record before the tribunal.

UME

The tribunal considered the UME that began in 2019 in the Recommended Decision. RD at 98–103. It found that a waiver could still be granted despite the UME and provided recommendations related to this (see responses to comments 12 and 13 for my consideration of these recommendations). As described above, elevated gray whale strandings occurred along the west coast of North America from Mexico through Alaska beginning in 2019. The Working Group on Marine Mammal Unusual Mortality Events determined the recent UME ended as of November 2023.

NMFS documented 690 strandings during the 2019–2023 UME ([\[www.fisheries.noaa.gov/national/marine-life-distress/2019-2023-gray-whale-unusual-mortality-event-along-west-coast-and\]\(https://www.fisheries.noaa.gov/national/marine-life-distress/2019-2023-gray-whale-unusual-mortality-event-along-west-coast-and\), accessed March 17, 2024\) with peak strandings occurring from December 17, 2018, to December 21, 2020. From the 2015/2016 survey season to the 2022/2023 survey season, the abundance estimate for the ENP stock declined approximately 46 percent \(Eguchi *et al.* 2023a\). However, the PCFG abundance estimate did not experience a proportional decline from pre-UME levels to 2020 \(Harris *et al.* 2022\). To date, only one stranded whale during the UME has been matched by photo-identification to the PCFG. Genetic analysis on samples collected from stranded whales has not yet been completed.](https://</p></div><div data-bbox=)

As described above, the ENP gray whale population is known to undergo large-scale, periodic fluctuations in abundance, including during a prior and similar UME in 1999–2000 in which 651 gray whales stranded. Oceanographic factors that limited food availability for gray whales were identified as likely causes of the UME (Stewart *et al.* 2023).

Based on ecosystem conditions observed from 2010 to 2019, research found changes in the gray whale distribution and feeding behaviors as well as changes in gray whale prey associated with ecosystem changes in the sub-Arctic and Arctic feeding areas (Moore *et al.* 2022). The population model by Stewart *et al.* (2023), which focused on localized feeding areas in northern Bering and Chukchi seas, linked the 1999–2000 UME and the 2019–2023 UME to changes in sea ice cover and in the amount of gray whale prey. The team of scientists investigating the 2019–2023 UME determined the preliminary cause was localized ecosystem changes, which included both access to and the quality of prey in sub-Arctic and Arctic feeding areas, leading to poor nutritional conditions of the whales, decreased birth rates, and, in several whales, death due to malnutrition (<https://www.fisheries.noaa.gov/national/marine-life-distress/2019-2023-eastern-north-pacific-gray-whale-ume-closed>, accessed May 3, 2024).

Both the 1999–2000 UME and the 2019–2023 UME caused significant reductions to the ENP population; however, the population remains abundant and at a level where the effect of the limited hunt (25 whales over 10 years) on the population is so low that it is not appreciable. The gray whale population has demonstrated its resiliency in recovering from its endangered status caused by historical commercial whaling, being delisted

from the ESA 30 years ago in 1994, and recovering after each of the prior drops in its abundance. For example, scientists documented a healthy rebound of the ENP population after the 1999–2000 UME to about 27,000 whales in 2015/2016, and we predict it will rebound similarly from the 2019–2023 UME. NMFS will continue to monitor the population to track changes. The most recent abundance estimate shows an increase in abundance from the 2022/2023 season to the 2023/2024 season (Eguchi *et al.* 2024). Scientists have also documented that calf counts have increased and the body condition of gray whales has improved (Eguchi *et al.* 2023b).

The additional information that has emerged since the UME does not change my decision to adopt the tribunal's finding that a waiver may be granted during a UME. The 2019–2023 UME ended as of November 2023, and information on the UME that has emerged since the hearing suggests that ENP gray whales will recover from the 2019–2023 UME.

Carrying Capacity

As with abundance and calf production, it is expected that carrying capacity estimates will change over time. RD at 95. Stewart *et al.* (2023) constructed a demographic model of the ENP gray whale population using long-term datasets, as well as detailed temporal data on sea ice cover and crustacean (prey) biomass in the Arctic summer feeding grounds. The researchers estimated that the long-term average carrying capacity is 22,062 (18,967 to 24,725), which is lower than the median of the annual carry capacity values (24,500, 95 percent CI 21,771 to 27,797). The authors found that gray whale population dynamics were strongly linked to prey access and biomass, meaning that in years with low prey biomass and low access to prey (*i.e.*, high ice cover), gray whales experienced major mortality events. While the estimate in Stewart *et al.* (2023) is lower than the estimate in Punt and Wade (2012) that was available at the time of the hearing, this information is consistent with the hearing record as it is expected that carrying capacity will change over time (see Tab 102 at 29 to 31).

Carrying capacity is the upper bound of OSP. I have included precautions in the regulations to ensure that the stock is within OSP before a hunt is authorized and have required that hunting cease if the stock falls below the lower bounds of OSP. These measures are based on the tribunal's recommendation to set an abundance

threshold and the requirements of section 103(a) of the MMPA.

Stock Structure

The IWC Scientific Committee conducted annual (2014–2018) range-wide workshops on the status of North Pacific gray whales to identify plausible stock hypotheses consistent with the data available. At the time of the hearing, the two primary hypotheses deemed most plausible considered two separate “breeding stocks” or biological populations (western and eastern).

Hypothesis 3a assumes that the western breeding stock is extirpated, whales show maternal feeding ground fidelity, and the eastern breeding stock includes three feeding aggregations: PCFG, NFG, and a WFG. Hypothesis 5a assumes that both breeding stocks are extant, that the western breeding stock feeds in the western North Pacific, and whales feeding off Sakhalin include individuals from the western and eastern breeding stock. RD at 68; Tab 80B at 41.

More recently, the IWC identified hypotheses 4a and 7a as high priority for inclusion in the modeling framework used for assessing stock status of North Pacific gray whales (IWC 2021). Hypothesis 4a considers two breeding stocks characterized by maternal feeding ground fidelity. The eastern breeding stock consists of the NFG and PCFG whales. The second, unnamed breeding stock includes the western feeding group whales that breed with each other on the migration route to Mexico for overwintering. Hypothesis 7a considers three breeding stocks characterized by maternal feeding ground fidelity: (1) the eastern breeding stock consists of NFG and PCFG whales that overwinter in Mexico, (2) the western breeding stock consists of whales that feed in the western North Pacific and overwinter in the Vietnam-South China Sea sub-area, and (3) an unnamed breeding stock consists of whales that feed in the western North Pacific and breed with each other on the migration route to Mexico for overwintering (IWC 2021). Neither of these hypotheses conflicts with NMFS's characterization in the SARs that the ENP gray whale stock includes the PCFG.

In 2018, NMFS initiated a 5-year review of the endangered WNP gray whale under the ESA and solicited information from the public. 83 FR 4032, January 29, 2018. A 5-year review is a periodic analysis of a species' status conducted to ensure that the ESA-listing classification of a species is accurate. The WNP gray whale is listed under the ESA as a DPS. For the purpose of the ESA review, WNP gray whales were defined as “gray whales that spend all

or part of their lives in the western North Pacific.” Given that this definition for evaluating WNP gray whale DPS status differed fundamentally from the 1993 listing language (58 FR 3121, January 7, 1993), an SRT was convened. The SRT found that the definitions of ENP and WNP gray whales provided in the Notice of Determination to Delist the Eastern North Pacific Stock (58 FR 3121, January 7, 1993) and in the Final Rule to Remove the Eastern North Pacific Population of the Gray Whale From the List of Endangered Wildlife (59 FR 31094, June 16, 1994) did not accurately describe how gray whales utilize and partition their habitat in the North Pacific and those definitions were no longer valid based on the best available scientific evidence (Weller *et al.* 2023).

The SRT found that three gray whale groups or “units” met the ESA DPS policy criteria for discreteness and significance: (1) gray whales that spend their entire lives in the WNP (termed the “WNP-only unit”); (2) gray whales that feed in the WNP in the summer and fall and migrate to the ENP (including Mexico) in the winter (“WNP–ENP unit”); and (3) a single unit consisting of both the WNP-only and WNP–ENP units (Weller *et al.* 2023). Given this, they considered two mutually exclusive options for a recommended DPS listing: (1) WNP-only and WNP–ENP units are separate DPSs or (2) WNP-only and WNP–ENP are single DPS. The SRT recommended that the combined units be used to designate a single DPS given that it is not possible to readily assign whales to either unit and, thus, not scientifically practicable to assess the status of each unit separately (Weller *et al.* 2023).

Based on the review of the best available scientific and commercial information, NMFS determined that the WNP gray whale population meets the discreteness and significance criteria of the DPS (NMFS 2023b). The SRT team concluded that the evidence supporting the discreteness of a WNP-only and the combined unit from gray whales that spend their entire lives in the ENP was “very strong” (Weller *et al.* 2023). The 5-year review also recommended that the WNP DPS remain classified as endangered (NMFS 2023b). The status and 5-year reviews do not provide new information that would change my determination regarding the stock definitions for gray whales under the MMPA.

Body Condition

One party commented that a recent study by Lemos *et al.* (2020) provides new information that must be added to

the record. Lemos *et al.* (2020) is described in the FEIS (NMFS 2023a). Using drone photogrammetry, Lemos *et al.* (2020) applied an index of body area to measure and compare body condition of ENP gray whales foraging off the coast of Oregon between 2016 and 2018. Similar to the body mass index for humans, the body area index (BAI) is a continuous, unitless metric to measure and compare whale body condition. Lemos *et al.* (2020) found that BAI varied with age, sex, and reproductive status, with calves and pregnant females displaying the highest BAI followed by resting females, mature males, and, finally, lactating females. That is, lactating females are one of the most depleted groups; pregnant females are one of the most robust groups. Body condition was significantly better in 2016 than in 2017 and 2018, which was associated with 2 prior years of poor local upwelling conditions that may have caused reduced prey availability (Lemos *et al.* 2020). That there are fluctuations in gray whale body condition based on sex, age, reproductive status, seasonality and environmental conditions, including prey availability, is not a novel concept that would change any of my determinations.

Gray Whale Morphology

Bierlich *et al.* (2023) investigated morphological differences (length, skull, and fluke span) and compared length-at-age growth curves for ENP and PCFG whales. The researchers analyzed estimated morphological measurements of PCFG whales from 2016–2022 using drone-based measurement techniques. The length-at-age data on ENP gray whales was obtained from prior studies using stranding, whaling, and photogrammetry data (1926–1997); fluke and skull measurements were from data collected during scientific whaling from 1959–1969. PCFG and ENP whales were found to have similar growth rates, while PCFG whales reached shorter asymptotic lengths (about 8.3 percent shorter for females and 3.8 percent for males). The authors also found that PCFG gray whales have significantly smaller skulls (about 2 percent smaller) and flukes (about 1 percent smaller) than historical ENP gray whales.

The authors suggest several reasons as to why PCFG whales are smaller, including (1) differences in phenotypic plasticity and (2) differences in foraging tactics. Phenotypic plasticity is the capacity of a single genotype to exhibit alternate phenotypes depending on the environment. The IWC Stock Definition and DNA Testing Working Group reviewed the research. They noted that

the morphometric differences could reflect ecological divergence driven by selection for a smaller body size in PCFG whales due to prey resource limitations or aspects of the foraging niche. However, this pattern could also develop if whales with small body sizes are more likely to recruit into the PCFG rather than making the full migration to the Arctic feeding grounds (IWC 2023). The Working Group also found that the existing photo-identification and genetic data (citing to Lang *et al.* 2012, Lang *et al.* 2019, Calambokidis *et al.* 2019) suggest a degree of external recruitment into the PCFG, and that the morphological data collected on the PCFG range could contain a mixture of animals from either of these two groups (external versus internal recruits).

The results in Bierlich *et al.* (2023) must be viewed cautiously given the disparate data sets, differences in measurement methodologies, and lack of temporal overlap in the PCFG and non-PCFG ENP data being compared. While the researchers documented differences in morphology, the underlying causes for these differences are not known and may be driven by processes not related to population structure.

Morphological data is one factor that can be considered in delineating demographically independent populations (DIPs). However, the DIP handbook cautions against its use to compare groups of animals when, among other conditions (1) data collection methods differ between investigators and (2) differences between groups could be explained by phenotypic plasticity (Martien *et al.* 2019). In this case, Bierlich *et al.* (2023) rely on data collected using different methods and during different time periods for the two groups being compared. In addition, they acknowledge the genetic similarity between the ENP and PCFG and propose phenotypic plasticity as an explanation for the differences found. Phenotypic plasticity is common in animal populations and in itself is not a criterion for stock designation (NMFS 2019; NMFS 2023c).

Other lines of evidence support the conclusion that the PCFG is a feeding group within the ENP stock. For example, external recruitment to the PCFG continues to be an important influence in maintaining or increasing the size of the PCFG population, and the PCFG do not differ from other ENP gray whales with respect to nuclear DNA markers. RD at 65, 106. The conclusions about the PCFG belonging to the broader ENP stock are not changed due to Bierlich *et al.* (2023).

Similarly, IWC reviewed this research and found: “In considering new information indicating that morphological differences exist between whales feeding on the PCFG feeding ground and those that migrated past central California, the Committee noted that, given evidence of immigration into the PCFG, morphological data collected from PCFG whales may contain a mix of internally and externally recruited individuals.” They concluded that no changes were needed to the current gray whale stock structure hypotheses or their modeling approach in which PCFG whales belong to a feeding group within the ENP stock (IWC 2023).

Based on the information above, I have concluded that the ENP gray whale morphology paper (Bierlich *et al.* 2023), the WNP status review (Weller *et al.* 2023), and the WNP 5-year review (NMFS 2023b) do not present significant new information necessitating a remand. The information presented is consistent with the information in the record of the ALJ proceeding that there are two stocks of gray whales, ENP and WNP, and the PCFG are a feeding group within the ENP stock.

Impacts to WNP Gray Whales

In 2023, Moore *et al.* updated the estimates of the probability of approaching, unsuccessfully striking, or striking a WNP gray whale during the proposed Makah hunt. The re-estimate of the probability of striking a WNP was based on the updated population estimate and the likelihood of ENP and WNP gray whale occurrence in the hunt area. The same model used in 2018 and 2019 analyses (see Tab 61D) was used to generate the new estimates (Moore *et al.* 2023).

Moore *et al.* (2023) estimated that for a single interaction with a gray whale, the expected probability of it being a WNP whale is 0.8 percent to 1.2 percent, assuming an ENP abundance between approximately 16,000 to 11,000 animals. This is up slightly from the estimate of 0.5 in 2019. Tab 61D. This change is largely driven by using a lower abundance estimate for ENP population size. A population of 16,000 to 11,000 animals is below the most recent abundance estimate of 19,260 (95 percent CI = 17,500–21,300.5), animals (Eguchi *et al.* 2024). As described in section III of this Final Decision and the Response to comment 13, the UME was closed as of November 2023, and there are signs that the population is recovering. Increases in abundance were seen following previous periods of decline and in the most recent abundance estimate would be expected

to result in a decline in the risk to WNP whales.

According to Moore *et al.* (2023) and using abundance of between 16,000 and 11,000 animals, the probability of striking one WNP gray whale over the 10-year waiver period is between 11.1 and 16.3 percent, assuming all fifteen winter/spring strikes are used. Applying those percentages to a population estimate of 11,000 to 16,000 results in 0.12 to 0.18 WNP gray whales struck over the waiver period; in other words, one WNP gray whale struck every 61 to 90 years. There may also be 0.71 to 1.06 unsuccessful harpoon throws over the course of the waiver. However, it is unlikely that all of the assumptions of the analysis will be met. If 3,530 approaches are made during the 10-year waiver, we would expect up to 27.7 to 41.6 WNP whales to be approached. As described above, the analysis of risk to WNP gray whales is conservative and likely overestimates the risk. In addition, the most recent abundance estimate (Eguchi *et al.* 2024) is higher than the estimates used in the Moore *et al.* (2023) risk analysis. Given the likelihood of this analysis overestimating the risk to WNP gray whales and the slight increase in the likelihood of striking a WNP gray whale, the new information represents similar risk levels to those in the earlier estimates. Thus, Moore *et al.* (2023) does not present significant new information that would change my determinations. There remains a remote risk to WNP gray whales that calls for management. In light of this risk, NMFS must assess whether take is anticipated at the permitting stage. If take of WNP gray whales is anticipated, separate take authorization will be required for the winter/spring hunt.

Summary of New Information

For the reasons discussed above, the additional scientific information developed after the hearing does not warrant a remand because the additional information is consistent with or confirms the record developed in the ALJ proceeding and would not change any of my determinations. NMFS and external researchers developed and I reviewed additional information related to gray whales following the hearing. I used this information to assess whether a remand was warranted and provided the parties with ample opportunity to comment on the information.

On July 1, 2022, NMFS issued a SDEIS and announced a 45-day comment period on the SDEIS, which was extended until October 14, 2022, and then reopened from October 28

through November 3, 2022. After NMFS released its FEIS, I provided the parties with an opportunity to submit comments on what, if any, procedural steps may be necessary prior to rendering a final decision on the waiver and regulations. I also informed the parties that they could utilize the comment period to address new analyses on gray whales that emerged since the comment period on the SDEIS ended. The comment period began on November 27, 2023, and ended December 20, 2023. I then gave the parties an opportunity to respond to the comments of other parties by January 17, 2024.

No parties made a strong showing that remand was warranted during the final comment and response period or explained why the trial-type proceedings associated with a remand were justified. In supporting the need for additional process steps, AWI and PCPW focused much of their comments on the recent study by Bierlich *et al.* (2023) described above. That study found significant morphological differences between PCFG and ENP gray whale. Based on Bierlich *et al.* (2023), PCPW suggests that NMFS must convene a task force to reassess the status of PCFG whales; AWI contends that remand is warranted given this new information. NMFS's hearing regulations guiding the permissible procedures in this process do not provide for convening a scientific workgroup.

The commenters contend that the study suggests internal recruitment of PCFG whales dominates, assert that NMFS has not recently revisited the question of ENP stock structure, and suggest that the morphology data is an additional line of evidence supporting designation of the PCFG as a stock. Commenters also note that the authors conclude their results encourage re-evaluating the population management designation of ENP gray whales to consider the PCFG as a separate management unit.

While morphological data is a consideration in stock delineation, the DIP delineation handbook cautions against such use when, as is the case here, data collection methods differ and differences in between the groups can be explained by phenotypic plasticity. The authors of the study acknowledge the genetic similarity between ENP and PCFG whales and propose phenotypic plasticity as a plausible explanation (Bierlich *et al.* 2023). The underlying causes for the differences in PCFG and ENP morphology was not identified through this study and may be driven by processes not related to stock structure.

Other lines of evidence continue to support that the PCFG is a feeding aggregation within the ENP. The PCFG do not differ from other ENP gray whales with respect to nuclear DNA. RD at 106. In addition, external recruitment and breeding between PCFG and ENP gray whales continues to occur. RD at 63, 65. The IWC in reviewing Bierlich *et al.* (2023) concluded that "given the evidence of immigration into the PCFG, morphological data collected from PCFG whales may contain a mix of internally and externally recruited individuals" (IWC 2023). The information in Bierlich *et al.* (2023) does not represent significant new information that warrants revisiting the determinations made by the tribunal related to gray whale stock structure. NMFS regularly reviews the status of the ENP gray whale stock through its SARs developed under section 117 of the MMPA. The most recent SAR (NMFS 2021) for ENP gray whales continues to consider the PCFG as a feeding aggregation within the ENP. In addition, the regulations include measures specific to the PCFG to ensure they maintain their current stable population status, which ensures the hunt will not preclude the PCFG from being designated a stock in the future, if warranted.

IX. Required Statements Related to Final Regulations

The MMPA requires that either before or concurrent with the publication of these regulations I make certain statements. 16 U.S.C. 1373(d). This section includes those statements.

Statement of the Estimated Existing Levels of the Species and Population Stocks of the Marine Mammal Concerned

ENP gray whales are the subject of the waiver and regulations. The ENP gray whale abundance estimate is 19,260 (95 percent CI = 17,500–21,300.5), and the resultant minimum abundance estimate is 18,430.

Statement of the Expected Impact of the Proposed Regulations on the OSP of Such Species or Population Stock

Punt and Wade (2012) estimated the 2009 population to be at 85 percent of the carrying capacity (posterior mean of 25,808) and at 129 percent of MNPL. Based on data in Punt and Wade (2012), MNPL was approximately 16,000 whales at that time. This and the most recent abundance of gray whales (19,260) (Eguchi *et al.* 2024) suggest the stock is above MNPL (*i.e.*, within OSP). Analyses that are more recent suggest that the carrying capacity of the ENP stock has changed. Stewart *et al.* (2023)

estimate long-term average carrying capacity at 22,062. In the absence of direct measurements, a model-derived value of 60 percent of carrying capacity can be used to estimate MNPL, which is the lower bound of OSP. Using this approach, the data in Stewart *et al.* (2023) suggests that MNPL is 13,237 animals. This also suggests the ENP stock is currently within OSP. Because the level of hunting is so low and because hunting can only occur if the stock is within OSP and will not cause the stock to fall below OSP, the regulations have no effect on the OSP of ENP gray whales.

Statement Describing the Evidence Before the Agency That Forms the Basis for the Regulations

In developing the waiver and regulation, I relied on the proposed waiver and regulations, the record assembled by the tribunal, the Recommended Decision, and the public comments submitted in accordance with 50 CFR 228.20(d). After the Recommended Decision was issued, I considered additional information in assessing whether a remand was warranted as described in section IX of this Final Decision.

Any Studies/Recommendations Made by or for the Agency or the MMC That Relate to the Establishment of the Regulations

The record assembled by the tribunal includes numerous studies and recommendations relevant to the establishment of these regulations. Additional studies since the hearing are considered in section IX. Based on these studies, I determined a remand was not warranted. As described in section VIII, NMFS consulted with the MMC and considered their recommendations in developing the proposed and final regulations.

X. Ultimate Findings and Conclusions

The waiver and the implementing regulations are based on the best scientific evidence available. In making this Final Decision, NMFS considered the voluminous scientific record assembled by the tribunal. After the comment period closed on the Recommended Decision, I evaluated the latest scientific information and determined that a remand to the tribunal was not warranted. NMFS has consulted with the MMC on numerous occasions. The MMC submitted comments on the 2015 DEIS and provided written advice in response to two NMFS requests for consultation in 2017. Tabs 1I, 1K, 1L, 1O, 1P. The MMC also provided proposed findings of fact

and conclusions of law in March 2020. Tab 114. In October 2021, I sent a letter to the Executive Director of the MMC welcoming further consultation during the public comment period on the Recommended Decision. The MMC submitted comments on the Recommended Decision during the public comment period. The MMC also submitted comments on the SDEIS and provided a response to other parties' comments in January 2024.

In issuing this waiver, I have given due regard to the effect of the waiver on the distribution of ENP gray whales, including their distribution within the PCFG range; abundance; breeding habits; and times and lines of migratory movements of the ENP gray whale stock. Consistent with the tribunal's determinations, I find that the effect of the hunt on all four factors is minimal. RD at 112. The waiver is in accord with sound principles of resources protection and conservation as provided in the MMPA's purposes and policies, and the regulations are consistent with the MMPA's purposes and policies. The tribunal found it "reasonable for NMFS to conclude that the health and stability of the ecosystems in which gray whales function will not be adversely affected by the proposed waiver and regulations," and I agree. RD at 116. The ENP stock is well studied and capable of obtaining and maintaining OSP despite decades of hunting at far greater levels than I am authorizing. To insure that the taking under the regulations will not disadvantage the stock, hunting is not permitted unless the stock is within its OSP.

I have fully considered the effect of the regulations on existing and future levels of the ENP and WNP gray whale stocks, the marine ecosystem and related environmental considerations, and existing international and treaty obligations of the United States. I have also fully considered the economic and technological feasibility of the implementation of the proposed regulations. I have determined the regulations will not affect the conservation, development, and utilization of fishery resources. Risk to WNP gray whales from the implementation of the regulations is an additional factor that I have fully considered in promulgating the regulations.

I have given full consideration to all relevant factors and, for the reasons described herein, am issuing the waiver and the regulation to provide a framework for a limited ceremonial and subsistence hunt for ENP gray whales by the Makah Indian Tribe in accordance with their reserved whaling rights under

the Treaty of Neah Bay of 1855 and the MMPA.

XI. Classification

Rulemaking Authority

I have waived the MMPA take moratorium pursuant to 16 U.S.C. 1371(a)(3)(A) to allow for a limited hunt on ENP gray whales by the Makah Tribe and promulgated regulations to govern the issuance of hunt permits and the hunt itself pursuant to 16 U.S.C. 1373.

NEPA

NMFS prepared an FEIS for this action. The FEIS was filed with the Environmental Protection Agency on November 10, 2023. A notice of availability was published on November 17, 2023. 88 FR 80300. NMFS issued a ROD identifying the selected alternative. A copy of the ROD is available from NMFS (see **ADDRESSES**) and at <https://www.fisheries.noaa.gov/west-coast/marine-mammal-protection/makah-tribal-whale-hunt>.

Tribal Impact Statement (E.O. 13175)

E.O. 13175 of November 6, 2000, Presidential Memoranda of April 29, 1994; November 5, 2009; and January 26, 2021 (titled Memorandum on Government-to-Government Relations with Native American Tribal Governments; Presidential Memorandum on Tribal Consultation; and Tribal Consultation and Strengthening Nation-to-Nation Relationships, respectively), Department of Commerce Administrative Order 218–8: Consultation and Coordination with Indian Tribal Governments (April 26, 2012), Department of Commerce Tribal Consultation and Coordination Policy (May 21, 2013), and NOAA's Procedures for Government to Government Consultation with Federally Recognized Indian Tribal Governments (November 2013, amended June 2023) outline the responsibilities of NMFS in matters affecting Tribal interests. Section 161 of Public Law 108–199 (188 Stat. 452), as amended by section 518 of Public Law 108–447 (118 Stat. 3267), extends the consultation requirements of E.O. 13175 to Alaska Native corporations. E.O. 13175 requires that NMFS: (1) Have regular and meaningful consultation and collaboration with Indian Tribal governments in the development of Federal regulations that significantly or uniquely affect their communities; (2) reduce the imposition of unfunded mandates on Indian Tribal governments; and (3) streamline the applications process for and increase the availability of waivers to Indian Tribal governments.

Under the E.O., Presidential Memoranda, and Agency policies, NMFS must ensure meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications. Section 5(b)(2)(B) of E.O. 13175 requires NMFS to prepare a Tribal summary impact statement as part of the final rule. This statement must contain: (1) a description of the extent of the agency's prior consultation with Tribal officials; (2) a summary of the nature of their concerns; (3) the agency's position supporting the need to issue the regulation; and (4) a statement of the extent to which the concerns of Tribal officials have been met.

Prior Consultation With Tribal Officials

NMFS developed these regulations in response to a request from the Makah Tribe, received on February 14, 2005. The Tribe requested a waiver of the MMPA's take moratorium to allow a limited ceremonial and subsistence hunt of ENP gray whales. Consistent with the E.O. directives, NMFS consulted with the Makah Tribe in developing the proposed waiver and regulations that were published on April 5, 2019. 84 FR 13604. As described above, publication of the proposed waiver and regulations initiated a formal rulemaking proceeding.

Six parties, including the Makah Indian Tribe, participated in the proceedings, including a trial-type hearing in November of 2019. The hearing concluded after 6 days of testimony from 17 witnesses. Hearings under this formal rulemaking process are subject to requirements of the APA and regulations promulgated by NMFS. 5 U.S.C. 556–557; 50 CFR 228.1 through 228.21. The APA imposes certain restrictions on communication regarding the merits of the proceedings during formal rulemaking. These restrictions begin when the agency publishes the notice of hearing or has knowledge that it will be published and remain in place until the formal rulemaking process is complete.

On April 5, 2019, NMFS published a notice of hearing on this matter. 84 FR 13639. Given the APA's restrictions, we have not engaged in government-to-government consultation with the Makah Indian Tribe since the formal proceedings were initiated. We will conduct further government-to-government consultation on the related processes following publication of this Final Decision on the waiver and the regulations.

That we have not engaged in government-to-government consultation

since initiation of the formal proceedings does not mean that we have not heard the Makah's support for and concerns related to this action. In accordance with the rules governing the proceeding, the parties, including the Makah Tribe, submitted direct and rebuttal testimony, along with supporting exhibits, in advance of the hearing. Following the hearing, the Makah Tribe submitted post-hearing briefs and proposed findings of fact and conclusions of law as well as comment on the tribunal's Recommended Decision. The Makah Tribe submitted comments on the DEIS and its supplement. The Tribe also submitted comments and rebuttal during the party comment period following the publication of the FEIS.

We received additional comments in support of the waiver from the Northwest Indian Fisheries Commission, Tulalip Tribes, Jamestown S'Klallam Tribe, Puyallup Tribe of Indians, Squaxin Island Tribe, Lower Elwha Klallam Tribe, Suquamish Tribe, Swinomish Indian Tribal Community, and the Washington Indian Gaming Association. We have summarized the Tribal concerns below. In addition, comments and our responses on the tribunal's Recommended Decision are addressed above, and comments on the DEIS/SDEIS are included in the appendices to the FEIS.

Summary of the Nature of Tribal Concerns

This action is being taken in response to a request from the Makah Tribe to conduct a limited ceremonial and subsistence harvest of ENP gray whales. The Makah Tribe has at least a 1,000-year-old whaling tradition and reserved an express right to take whales in the Treaty of Neah Bay of 1855. The Tribe agreed with the tribunal that NMFS had satisfied all the requirements for the waiver and that the tribunal's recommendation to issue the waiver and promulgate final regulations relied on the best available science and appropriately weighted the supporting materials and conclusions presented. The Tribe also supported NMFS's pre-hearing proposed revisions to the proposed regulations, including clarifying that members of the Tribe living off-reservation may share edible products at their residences with non-Makah family members and guests.

The Tribe's concerns with the tribunal's recommended decision centered around four themes: (1) the Treaty of Neah Bay of 1855; (2) specifying low abundance thresholds; (3) training approaches on calves and adult whales accompanying a calf; and

(4) consideration of WNP whales. The Makah Tribe notes that the Recommended Decision asserted that the MMPA and not the Treaty of Neah Bay is the controlling law on whether a hunt may proceed. The Tribe believes that because the MMPA did not abrogate the Treaty, the Treaty and the MMPA must be harmonized in evaluating whether the hunt may proceed.

With respect to abundance thresholds, the Tribe did not object in principle to the tribunal's recommendation to set a low abundance threshold for the ENP populations but did not think it is necessary. Described in more detail in their comment letter, the Tribe concluded that "establishing an abundance threshold that would suspend the hunt is not necessary to protect the ENP population as a whole in light of its long-term abundance trend, the limited number of strikes that would be authorized, the practice of transferring unutilized whales to the Russian Federation and the IWC Scientific Committee's conclusion that the proposed hunt—without such a threshold—will meet all applicable IWC conservation objectives." If a low abundance threshold is included, the Makah Tribe recommended that a threshold of 15,788, MNPL based on Punt and Wade (2012), would be appropriate until NMFS conducts an updated analysis.

The Tribe expressed concern about including a prohibition on all approaches of calves or adults accompanying calves given (1) an asserted lack of scientific evidence presented that demonstrated an adverse effect from these approaches; (2) a broad prohibition would impair training regarding avoidance of calves and cow-calf pairs during a hunt; and (3) the difficulties of identifying a calf or cow-calf pair from the whaling canoe leading to inadvertent violation of the proposed regulations.

The Makah Tribe conveyed a number of concerns related to the consideration of WNP gray whales during the proceedings and in the Recommended Decision. First, the Tribe does not support the tribunal's recommendation to add a separate requirement that the Tribe obtain an ITA for the take of WNP gray whales prior to the issuance of a hunt permit. The Tribe does not agree with this recommendation but noted that should NMFS adopt it, it should be limited to non-lethal approaches of WNP gray whales as all other forms of take are a very remote possibility and will be adequately addressed under § 216.113(a)(7)(vii) of the proposed regulations.

Second, the Tribe maintains that the WNP stock is not a listed species under the ESA, and therefore, is not a depleted stock under the MMPA. They argue that the WNP stock's essential attributes are fundamentally different from those of the stock that remained listed in 1994. They also assert that there is no evidence that the non-lethal approaches of WNP gray whales that would occur over the waiver period would be detrimental to, much less disadvantage, the stock by affecting its ability to attain or maintain OSP.

Comments from other Tribal Nations supported the Tribe's efforts to exercise its Treaty rights, encouraged granting the waiver in a timely manner, and encouraged government-to-government consultation with the Makah Tribe. They also noted that the Recommended Decision relied on an extensive scientific record and that the proposed waiver complies with all requirements under the MMPA.

Agency's Position Supporting the Need To Issue the Regulation

The Makah Tribe reserved the right to hunt whales through the Treaty of Neah Bay of 1855. Section 4 of the Treaty specifically provides: "The right of taking fish and of whaling or sealing at usual and accustomed grounds and stations is further secured to said Indians in common with all citizens of the United States." In *Anderson v. Evans*, 371 F.3d 475 (9th Cir. 2004), the U.S. Court of Appeals for the Ninth Circuit held that the Makah Tribe and NMFS must comply with the MMPA's waiver process in order for the Tribe to exercise their right to whale.

In light of the decision in *Anderson*, in 2005 the Makah Tribe asked NMFS to waive the MMPA's moratorium and authorize a limited ceremonial and subsistence hunt for ENP gray whales. This action is consistent with the United States Government's obligations to the Tribe under the Treaty of Neah Bay of 1855 and the Federal trust responsibility and aims to fulfill the Tribe's cultural and subsistence needs. This action is consistent with E.O. 13175; Presidential Memoranda of April 29, 1994; November 05, 2009, and January 26, 2021; Department of Commerce's Tribal Consultation Policy (Administrative Order 218–8 of April 26, 2012 and Tribal Consultation and Coordination Policy of the U.S. Department of Commerce); and NOAA's Tribal Consultation Policy.

Statement of the Extent to Which the Concerns of Tribal Officials Have Been Met

NMFS carefully considered the concerns of the Makah Indian Tribe in developing the final regulations. The Makah maintain that "because the MMPA did not abrogate the Treaty, the MMPA and Treaty must be harmonized in evaluating whether the hunt may proceed." I have not adopted the sections of the Recommended Decision that suggest the Treaty of Neah Bay is not relevant (see comment 46). I have also provided a process through which the Tribe may request a modification to the final regulations (see comment 46).

We agree with several of the concerns that the Tribe raised with respect to approaches on calves and adults with calves (see comment 34). To address these concerns, I have modified the requirements in the Recommended Decision to prohibit approaches on these animals only after a member of the whaling team has identified a calf or an adult with a calf.

The Makah Tribe did not support the recommendation to include a requirement that an ITA be obtained prior to permitting winter/spring hunt activities. Although the tribunal determined that an ITA was necessary during the winter/spring hunt, the final regulations adopt a more adaptive approach based on an assessment of the risk to WNP gray whales associated with the hunting authorized under a permit. Under the final regulations, NMFS is required to assess whether take of WNP gray whales is anticipated based on the hunting proposed in the Makah's permit application. If take is anticipated, then separate authorization is required during the winter/spring hunt. This approach requires NMFS to address risks to WNP gray whales by ensuring that anticipated takes are authorized but allows for consideration of the hunt structure proposed in the permit application and the best available scientific information at that time (see comment 21 and section VIII, *Risk to WNP Gray Whales*).

While the Makah Tribe did not object in principle to the tribunal's recommendation to set a low abundance threshold for the ENP populations, they do not think it is necessary. The Tribe further recommended a low abundance threshold, if included, of 15,788, MNPL based on Punt and Wade (2012). MNPL is the lower bound of OSP. The regulations specify that the ENP gray whale population must be within its OSP to authorize hunt activities, which is consistent with the Tribe's suggestion to base the low abundance threshold on

MNPL but provides for consideration of the best available information at the time of the issuance of a hunt permit (see comment 12) and ensures consistency with section 103(a) of the MMPA.

The Makah Tribe also provided comments on gray whale stock structure and the disadvantage test with respect to WNP gray whales. Those comments are fully addressed in section V of this Final Decision.

E.O. 12866 and E.O. 13563—Improving Regulation and Regulatory Review

E.O. 12866 provides that significant regulatory actions be submitted for review to the Office of Information and Regulatory Affairs, and the Office of Management and Budget. Section 3(d)(1) of E.O. 12866 provides that regulations "issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556 and 557" are not regulations covered by that E.O. In accordance with 16 U.S.C. 1373(d) and 50 CFR 228.3, these regulations were developed in accordance with the formal rulemaking procedures of 5 U.S.C. 556 and 557 and are thus exempt from review under E.O. 12866.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. It also emphasizes that regulations must be based on the best available science and that the rulemaking process must allow for public participation. NMFS has developed this rule in a manner consistent with these requirements.

RFA

The RFA (5 U.S.C. 601 *et seq.*) requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice of proposed rulemaking requirements under the APA unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA defines small entities, in pertinent part, as small businesses, small organizations and small governmental jurisdictions. This rule affects only a single tribe. Tribes are not considered small entities under the RFA. The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel

for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

Paperwork Reduction Act

This final rule contains no information collection requirements subject to the Paperwork Reduction Act.

CZMA

To the extent that the enforceable policies of the WCZMP apply, NMFS determined that this action will be implemented in a manner that is consistent, to the maximum extent practicable, with the enforceable policies of WCZMP. This determination was submitted for review to the State of Washington under section 307 of the CZMA. On June 2, 2023, the State of Washington, through its Department of Ecology, agreed with NMFS's determination that this action is consistent with the enforceable policies of WCZMP.

E.O. 13132—Federalism

E.O. 13132 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 examine the statutory authority supporting any action that would limit the policy-making discretion of the states, and to the extent practicable, must consult with state and local officials before implementing any such action. This rule does not have substantial direct effects on the states and therefore does not have the type of federalism implications contemplated by the E.O. We do not foresee that the rule would significantly affect the distribution of power and responsibilities among the various levels of government or limit the policy-making discretion of the states.

ESA

Informal consultations under section 7 of the ESA were concluded with FWS and NMFS West Coast Regional Office March 15, 2023, and November 8, 2023, respectively. As a result of the informal consultation, the FWS and NMFS WCR determined that activities conducted

under this rule are not likely to adversely affect endangered or threatened species or critical habitat under their jurisdiction.

E.O. 12898—Environmental Justice

Under E.O. 12898, each Federal agency must 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, denying persons the benefits of, or subjecting persons to discrimination under such programs, policies, and activities because of their race, color, or national origin. Section 4–4, Subsistence Consumption of Fish and Wildlife, of E.O. 12898, requires Federal agencies to ensure protection of populations with differential patterns of subsistence consumption of fish and wildlife and to communicate to the public the human health risks of those consumption patterns. NMFS has evaluated the data available on contaminant loads in ENP gray whales and has summarized this information in the FEIS. NMFS communicated this information to the Makah Indian Tribe prior to issuing the proposed rule and will provide any updated information included in the FEIS to the Tribe.

References and Literature Cited

A complete list of all references cited in this rulemaking is available on our website and upon request.

List of Subjects in 50 CFR Part 216

Administrative practice and procedure, Exports, Fish, Imports, Indians, Labeling, Marine mammals.

Dated: June 5, 2024.

Janet Coit,

Assistant Administrator, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 216 is amended as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

■ 2. Subpart J is added to read as follows:

Subpart J—Taking of Eastern North Pacific (ENP) Gray Whales (*Eschrichtius robustus*) by the Makah Indian Tribe Off the Coast of Washington State

Sec.

216.110 Purpose.

216.111 Scope.

216.112 Definitions.

216.113 Issuance and duration of permits.

216.114 Hunt management requirements and restrictions.

216.115 Accounting and identification of gray whales.

216.116 Use of edible and nonedible whale products.

216.117 Prohibited acts.

216.118 Requirements for monitoring, reporting, and recordkeeping.

216.119 Expiration and amendment.

§216.110 Purpose.

The purpose of this subpart is to establish regulations governing the take of whales from the Eastern North Pacific (ENP) gray whale (*Eschrichtius robustus*) stock by the Makah Indian Tribe and its enrolled members in accordance with the Secretary's determination to issue a waiver of the Marine Mammal Protection Act (MMPA) take moratorium pursuant to 16 U.S.C. 1371(a)(3).

§216.111 Scope.

This subpart authorizes the taking of ENP gray whales only by enrolled members of the Makah Indian Tribe only.

§216.112 Definitions.

In addition to the definitions provided in the MMPA, for purposes of this subpart, the following definitions apply:

Barter means the exchange of parts from gray whales taken under this subpart for other wildlife or fish or their parts or for other food or for nonedible items other than money if the exchange is of a noncommercial nature.

Bonilla-Tatoosh Line means the line running from the western end of Cape Flattery (48°22'53" N lat., 124°43'54" W long.) to Tatoosh Island Lighthouse (48°23'30" N lat., 124°44'12" W long.) to the buoy adjacent to Duntze Rock (48°28'00" N lat., 124°45'00" W long.), then in a straight line to Bonilla Point (48°35'30" N lat., 124°43'00" W long.) on Vancouver Island, British Columbia.

Calf means any gray whale less than 1 year old.

Enrolled member or *member* of the Makah Indian Tribe means a person whose name appears on the membership roll maintained by the Makah Tribal Council.

ENP gray whale means a member of the Eastern North Pacific stock of gray whales (*Eschrichtius robustus*).

Export means the act of sending goods from one country to another.

Gray whale means a member of the species *Eschrichtius robustus*.

Harpooner means a member of the Makah Indian Tribe who has been certified by the Tribe as having demonstrated the qualifications commensurate with the duties and responsibilities of harpooning a gray whale.

Hunt and hunting mean to pursue, strike, harpoon, shoot, or land a gray whale under a hunt permit issued under § 216.113(b) or to attempt any such act, but does not include hunting approaches, training approaches, or training harpoon throws. As a noun, *hunt* also means any act of hunting.

Hunt permit means a permit issued by NMFS in accordance with 16 U.S.C. 1374 and this subpart.

Hunting approach means to cause, in any manner, a vessel to be within 100 yards (91.5 m) of a gray whale during a hunt.

Land and landing mean bringing a gray whale or any products thereof onto the land in the course of hunting.

Makah Indian handicrafts means articles made by a member of the Makah Indian Tribe that contain any nonedible products of an ENP gray whale that was obtained pursuant to a permit issued under this subpart, are significantly altered from their natural form, and are produced, decorated, or fashioned in the exercise of traditional Makah Indian handicrafts without the use of pantographs, multiple carvers, or similar mass copying devices. Makah Indian handicrafts include, but are not limited to, articles that are carved, beaded, drawn, or painted.

Makah Indian Tribe or Tribe means the Makah Indian Tribe of the Makah Indian Reservation as described in the list of federally recognized Indian tribes maintained by the U.S. Department of the Interior.

Minimum population estimate for Pacific Coast Feeding Group (PCFG) gray whales is the lower 20th percentile of the PCFG population estimate.

NMFS means the National Marine Fisheries Service.

NMFS hunt observer means a person designated by NMFS to accompany and observe a hunt.

Pacific Coast Feeding Group (PCFG) gray whale or PCFG whale means an ENP gray whale photo-identified during 2 or more years between June 1 and November 30 within the region between northern California and northern Vancouver Island (from 41° N lat. to 52°

N lat.) and entered into a photo-identification catalog(s) recognized by the Regional Administrator.

PCFG population estimate means an abundance estimate based on data derived from photo-identification surveys and catalog(s) recognized by the Regional Administrator. Such data will also be the basis for projecting PCFG population estimates in future hunting seasons.

Recordkeeping and reporting mean the collection and delivery of photographs, biological data, harvest data, and other information regarding activities conducted under the authority of this subpart.

Regional Administrator means the Regional Administrator of NMFS for the West Coast Region.

Rifleman means a member of the Makah Indian Tribe who has been certified by the Tribe as having demonstrated the qualifications commensurate with the duties and responsibilities of shooting a gray whale.

Safety officer means a member of the Makah Indian Tribe who has been certified by the Tribe as having demonstrated the qualifications commensurate with the duties and responsibilities of evaluating hunt conditions including, but not limited to visibility, target range and bearing, and sea condition.

Share means to voluntarily transfer or gift edible or nonedible parts from gray whales taken under this subpart to another person without compensation.

Strike or struck means to cause a harpoon, darting gun, or other weapon, or a projectile from a rifle or other weapon, to penetrate a gray whale's skin or an instance in which a gray whale's skin is penetrated by such a weapon or projectile during hunting. Multiple strikes on the same whale are considered a single strike.

Struck and lost refers to a gray whale that is struck but not landed.

Summer/fall hunt means a hunting season spanning 4 consecutive months from July 1 to October 31.

Training approach means to cause, in any manner, a training vessel to be within 100 yards (91.5 m) of a gray whale.

Training harpoon throw means an attempt to contact a gray whale with a blunted spear-like device that is incapable of penetrating the skin of a gray whale.

Training vessel means a canoe or other watercraft used to train for a hunt that does not carry weapons ordinarily used by a harpooner or rifleman to strike a gray whale.

Tribal hunt observer means a Tribal member or representative designated by the Tribe who has been certified by the Tribe as having demonstrated the qualifications commensurate with the duties and responsibilities of monitoring and reporting on a hunt.

U&A or Makah Indian Tribe's U&A means the Tribe's usual and accustomed fishing grounds, which area consists of the United States waters in the western Strait of Juan de Fuca west of 123°42'17" W long. and waters of the Pacific Ocean off the mainland shoreline of the Washington coast north of 48°02'15" N lat. (Norwegian Memorial) and east of 125°44'00" W long.

Unsuccessful strike attempt means any attempt to strike a gray whale while hunting that does not result in a strike.

Western North Pacific (WNP) gray whale means a member of the Western North Pacific stock of gray whales (*Eschrichtius robustus*).

Whaling captain means a member of the Makah Indian Tribe who has been certified by the Tribe as having demonstrated the qualifications commensurate with the duties and responsibilities of leading a hunt and is authorized by the Makah Indian Tribe to be in control of the whaling crew.

Whaling crew means those members of the Makah Indian Tribe taking part in a hunt under the control of a whaling captain, not including the Tribal hunt observer.

Winter/spring hunt means a hunting season spanning 6 consecutive months from December 1 to May 31 of the calendar year following a summer/fall hunt.

§ 216.113 Issuance and duration of permits.

(a) *Application.* (1) To obtain an initial hunt permit, the Makah Indian Tribe must submit an application to the Regional Administrator signed by an official of the Makah Tribal Council that contains the following information and statements:

(i) The proposed duration of the permit;

(ii) The maximum number of gray whales to be subjected to hunting or training approaches, struck, landed, and subjected to unsuccessful strike attempts;

(iii) A demonstration that the proposed method of taking is humane;

(iv) A demonstration that the proposed taking is consistent with this subpart;

(v) A copy of the currently enacted Makah Indian Tribal ordinance governing whaling by Makah Indian Tribal members;

(vi) A description of the certification process for whaling captains, riflemen,

harpooners, Tribal hunt observers, and safety officers, including any guidelines or manuals used by the Tribe to certify such persons;

(vii) Any additional hunt permit conditions proposed by the Tribe and a justification for the proposed conditions; and

(viii) Any modification to this subpart sought by the Tribe and a justification for the proposed modification.

(2) To obtain subsequent hunt permits, the Makah Indian Tribe must submit an application to the Regional Administrator, signed by an official of the Makah Tribal Council, that contains the information required in paragraph (a)(1) of this section and the following information and statements:

(i) A description of how the Makah Indian Tribe has complied with the requirements of this subpart and previously issued hunt permits;

(ii) A description of circumstances associated with gray whale(s) struck and lost under the most recently issued hunt permit, a description of the measures taken to retrieve such whale(s), and a description of measures taken by the Makah Indian Tribe to minimize future incidents of struck and lost gray whales; and

(iii) A description of products obtained from gray whales landed under the most recently issued hunt permit, including a description of the disposition of any gray whale products deemed unsuitable for use by Makah Indian Tribal members.

(3) The Regional Administrator will notify the Makah Indian Tribe of receipt of the application and will review the application for completeness. Incomplete applications will be returned with explanation. If the Makah Indian Tribe fails to resubmit a complete application within 60 days, the application will be deemed withdrawn.

(4) After receipt of a complete application and the preparation of any National Environmental Policy Act (NEPA) documentation that the Regional Administrator has determined to be necessary, the Regional Administrator will publish a notice of receipt in the **Federal Register** and review the application as required by 16 U.S.C. 1374.

(b) *Issuance.* (1) The Regional Administrator may issue hunt permits to the Makah Indian Tribe authorizing hunting of ENP gray whales, as well as hunting approaches, training approaches, and training harpoon throws by enrolled members in accordance with 16 U.S.C. 1374 and the requirements of this subpart.

(2) The Regional Administrator may not authorize hunting, hunting approaches, training approaches, or training harpoon throws from December 1 through May 31 unless:

(i) The Tribe has obtained separate authorization to take WNP gray whales under any applicable provision of the MMPA; or

(ii) The Regional Administrator determines, in consultation with the NMFS Office of Protected Resources, that take of WNP gray whales is not anticipated.

(3) The Regional Administrator may not authorize hunting unless the population of the ENP gray whale stock is within its Optimum Sustainable Population (OSP) and the hunting authorized under the permit would not cause the stock to diminish below OSP.

(4) The duration of the initial hunt permit may not exceed 3 years from its effective date, and thereafter the duration of a hunt permit may not exceed 5 years.

(5) Each hunt permit will specify the following terms and conditions:

(i) Those terms required by 16 U.S.C. 1374(b);

(ii) The limits established under § 216.114(c);

(iii) The area where hunts, hunting approaches, training approaches, and training harpoon throws are allowed, which will be limited to the waters of the Makah Indian Tribe's U&A west of the Bonilla-Tatoosh Line except as provided in § 216.117(a)(9), and any site and time restrictions to protect Olympic Coast National Marine Sanctuary resources pursuant to consultation under 16 U.S.C. 1434(d) of the National Marine Sanctuaries Act;

(iv) The beginning and ending dates in each calendar year when the Makah Tribe may engage in hunting activities, as described in § 216.114(a), and training activities, as described in § 216.114(b);

(v) The type and timing of notice that the Makah Indian Tribe must provide to NMFS before issuing a Tribal whaling permit authorizing a hunt, hunting approaches, training approaches, or training harpoon throws;

(vi) Measures to be taken by the hunt permit holder to provide for the safety of the whaling crew, the public, and others during a hunt;

(vii) That the hunt permit authorizes only the take of ENP gray whales and not the take of any other marine mammals; and

(viii) Such other provisions as the Regional Administrator deems necessary.

(6) Before issuing a hunt permit, the Regional Administrator must make the following determinations:

(i) The authorized manner of hunting is humane;

(ii) The Makah Indian Tribe has enacted a Tribal ordinance governing hunting that is consistent with this subpart;

(iii) The Makah Indian Tribe has in place certification procedures for whaling captains, riflemen, harpooners, Tribal hunt observers, and safety officers and a process to ensure compliance with those procedures;

(iv) There are adequate photo-identification catalogs and processes available to allow for the identification of WNP gray whales and PCFG whales as described in § 216.115(b);

(v) The most recent PCFG population estimate is at least 192 whales and the associated minimum population estimate is at least 171 whales;

(vi) The PCFG population estimate for the first hunting season covered by the permit is projected to be at least 192 whales and the associated minimum population estimate is projected to be at least 171 whales;

(vii) Whether take authorization for WNP gray whales is required by the permit for the winter/spring hunt, or, if not, that the Regional Administrator, in consultation with the Office of Protected Resources, has determined that take of WNP gray whales is not anticipated;

(viii) The population of the ENP gray whale stock is within its OSP and the hunting authorized in the permit will not cause the stock to diminish below OSP; and

(ix) Except for the initial hunt permit, before issuing a hunt permit the Regional Administrator must determine that the Makah Indian Tribe has complied with the requirements of this subpart and all prior permit terms and conditions, or if the Makah Indian Tribe has not fully complied, that it has adopted measures to ensure compliance.

§ 216.114 Hunt management requirements and restrictions.

(a) *Hunting seasons.* Summer/fall hunts and hunting approaches will only be authorized from July 1 through October 31, and winter/spring hunts and hunting approaches will only be authorized from December 1 through May 31 of the following calendar year, provided that:

(1) Throughout the duration of the waiver, the authorized hunting dates will alternate between winter/spring hunts and summer/fall hunts, with winter/spring hunts starting in December of the same calendar year as a summer/fall hunt and summer/fall

hunts starting in the calendar year following the year in which a winter/spring hunt has ended;

(2) If the start date in the initial hunt permit falls within a winter/spring hunt period, the subsequent summer/fall hunt will commence in the calendar year following the ending date of said winter/spring hunt; and

(3) If the start date in the initial hunt permit of the initial hunt season falls within a summer/fall hunt period, the subsequent winter/spring hunt will commence in December of the same calendar year as said summer/fall hunt.

(b) *Training period.* Hunt permits may authorize training approaches in any month and training harpoon throws in any month, except as provided in paragraph (c)(2) of this section and provided all necessary authorizations have been obtained. The authorized training period shall be specified in the permit, as provided in § 216.113(b)(5)(iv).

(c) *Hunting and training limits.* The following limits on the number of ENP gray whales approached, subjected to unsuccessful strike attempts, struck, struck and lost, and landed apply.

(1) A hunt permit may authorize no more than 353 approaches, including both hunting and training approaches, each calendar year of which no more than 142 of such approaches may be on PCFG whales. Any hunting approach on a gray whale that has already been struck will not count against these limits.

(2) A hunt permit may authorize no more than 18 unsuccessful strike attempts during winter/spring hunts and no more than 12 unsuccessful strike attempts during summer/fall hunts. Any unsuccessful strike attempt on a gray whale that has already been struck will not count against these limits. Training harpoon throws may be authorized between July 1 and October 31 in years of summer/fall hunts and at any time during winter/spring hunts as well as the subsequent 7 months of the calendar year in which those winter/spring hunts end. Each training harpoon throw will count against the unsuccessful strike attempt limit during the calendar year in which the harpoon throw is made.

(3) A hunt permit may authorize no more than three ENP gray whales to be struck in a winter/spring hunt and no more than two ENP gray whales to be struck in a summer/fall hunt. Multiple strikes on the same whale will count as a single strike. In a winter/spring hunt, a hunt permit may authorize no more than one ENP gray whale to be struck within the 24-hour period commencing at the time of the initial strike against the whale. The Regional Administrator

may authorize the full number of ENP gray whales to be struck in the initial hunt permit and will adjust strikes downward in subsequent permits if necessary to ensure that no more than 16 PCFG whales are struck over the waiver period, of which no more than 8 struck whales may be PCFG females.

(4) A hunt permit may authorize no more than three ENP gray whales to be struck and lost in any calendar year.

(5) A hunt permit may authorize no more than three ENP gray whales to be landed in a winter/spring hunt and no more than one ENP gray whale to be landed in a summer/fall hunt; the number of ENP gray whales that the hunt permit may authorize to be landed in any calendar year will not exceed the number agreed between the United States and the Russian Federation as the United States' share of the catch limit established by the International Whaling Commission.

(d) *Limits on PCFG whales.* (1) Thirty days prior to the beginning of a hunting season specified in paragraph (a) of this section, the Regional Administrator will notify the Makah Indian Tribe in writing of the maximum number of PCFG whales, including females, that may be struck during the upcoming hunting season. The limit will take into account the abundance of PCFG whales relative to the conditions specified under § 216.113(b)(6)(v) and (vi) and the number of strikes made on PCFG whales as described under paragraph (c)(3) of this section.

(2) By November 1 of each year, the Regional Administrator will notify the Makah Indian Tribe in writing of the proportion of gray whales in the hunt area that will be presumed to be PCFG whales and the proportion of PCFG whales that will be presumed to be females for each month of the upcoming calendar year. The presumed proportion of PCFG whales will be based on the best available evidence for the months of December through May and will be 100 percent for the months of June through November. The presumed proportion of female PCFG whales will be based on the best available information for each month. These proportions will be used for purposes of accounting for PCFG whales that are not otherwise identified or accounted for as provided under § 216.115(b).

(3) The Regional Administrator will notify the Makah Indian Tribe in writing when the Tribe has reached the limit of PCFG whales that may be struck in any hunting season.

(4) Notwithstanding the limits specified in this section, no hunting will be authorized for an upcoming season if the Regional Administrator determines,

and notifies the Makah Indian Tribe pursuant to paragraph (d)(1) of this section, that either of the following conditions applies:

(i) The most recent PCFG population estimate, based on photo-identification surveys, is less than 192 whales or the associated minimum population estimate is less than 171 whales; or

(ii) The PCFG population estimate for the upcoming hunting season is projected to be less than 192 whales or the associated minimum population estimate is projected to be less than 171 whales.

(e) *ENP gray whales.* If the Regional Administrator determines and notifies the Makah Indian Tribe in writing that the population of the ENP gray whale stock has fallen below OSP, hunting must cease until the Regional Administrator notifies the Tribe in writing that the stock has obtained OSP.

(f) *WNP gray whales.* The hunt permit will provide that in the event the Regional Administrator determines a WNP gray whale was struck during a hunt, the Regional Administrator will notify the Makah Indian Tribe in writing and require that the Tribe cease hunting for the duration of the permit unless and until the Regional Administrator determines that measures have been taken to ensure no additional WNP gray whales will be struck during the duration of the permit. No further hunt permits will be issued unless and until the Regional Administrator determines that measures have been taken to prevent additional WNP gray whale strikes during the remainder of the waiver period.

§ 216.115 Accounting and identification of gray whales.

(a) *Images and samples.* NMFS hunt observers, Tribal hunt observers, and members of the Makah Indian Tribe may collect still or motion pictures as needed to document hunting and training approaches, strikes (successful and unsuccessful attempts), and landings. Persons designated by NMFS and by the Makah Indian Tribe may also collect, store, transfer, and analyze specimen samples from struck gray whales. Such designated personnel should make every reasonable attempt to collect genetic samples from struck whales without compromising the safety of the hunt.

(b) *Identification and accounting of gray whales—*(1) *Winter/spring hunts.* Based on the best available evidence, the Regional Administrator will determine in writing whether a gray whale that is struck in a winter/spring hunt is a WNP gray whale or a PCFG whale or neither, or cannot be identified

due to a lack of photographs or genetic data useful for making identifications. A whale affirmatively identified as a PCFG whale will be counted accordingly. A whale that cannot be identified will be presumed to be a PCFG whale in accordance with the proportions specified in § 216.114(d)(2) and will be counted accordingly. If the sex of a whale that is counted, in whole or in part, as a PCFG whale cannot be identified, the proportions specified in § 216.114(d)(2) will be applied.

(2) *Summer/fall hunts.* Based on available evidence, the Regional Administrator will determine in writing whether a gray whale that is struck in a summer/fall hunt is a WNP gray whale or cannot be identified due to a lack of photographs or genetic data useful for making identifications. A gray whale that cannot be identified as a WNP gray whale will be counted as a PCFG whale. If the sex of a whale that is counted as a PCFG whale cannot be identified, the proportions specified in § 216.114(d)(2) will be applied.

(3) *Hunting and training approaches.* Gray whales subjected to hunting or training approaches are presumed to be PCFG whales in accordance with the proportions specified in § 216.114(d)(2).

(4) *Unauthorized strikes.* If a Tribal member strikes an ENP gray whale without authorization under this subpart, the strike will be counted against the total number of strikes allowed under this subpart and will be counted against the United States' share of any applicable catch limit established by the International Whaling Commission.

§ 216.116 Use of edible and nonedible whale products.

(a) Gray whales landed under a hunt permit may be utilized as follows:

(1) *Edible products of ENP gray whales.* Enrolled members of the Makah Indian Tribe may possess, consume, and transport edible whale products and may share and barter such products with other enrolled members, both within and outside the Makah Indian Tribe's reservation boundaries, subject to the following restrictions:

(i) Within the Tribe's reservation boundaries, enrolled members of the Makah Indian Tribe may share edible ENP gray whale products with any person.

(ii) Outside the Makah Indian Tribe's reservation boundaries, enrolled members of the Makah Indian Tribe may share edible ENP gray whale products:

(A) At the Tribal member's residence with any person, provided the products are shared for consumption at the Tribal member's residence; or

(B) With any person attending a Tribal or intertribal gathering sanctioned by the Makah Tribal Council, so long as there is not more than 2 pounds of such edible product per person attending the gathering.

(iii) Any person who is not an enrolled member of the Makah Indian Tribe may possess, consume, and transport edible ENP gray whale products within the Makah Indian Tribe's reservation boundaries so long as the products are shared by an enrolled member of the Makah Indian Tribe. Outside the Tribe's reservation boundaries, any person who is not an enrolled member of the Makah Indian Tribe may possess, consume, and transport edible gray whale products only at a Tribal member's residence or at a Tribal or intertribal gathering sanctioned by the Makah Tribal Council if such products are shared by an enrolled member of the Makah Indian Tribe and the person consumes the products at the gathering.

(2) *Nonedible products of ENP gray whales.* (i) Enrolled members of the Makah Indian Tribe may possess nonedible whale products that have not been fashioned into Makah Indian handicrafts and Makah Indian handicrafts that have not been marked and certificated per paragraph (a)(2)(iii) of this section, may transport such products, and may share and barter such products with other enrolled members both within and outside the Makah Indian Tribe's reservation boundaries. (ii) Enrolled members of the Makah Indian Tribe may share or barter Makah Indian handicrafts that have not been marked and certificated per paragraph (a)(2)(iii) of this section with any person within the Tribe's reservation boundaries.

(iii) Any person may possess, transport, share, barter, offer for sale, sell, or purchase a Makah Indian handicraft in the United States, provided the handicraft is permanently marked with a distinctive marking approved by the Makah Tribal Council, and is accompanied by a certificate of authenticity issued by the Makah Tribal Council or its designee and entered in the Tribe's official record of Makah Indian handicrafts. Such handicrafts may be delivered, carried, transported, or shipped in interstate commerce.

(iv) Within the Makah Indian Tribe's reservation boundaries, any person who is not an enrolled member of the Makah Indian Tribe may possess and transport Makah Indian handicrafts that have not been marked and certificated per paragraph (a)(2)(iii) of this section, provided the handicraft was shared by or bartered from an enrolled member.

Within the Makah Indian Tribe's reservation boundaries, persons not enrolled as a member of the Makah Indian Tribe may share or barter such handicrafts only with enrolled members.

(b) The Makah Indian Tribe is responsible for managing all activities of any Makah Indian Tribal member carried out under this section.

§ 216.117 Prohibited acts.

(a) It is unlawful for the Makah Indian Tribe or any enrolled member of the Makah Indian Tribe to:

(1) Take any gray whale except as authorized by a hunt permit issued under § 216.113(b) or by any other provision of this part.

(2) Participate in a hunt while failing to carry onboard the vessel at all times a hunt permit issued by NMFS and a Tribal whaling permit issued by the Makah Indian Tribe, or an electronic copy or photocopy of these permits.

(3) Make a training approach or a training harpoon throw while failing to carry onboard the training vessel at all times an electronic copy or photocopy of the hunt permit issued by NMFS and a training logbook approved by the Makah Indian Tribe for recording training approaches and training harpoon throws.

(4) Participate in a hunt as a whaling captain, rifleman, harpooner, Tribal hunt observer, or safety officer, unless the individual's name is included in a Tribal certification report issued under § 216.118(a)(6)(i).

(5) Violate any provision of any hunt permit issued under § 216.113(b).

(6) Make an approach on a calf or an adult gray whale accompanying a calf after a member of the whaling crew has identified the presence of a calf.

(7) Fail to remain at least 100 yards (91.5 m) away from a calf or an adult accompanying a calf after a member of the whaling crew has identified the presence of a calf.

(8) Hunt or make a training harpoon throw on a calf or an adult gray whale accompanying a calf.

(9) Hunt outside the geographic area identified in § 216.113(b)(5)(iii) unless in pursuit of a gray whale that has already been struck within that area.

(10) Hunt, make a hunting or training approach, or make a training harpoon throw after reaching the limits specified in the hunt permit per § 216.113(b)(5)(i) through (viii).

(11) Hunt if the limit on PCFG whales or PCFG females that may be struck is less than one as a result of accounting per § 216.115(b)(1) through (3).

(12) Hunt after the Makah Indian Tribe has been notified in writing by the

Regional Administrator under § 216.114(d)(3) that the limit of PCFG whales that may be struck has been reached or that the PCFG abundance is below the limits specified in § 216.114(d)(4).

(13) Hunt after a gray whale has been landed and before the Makah Indian Tribe has received notification from the Regional Administrator in accordance with § 216.115(b).

(14) Hunt after the Makah Tribe has been notified by the Regional Administrator under § 216.114(e) that the ENP gray whale population has fallen below OSP.

(15) Sell, offer for sale, or purchase any gray whale products, except Makah Indian handicrafts that have been marked and certificated per § 216.116(a)(2).

(16) Export any gray whale products.

(17) Barter edible gray whale products with any person not enrolled as a member of the Makah Indian Tribe.

(18) Share edible gray whale products outside the Makah Indian Tribe's reservation boundaries with any person not enrolled as a member of the Makah Indian Tribe, except at a Tribal member's residence or with persons attending a Tribal or intertribal gathering sanctioned by the Makah Tribal Council, so long as there is not more than 2 pounds of edible product per person attending the gathering per § 216.116(a)(1)(ii)(B).

(19) Share or barter nonedible gray whale products:

(i) Outside the Makah Indian Tribe's reservation boundaries with any person not enrolled as a Makah Indian Tribal member, except Makah Indian handicrafts that are permanently marked and certificated per § 216.116(a)(2).

(ii) Within the Makah Indian Tribe's reservation boundaries with any person not enrolled as a Makah Indian Tribal member except a product that has been fashioned into a Makah Indian handicraft whether or not it has been marked and certificated per § 216.116(a)(2)(iii).

(20) Make a false statement in an application for a hunt permit or in a report required under this subpart.

(21) Transfer or assign a hunt permit issued under this subpart.

(22) Fail to submit reports required by this subpart.

(23) Deny persons designated by NMFS access to landed gray whales for the purpose of collecting specimen samples.

(24) Fail to provide required permits and reports for inspection upon request by persons designated by NMFS.

(25) Allow anyone other than enrolled Makah Indian Tribal members to be part of a whaling crew or to allow anyone other than such members or Tribal hunt observers to be in a training vessel engaged in hunt training.

(26) Hunt, or engage in hunting approaches, training approaches, or training harpoon throws without additional authorization to take WNP gray whales, if the Regional Administrator has notified the Tribe that additional authorization is required for the take of WNP gray whales.

(b) It is unlawful for any person who is not an enrolled member of the Makah Indian Tribe to:

(1) Share barter, purchase, sell, export, or offer to share, barter, purchase, sell, or export edible gray whale products.

(2) Possess, consume, or transport edible gray whale products except:

(i) Within the Makah Indian Tribe's reservation boundaries, when such products have been shared by an enrolled Makah Indian Tribal member;

(ii) At the residence of a Tribal member, whether or not the residence is within the Tribe's reservation boundaries; and

(iii) At Tribal or intertribal gatherings sanctioned by the Makah Tribal Council, whether or not the gathering is within the Tribe's reservation boundaries.

(3) Purchase, sell, or offer to purchase or sell nonedible gray whale products except Makah Indian handicrafts that are marked and certificated per § 216.116(a)(2).

(4) Export any gray whale products.

(5) Outside the Makah Indian Tribe's reservation boundaries, possess, transport, share, or barter nonedible gray whale products except Makah Indian handicrafts that are marked and certificated per § 216.116(a)(2)(iii).

(6) Within the Makah Indian Tribe's reservation boundaries, possess, transport, share, or barter any nonedible gray whale product except as provided in § 216.116(a)(2)(iii) and (iv).

§ 216.118 Requirements for monitoring, reporting, and recordkeeping.

(a) In addition to the reporting provisions described in § 230.8 of this chapter, the Makah Indian Tribe will:

(1) Ensure a certified Tribal hunt observer accompanies each hunt. The Tribal hunt observer will record in a hunting logbook the time, date, and location (latitude and longitude, accurate to at least the nearest second) of each hunting approach of a gray whale, each attempt to strike a gray whale, and each gray whale struck. For each gray whale struck, the Tribal hunt

observer will record whether the whale was landed. If not landed, the Tribal hunt observer will describe the circumstances associated with the striking of the whale and estimate whether the animal suffered a wound that might be fatal. For every gray whale approached by the whaling crew, the Tribal hunt observer must make every reasonable attempt to collect digital photographs useful for photo-identification purposes.

(2) Ensure that each vessel involved in a training approach has onboard a training logbook for recording the date, location, and number of gray whales approached and the number of training harpoon throws. Each training approach and training harpoon throw must be reported to the Tribal hunt observer within 24 hours.

(3) Maintain hunting and training logbooks specified in paragraphs (a)(1) and (2) of this section and allow persons designated by NMFS to inspect them upon request.

(4) Ensure that each whaling captain allows a NMFS hunt observer to accompany and observe any hunt.

(5) Maintain an official record of all articles of Makah Indian handicraft, including the following information for each article certified by the Makah Tribal Council or its designee: the date of the certification; the permanent distinctive mark identifying the article as a Makah Indian handicraft; a brief description of the handicraft, including artist's full name, gray whale product(s) used, and approximate size; and at least one digital photograph of the entire handicraft. A copy of the official record of Makah Indian handicrafts must be provided to NMFS personnel, including NMFS enforcement officers, upon request.

(6) Ensure that the following reports are filed electronically with the NMFS West Coast Region's office in Seattle, Washington, by the indicated date:

(i) *Tribal certification report.* Thirty days prior to the beginning of a hunting season, a report that includes the names of all Tribal hunt observers and enrolled Makah Indian Tribal members who have been certified to participate in a hunt as whaling captains, riflemen, harpooners, and safety officers. The Tribe may provide additional names during the hunting season.

(ii) *Incident report.* An incident report must be submitted within 48 hours after striking a gray whale. The report may address multiple gray whales so long as the Tribe submits the report within 48 hours of the first gray whale being struck. An incident report must contain the following information:

(A) Struck and lost gray whale(s): The whaling captain's name; the Tribal hunt observer's name; the date, location (latitude and longitude, accurate to at least the nearest second), time, and number of strikes and attempted strikes if any; the method(s) of strikes and attempted strikes; an estimate of the whale's total length. The report will describe the circumstances associated with the striking of the whale and estimate whether the animal suffered a wound that might be fatal. The report will include all photographs taken by a Tribal hunt observer of gray whales struck and lost by the whaling crew. The report may also contain any other observations by the Makah Indian Tribe concerning the struck and lost whale(s) or circumstances of the hunt.

(B) Struck and landed gray whale(s): The whaling captain's name; the Tribal hunt observer's name; the date, location (latitude and longitude, accurate to at least the nearest second), time, and number of strikes and attempted strikes if any; the method(s) of strikes and attempted strikes; the whale's body length as measured from the point of the upper jaw to the notch between the tail flukes; an estimate of the whale's maximum girth; the extreme width of the tail flukes; the whale's sex and, if female, lactation status; the length and sex of any fetus in the landed whale; photographs of the whale(s), including the entire dorsal right side, the entire dorsal left side, the dorsal aspect of the fluke, and the ventral aspect of the fluke. All such photographs must include a ruler to convey scale and a sign specifying the Makah Indian Tribe's name, whaling captain's name, whale species, and date. The report must also describe the time to death (measured from the time of the first strike to the time of death as indicated by relaxation of the lower jaw, no flipper movement, or sinking without active movement) and the disposition of all specimen samples collected and whale products, including any whale products deemed unsuitable for use by Makah Indian Tribal members. The report may also contain any other observations by the Makah Indian Tribe concerning the landed whale or circumstances of the hunt.

(iii) *Hunt report.* Within 30 days after the end of each hunting season, a report that describes the following information for each day of hunting:

(A) Struck and lost gray whale(s): The report must contain the information specified in paragraph (a)(6)(ii)(A) of this section.

(B) Struck and landed gray whale(s): The report must contain the information specified in paragraph (a)(6)(ii)(B) of this section.

(C) Hunting approaches and unsuccessful strike attempt(s): For each gray whale approached or subjected to an unsuccessful strike attempt(s), the report must contain: The whaling captain's name; the Tribal hunt observer's name; the date, location (latitude and longitude, accurate to at least the nearest second), time, and number of approaches and unsuccessful strike attempts; the method of attempted strikes; an estimate of the total length of any whale subjected to an unsuccessful strike attempt; and all photographs taken by a Tribal hunt observer of gray whales approached by the whaling crew. The report may also contain any other observations by the Makah Indian Tribe concerning the whale(s) approached or subjected to unsuccessful strike attempts or circumstances of the hunt.

(iv) *Annual approach report.* By January 15 of each year, a report containing the dates, location, and number of gray whales subjected to hunting approaches, training approaches, and training harpoon throws during the previous calendar year. The report may also contain any other observations by the Makah Indian Tribe concerning the approached whales or circumstances of the approaches and training harpoon throws.

(v) *Annual handicraft report.* By April 1 of each year, a report that describes all Makah Indian handicrafts certified by the Makah Tribal Council or its designee during the previous calendar year. The report must contain the following information for each handicraft certified: The date of the certification; the permanent distinctive mark identifying the article as a Makah Indian handicraft; a brief description of the handicraft, including artist's full name, gray whale product(s) used, and approximate size; and at least one digital photograph of the entire handicraft.

(vi) *Availability of reports.* The hunt report, annual approach report, and annual handicraft report collected pursuant to this section will be maintained and made available for public review in the NMFS West Coast Region's office in Seattle, Washington.

(b) Upon receiving an incident report specified in paragraph (a)(6)(ii) of this section documenting that eight gray whales have been struck, the Regional Administrator will evaluate:

(1) The photo-identification and notification requirements described in §§ 216.113(b)(6)(iv) and 216.115. The evaluation will address the status of gray whale photo-identification catalogs used to manage gray whale hunts authorized under this subpart, the survey efforts employed to keep those catalogs updated, the level of certainty associated with identifying cataloged WNP gray whales and PCFG whales, the role of ancillary information such as genetic data during catalog review, and any other elements deemed appropriate by the Regional Administrator. The evaluation will be made available to the public no more than 120 days after receiving the subject incident report.

(2) The humaneness of the authorized manner of hunting as specified in § 216.113(a)(1)(iii). To evaluate humaneness, NMFS will convene a team composed of a veterinarian, a marine mammal biologist, and all Tribal hunt observers and NMFS hunt observers who were witness to the strikes described in the incident reports required by this section. The team's evaluation will address the effectiveness of the hunting methods used by the Makah Indian Tribe, the availability and practicability of other such methods, and the time to death of hunted whales, and any other matters deemed appropriate by the Regional Administrator and the team. The team's evaluation will be made available to the public no more than 120 days after receiving the subject incident report.

(c) The NMFS West Coast Region's Seattle office is located at 7600 Sand Point Way NE, Seattle, WA 98115-0070.

§ 216.119 Expiration and amendment.

(a) The 10-year waiver period begins the first day of the first season after issuance of the initial hunt permit. The waiver and this subpart will expire 10 years after the effective date of the initial hunt permit specified under § 216.113(b), unless extended.

(b) If the initial permit begins during a hunt season, resulting in only a partial season being authorized, the Regional Administrator may authorize a partial season that is equivalent in duration to the difference between the partial season in the first hunt year and the full season. This second partial season can only be authorized in the final calendar year during the waiver period.

(c) This subpart may be periodically reviewed and modified as provided in 16 U.S.C. 1373(e).

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Part III

Department of Commerce

Bureau of Industry and Security

15 CFR Parts 734, 740, 744, et al.

Implementation of Additional Sanctions Against Russia and Belarus Under the Export Administration Regulations (EAR) and Refinements to Existing Controls; Final Rule

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Parts 734, 740, 744, 746, and 774**

[Docket No. 240610–0156]

RIN 0694–AJ67

Implementation of Additional Sanctions Against Russia and Belarus Under the Export Administration Regulations (EAR) and Refinements to Existing Controls**AGENCY:** Bureau of Industry and Security, Department of Commerce.**ACTION:** Final rule.

SUMMARY: In this final rule, the Bureau of Industry and Security (BIS) makes changes to the Russia and Belarus sanctions under the Export Administration Regulations (EAR). This final rule imposes additional export control measures against Russia and Belarus by expanding the scope of items identified under two EAR supplements that are subject to the EAR's Russian and Belarusian industry sector sanctions; imposing a "software" license requirement for certain EAR99-designated "software" when destined to or within Russia or Belarus; and narrowing the scope of commodities and software that may be authorized for export, reexport, or transfer (in-country) to or within Russia or Belarus under License Exception Consumer Communications Devices (CCD). To promote clarity and facilitate compliance, this final rule also consolidates the EAR's Russian and Belarus sanctions into a single section, while maintaining the existing related regulatory supplements identifying items that are subject to certain of those sanctions. This final rule also amends the EAR by adding five entities and eight addresses to the Entity List and making changes to the Entity List structure. These entries are listed on the Entity List under the destinations of the People's Republic of China (China) and Russia and have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. Lastly, this final rule makes two additional revisions to the EAR: one to confirm the criteria used when revising, suspending, or revoking EAR license exceptions and one revision to clarify the control status of fasteners for purposes of the EAR's Russian and Belarusian industry sector sanctions.

DATES: This rule is effective on June 12, 2024, except for amendatory instruction

14, which is effective September 16, 2024.

FOR FURTHER INFORMATION CONTACT: For general questions on this final rule, contact Collmann Griffin, Senior Policy Advisor, International Policy Office, Bureau of Industry and Security, Department of Commerce, Phone: 202–482–1430, Email: william.griffin@bis.doc.gov. For questions on the Entity List changes in this final rule, contact Chair, End-User Review Committee, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: ERC@bis.doc.gov. For emails, include "Russia and Belarus, June 2024 export control measures" in the subject line.

SUPPLEMENTARY INFORMATION:**I. Background***A. Export Controls Implemented Against Russia and Belarus*

In response to Russia's February 2022 full-scale invasion of Ukraine, BIS imposed extensive sanctions on Russia under the EAR as part of the final rule, "Implementation of Sanctions Against Russia Under the Export Administration Regulations (EAR)" ("Russia Sanctions Rule") (87 FR 12226, March 3, 2022). To address Belarus's complicity in the invasion, BIS imposed similar sanctions on Belarus under the EAR in a final rule, "Implementation of Sanctions Against Belarus" ("Belarus Sanctions Rule") (87 FR 13048, March 6, 2022). During the last two years, BIS has published a number of additional final rules strengthening the export controls on Russia and Belarus, including measures undertaken in coordination with U.S. allies and partners.

B. Overview of This Final Rule

In this final rule, BIS makes changes to the Russia and Belarus sanctions under the EAR along with certain changes that are not specific to those two countries. Certain of these changes (see section II.A) are designed to better protect U.S. national security and foreign policy interests by expanding the scope of the current sanctions. Others (see sections II.B and C) will promote clarity and facilitate compliance. The four sets of changes this final rule makes are described in section II as follows:

A. Additional export control measures against Russia and Belarus;

B. Consolidation of Russia and Belarus sanctions into a single section;

C. Additions to the Entity List and changes to the Entity List structure; and

D. Confirmation of the standard used in connection with actions involving the availability of license exceptions and clarification of the scope of a commodity subject to the Russian and Belarusian industry sanctions.

II. Amendments to the EAR*A. Additional Export Control Measures Against Russia and Belarus*

This final rule imposes additional export control measures against Russia and Belarus by expanding the scope of items that are subject to the Russian and Belarusian industry sector sanctions under supplement nos. 4 and 6 to part 746 (see section II.A.1 and II.A.2); imposing a "software" license requirement for certain EAR99-designated "software" when destined for Russia or Belarus; and narrowing the scope of commodities and software that may be authorized for export, reexport, or transfer (in-country) to or within Russia and Belarus under License Exception CCD.

1. *Expansion of Russian and Belarusian industry sector sanctions by adding items to supplement no. 4 to part 746 consistent with the objective to undermine Russia's and Belarus's industrial bases and their ability to continue to support Russia's military aggression in Ukraine.*

This rule expands the list of items set forth in supplement no. 4 to part 746 (Russian and Belarusian Industry Sector Sanctions Pursuant to § 746.5(a)(1)(ii)) (this final rule relocates the restrictions of § 746.5(a)(1)(ii) to § 746.8(a)(5)), as detailed below in section II.B.2. Specifically, this rule adds 522 additional Harmonized Tariff Schedule (HTS)–6 Code entries to supplement no. 4; consequently, these items will now require a license for export to, reexport to, or transfer (in-country) within Russia or Belarus under § 746.8(a)(5). Restrictions on these industrial items are intended to further undermine the Russian and Belarusian industrial bases and their ability to continue to support Russia's military aggression in Ukraine. The complete list of 522 new HTS–6 Codes this rule adds to supplement no. 4 are identified in amendatory instruction 18.

Through the addition of these HTS codes, BIS intends to further limit Russia's access to items of potential military significance and expand the economic impact of controls that will deny Russia additional resources it needs to continue waging war.

Items controlled through amendments made by this rule were identified based on a review of public and non-public information regarding which items

Russia seeks to further its war against Ukraine, an evaluation of areas in which U.S. trade has continued to provide an economic benefit to Russia, and an assessment of how the United States could further degrade Russia's war effort. With these new controls, BIS also further minimizes opportunities for the circumvention of U.S. export controls on Russia and Belarus through misclassification of the HTS-6 code. Supplement no. 4 to part 746 will now cover, with the addition of these 522 HTS-6 codes, items subject to the EAR classified under all HTS codes in 18 additional chapters of HTS codes. Making these additions will minimize situations where persons could seek to circumvent export license requirements by changing the classification of an item that requires a license to the classification of an item in a similar HTS code that does not require a license. BIS estimates these changes to supplement no. 4 to part 746 will result in an additional five license applications submitted to BIS annually.

2. Expansion of Russian and Belarusian industry sector sanctions by adding items to supplement no. 6 to part 746 consistent with the objective to undermine Russia's and Belarus's industrial bases and their ability to continue to support Russia's military aggression in Ukraine.

In supplement no. 6 to part 746 (Russian and Belarusian Industry Sector Sanctions Pursuant to § 746.5(a)(1)(iii)) (this final rule relocates the restrictions of § 746.5(a)(1)(iii) to § 746.8(a)(6)), this final rule adds a new paragraph (h) to control certain riot control agents that are isomers of CS (o-Chlorobenzylidenemalononitrile or o-Chlorobenzalmalononitrile) (CAS 2698-41-1); CN (Phenylacetyl chloride or w-Chloroacetophenone) (CAS 532-27-4); or Oleoresin Capsicum (CAS 8023-77-6). Specifically, paragraphs (h)(1) through (10) describe these riot control agents that will be controlled under the EAR's Russian and Belarusian industry sector sanctions. These chemicals meet the definition of riot control agents under Article II (paragraph 7) of the Chemical Weapons Convention (CWC). These expanded controls will supplement the existing Commerce Control List (CCL) controls under ECCNs 1A984 and 1C607; in particular, they will address Russia's use of riot control agents as a method of warfare against Ukrainian forces in violation of the CWC. See May 1, 2024 State Department Fact Sheet announcing the imposition of sanctions on Russia under the Chemical and Biological Weapons Control and Warfare Elimination Act of 1991, available at <https://www.state.gov/>

imposing-new-measures-on-russia-for-its-full-scale-war-and-use-of-chemical-weapons-against-ukraine-2/. BIS estimates these changes to supplement no. 6 to part 746 will result in one additional license application submitted to BIS annually.

3. Imposing a license requirement for certain EAR99-designated "software" when destined to or within Russia or Belarus.

Prior to this final rule, apart from certain software described in paragraph (g)(9) in supplement no. 6 to part 746, the Russian and Belarusian industry sector sanctions (in prior § 746.5(a)(1)(iii)) did not extend to software and the license requirements under § 746.8(a)(1) did not extend to EAR99-designated software. This final rule strengthens the Russian and Belarusian export control measures by adding a new paragraph (a)(8) (*EAR99-designated software*) to § 746.8. These changes to paragraph (a)(8) described under amendment 14 will go into effect on September 16, 2024. New paragraph (a)(8)(i) specifies that a license is required to export, reexport, or transfer (in-country) to or within Russia or Belarus any EAR99-designated software described in paragraph (a)(8)(ii). New paragraph (a)(8)(ii) will apply to the following types of EAR99-designated "software": Enterprise resource planning (ERP); customer relationship management (CRM); business intelligence (BI); supply chain management (SCM); enterprise data warehouse (EDW); computerized maintenance management system (CMMS); project management software; product lifecycle management (PLM); building information modelling (BIM); computer aided design (CAD); computer-aided manufacturing (CAM); and engineering to order (ETO). New paragraph (a)(8)(ii) includes a sentence to specify that the license requirement also includes software updates of software identified in paragraph (a)(8)(ii), which will enhance the effectiveness of this control because of the need for regular software updates to ensure proper software functionality. BIS also has added a new paragraph (a)(12)(iv) in § 746.8 to exclude entities exclusively operating in the medical or agricultural sectors from this software license requirement. These changes to paragraph (a)(12)(iv) also described under amendment 14 will go into effect on September 16, 2024. BIS estimates these changes to § 746.8(a)(8), which take into account the new exclusion added under § 746.8(a)(12)(iv), will result in an additional 5 license applications submitted to BIS annually.

4. Narrowing the scope of eligible commodities and software under License Exception CCD for Russia and Belarus.

In § 740.19 (Consumer Communications Devices (CCD)), this final rule revises paragraph (b) (Eligible commodities and software) to limit the scope of eligible commodities and software that may be authorized for export, reexport, or transfer (in-country) under this section to and within Russia and Belarus. This final rule does so by revising the paragraph (b) introductory text to specify that the commodities and software described in revised paragraphs (b)(1) through (8) are eligible for export, reexport, and transfer (in-country) to or within Russia and Belarus, as well as to or within Cuba, and by adding a sentence to the end of the paragraph (b) introductory text to specify that commodities and software described in paragraphs (b)(9) through (18) are eligible for export, reexport, or transfer (in-country) under this section to or within Cuba only. This final rule also revises paragraphs (b)(1) through (17) accordingly, so that all the commodities and software that are eligible for Russia, Belarus, and Cuba are described under paragraphs (b)(1) through (8) and those that are eligible for Cuba only are in paragraphs (b)(9) through (18).

The redesignation of these paragraphs will make it easier for exporters, reexporters, and transferors to identify the commodities and software that may be eligible for License Exception CCD for export, reexport, or transfer (in-country) to or within each of these three countries. This final rule does not otherwise revise the scope of eligible items in paragraphs (b)(1) through (17), with the exception of paragraph (b)(15) (batteries, chargers, carrying cases and accessories for the equipment described in paragraphs (b)(1) through (5) of this section that are designated EAR99). Specifically, this final rule separates the contents of this paragraph into two paragraphs by adding paragraph (b)(6) to describe batteries, chargers, carrying cases, and accessories for the equipment described in paragraphs (b)(1) through (5) of this section that are designated EAR99, and adding a separate paragraph (b)(18) to describe batteries, chargers, carrying cases, and accessories for the equipment described in paragraphs (b)(8) through (17) of this section that are designated EAR99. BIS estimates these changes to § 740.19 will result in an additional 10 license applications submitted to BIS annually.

To further assist exporters and other parties in understanding the changes to

§ 740.19(b)(1) through (17), BIS includes a cross walk in Table 1 below:

TABLE 1—CROSS WALK FOR § 740.19(b)(1) THROUGH (17) REDESIGNATIONS

Original paragraph (b) designation	Paragraph (b) redesignation in this final rule	Eligible for Russia, Belarus, and Cuba	Eligible only for Cuba
(b)(1)	No change	X.	
(b)(2)	(b)(9)		X
(b)(3)	(b)(10)		X.
(b)(4)	(b)(3)	X.	
(b)(5)	(b)(4)	X.	
(b)(6)	(b)(11)		X.
(b)(7)	(b)(12)		X.
(b)(8)	(b)(5)	X.	
(b)(9)	(b)(2)	X.	
(b)(10)	(b)(13)		X.
(b)(11)	(b)(7)	X.	
(b)(12)	(b)(14)		X.
(b)(13)	(b)(15)		X.
(b)(14)	(b)(16)		X.
(b)(15)	(b)(18) and (b)(6)	Yes, for (b)(6)	Yes, for (b)(18).
(b)(16)	(b)(8)	X.	
(b)(17)	(b)(17)		X.
N/A	(b)(18) (Newly added paragraph, but substance was formerly in (b)(15)).		X.

B. Consolidation of Russia and Belarus Sanctions Into a Single Section

1. *Consolidation.* The embargoes, sanctions, and special controls implemented under the EAR are contained in part 746 of the EAR. For countries such as Cuba, North Korea, and Syria, there is a single section under part 746 that imposes embargo or country-specific sanctions. With respect to the export control measures against Russia and Belarus, BIS took a different approach, with certain controls added to new part 746 sections after the initial February 2014 Russian invasion of the Crimea region of Ukraine and various export control measures added to those existing part 746 sections, along with expansive measures imposed under new part 746 sections, as well as, in response to the February 2022 full-scale invasion of Ukraine and continuing Russian aggression against Ukraine. Prior to this final rule, license requirements for exports, reexports, and transfers (in-country) to or within Russia and Belarus added in or after February 2022 were primarily found in three sections in part 746 of the EAR: §§ 746.5 (for a variety of industrial goods), 746.8 (mostly for items on the Commerce Control List and items caught by the Russia and Belarusian-related foreign direct product rules), and 746.10 (for ‘luxury goods’). In this final rule, all of these license requirements are being consolidated into a revised and expanded § 746.8. Specifically, license requirements from former § 746.8 are now found in paragraphs (a)(1) through (3) of § 746.8; license requirements from

former § 746.5 are now found in paragraphs (a)(4) through (6) of § 746.8; and license requirements from former § 746.10 are now found in paragraph (a)(7) of § 746.8.

BIS has undertaken this consolidation in light of the increasingly wide-ranging and complex nature of the export control measures against Russia and Belarus. A single section under § 746.8 that specifies the EAR’s Russia and Belarus restrictions should enhance clarity and facilitate compliance. However, in the interest of maintaining certain aspects of the current regulatory structure governing these restrictions, the applicable supplements identifying items continue to be in force, namely, the Russian and Belarusian industry sector sanctions under supplement nos. 2, 4, and 6 to part 746, and the ‘Luxury Goods’ sanctions under supplement no. 5 to part 746. Nor has BIS made any changes to supplement nos. 3 and 7 to part 746, supplements that relate to other Russia and Belarus restrictions.

To implement this consolidation, this final rule removes and reserves §§ 746.5 (Russian and Belarusian industry sector sanctions) and 746.10 (‘Luxury goods’ sanctions against Russia and Belarus and Russian and Belarusian oligarchs and malign actors). The contents and related restrictions in those two EAR sections will now be located in the consolidated § 746.8, which with this final rule will become the primary part 746 section implementing export controls on Russia and Belarus.

For now, as noted above, the EAR will continue to maintain three supplements for industrial goods (supplement nos. 2,

4, and 6 to part 746) and one supplement for ‘luxury goods’ (supplement no. 5 to part 746). However, because controls on ‘luxury goods’ destined for certain Russian and Belarusian oligarchs and malign actors worldwide were removed from § 746.10 and added to § 744.8 of the EAR on March 21, 2024 (see 89 FR 20115, Mar. 21, 2024) as part of a broader action consolidating various end-user controls, the license requirements for ‘luxury goods’ now are effectively the same destination-based controls that apply to license requirements for items covered under other HTS–6 codes described in the three industrial goods lists set forth in supplement nos. 2, 4, and 6 to part 746, respectively. In future amendments to the EAR, BIS may consider consolidating these three lists, but has decided to keep them separate for now. To assist with compliance, BIS is also posting a list of all HTS codes set forth in supplement nos. 2, 4, and 5 to part 746 in downloadable XML format, available at https://www.bis.gov/russia-belarus_export_controls_resources#downloadable-compliance-resources.

In addition to consolidating various Russia and Belarus export, reexport, and transfer (in-country) licensing requirements in § 746.8, this final rule adds the applicable exclusions that were formerly set forth in §§ 746.5, 746.8 and 746.10 to paragraph (a)(12) of § 746.8 of the EAR. These exclusions include ones that apply for certain deemed exports or reexports, certain transactions involving mass market encryption commodities

and software destined to U.S. companies, and transactions from the Global Export Control Coalition (GECC) members described in supplement no. 3 to part 746 of the EAR. Specifically, the exclusion for deemed exports and reexports has been added to paragraph (a)(12)(i), the exclusion for mass market encryption commodities and software has been added to paragraph (a)(12)(ii), and the exclusion for members of the GECC has been added to paragraph (a)(12)(iii). The introductory text of paragraph (a) of § 746.8 will now reference paragraph (a)(12) containing these three sets of exclusions. This consolidation and reformatting of these requirements is intended to improve consistency and clarity, the objectives also met by the broader consolidation of the related licensing requirements.

Prior to this final rule, §§ 746.5, 746.8, and 746.10 of the EAR each contained instructional text that established an order of review among these three sections to clarify how to review each section in conjunction with the CCL and other sections of the EAR. Such review was necessary because a single HTS-6 code may cover both items that are classified under Export Control Classification Numbers (ECCN) on the CCL and items designated EAR99, and there may consequently be overlapping export controls that apply to an item in that HTS-6 code depending on how such item is classified. In this final rule, this order of review instructional text is being moved to the paragraph (a) introductory text in revised § 746.8, which will consolidate the licensing requirements previously set forth in three separate part 746 sections. This final rule also consolidates the three applicable licensing policies under the revised § 746.8(b) and consolidates the license exception availability contents previously found in §§ 746.5, 746.8, and 746.10 under the revised § 746.8(c). BIS estimates these conforming changes described in section II.B.1 will not result in any additional license applications submitted to BIS annually.

2. *Conforming changes relating to the consolidation of the Russia and Belarus sanctions into a single part 746 section.*

This final rule makes conforming changes to various provisions of the EAR to reflect the fact that the substantive contents formerly set forth in §§ 746.5 and 746.10 (e.g., licensing requirements and related license application review policies) are being consolidated with the requirements under § 746.8. Because §§ 746.5 and 746.10 are referenced in other EAR provisions, this final rule revises those EAR provisions (as described in section II.B.2). BIS estimates these conforming

changes described in section II.B.2 will not result in any additional license applications submitted to BIS annually.

In supplement no. 2 to part 734—Guidelines for *De Minimis* Rules, this final rule revises the third sentence of paragraph (a)(1) to make a conforming change to remove the references to §§ 746.8(a)(5) and 746.10(a)(3) and add in its place a reference to § 746.8(b)(3)(ii).

In supplement no. 4 to part 744—Entity List, this final rule revises 85 existing entries, consisting of one entry under Cyprus, 83 entries under Russia, and one entry under Switzerland that reference § 746.5, and updates the reference to § 746.8.

In part 746, this final rule revises supplement nos. 2, 3, 4, and 6 to part 746 that reference §§ 746.5 or 746.10 and updates the reference to § 746.8.

In supplement no. 1 to part 774, this final rule amends eight ECCNs: 0A998, 1C992, 3A229, 3A231, 3A232, 6A991, 8A992, and 8D999 by removing the reference to § 746.5 and adding in its place references to § 746.8. In addition to the license requirements that are applicable under the Russian and Belarusian industry sector sanctions, all exports, reexports, and transfers (in-country) to or within Russia and Belarus also require a license under § 746.8(a)(1) because these items are classified under ECCNs. Lastly, this rule revises the Related Controls paragraph under ECCN 1C992 to make minor clarifications to the text for clarity.

C. *Additions to the Entity List and Changes to the Entity List Structure*

1. *Background.* The Entity List (supplement no. 4 to part 744 of the EAR (15 CFR parts 730 through 774)) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in, activities contrary to the national security or foreign policy interests of the United States, pursuant to § 744.11(b). The EAR impose additional license requirements on, and limit the availability of, most license exceptions for exports, reexports, and transfers (in-country) when a listed entity is a party to the transaction. The license review policy for each listed entity is identified in the “License Review Policy” column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document that added the entity to the Entity List. BIS places entities on the Entity List pursuant to parts 744 (Control Policy: End-User and End-Use

Based) and 746 (Embargoes and Other Special Controls) of the EAR. The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and makes all decisions to remove or modify an entry by unanimous vote.

2. *Additions to the Entity List and changes to the Entity List structure.*

i. *Additions to the Entity List.*

The ERC determined to add Advantage Trading Co. Limited, Duling Technology (HK) Limited, and FY International Trading, all under the destination of China, to the Entity List. These companies have procured components, including U.S.-origin components, that are used to develop and produce Shahed-series UAV's, which have been used by Russia in Ukraine. This activity is contrary to U.S. national security and foreign policy interests under §§ 744.11 and 744.21 of the EAR. These entities will receive a footnote 3 designation because the ERC has determined that they are Russian or Belarusian ‘military end users’ in accordance with § 744.21. A footnote 3 designation subjects these entities to the Russia/Belarus-Military End User Foreign Direct Product (FDP) rule, detailed under § 734.9(g). These entities are added with a license requirement for all items subject to the EAR. License applications will be reviewed under a policy of denial for all items subject to the EAR, other than applications for food and medicine designated as EAR99, which will be reviewed on a case-by-case basis.

The ERC determined to add Shenzhen Daotong Intelligent Aviation Technology Co., Ltd., under the destination of China, to the Entity List. This entity is involved in the shipment of controlled items to Russia since Russia's invasion of Ukraine in February 2022 as well as acquiring and attempting to acquire U.S.-origin items, applicable to unmanned aerial vehicles, to be used by Chinese military entities. These activities are contrary to the national security and foreign policy interests of the United States under § 744.11 of the EAR. Licenses will be required for all items subject to the EAR. License applications will be reviewed with a license review policy of presumption of denial.

The ERC determined to add eight addresses under the destination of China to the Entity List. These addresses

are associated with significant transshipment of sensitive goods to Russia. BIS has verified that these addresses are associated with a significant number of entities, whose activities risk violating the EAR. These risks include associations with parties on the Entity List or the Unverified List at the listed addresses. These activities are contrary to U.S. national security and foreign policy interests under § 744.11 of the EAR. Licenses will be required for all entities at these addresses for all items on the Commerce Control List and supplement no. 7 of section 746 of the EAR and subject to the EAR. License applications will be reviewed with a license review policy of presumption of denial.

The ERC determined to add LLC Volgogradpromproyekt, under the destination of Russia, to the Entity List. This addition is being made because the ERC has determined that LLC Volgogradpromproyekt has been involved with, contributes to, and supports the Russian military and defense sectors and companies that have been added to the BIS Entity List and the Treasury Department's List of Specially Designated Nationals and Blocked Persons. Specifically, LLC Volgogradpromproyekt have sold a variety of chemicals for use in the activities of these Russian military and defense sectors and companies. This activity is contrary to the national security and foreign policy interests of the United States under § 744.11 and this entity qualifies as a military end user under § 744.21(g) of the EAR. This entity is receiving a Footnote 3 designation because the ERC has determined that it is a Russian or Belarusian 'military end user' pursuant to § 744.21. A Footnote 3 designation subjects this entity to the Russia/Belarus-Military End User Foreign Direct Product (FDP) rule, detailed in § 734.9(g). The entity is added with a license requirement for all items subject to the EAR and a license review policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis.

BIS estimates these additions to the Entity List will not result in any additional license applications submitted to BIS annually.

For the reasons described above, this final rule adds the following five entities and eight addresses under thirteen entries to the Entity List and includes, where appropriate, aliases:

China

- Address 01;
- Address 02;

- Address 03;
 - Address 04;
 - Address 05;
 - Address 06;
 - Address 07;
 - Address 08;
 - Advantage Trading Company Limited;
 - Duling Technology (HK) Limited;
 - FY International Trading Company;
- and
- Shenzhen Daotong Intelligent Aviation Technology Co., Ltd.

Russia

- LLC Volgogradpromproyekt.
- ii. *Entity List Structural Changes.*
- International transshipment through shell companies presents an export control compliance problem that cannot always be addressed effectively through conventional Entity List additions. Shell companies can easily be dissolved and reformed to evade sanctions and export controls because they lack non-cash assets, employees, fixed addresses, business reputations, or other features that would incentivize the pursuit of longevity. Shell companies rely on service providers to enable them, with addresses that can be listed on corporate paperwork, mailboxes where they can receive shipments, temporary office space, or accounting and other services necessary to engage in trade activity.

When BIS lists shell companies on the Entity List, it is often at the address of these service providers, though BIS has traditionally avoided listing the service providers by name because that name will not appear on export control paperwork and may remain unknown to the seller of items subject to the EAR. Nonetheless, some of these addresses present a high diversion risk for controlled items and appear multiple times on the Entity List or Unverified List under different company names.

While BIS has said that involvement of a company co-located with a listed entity presents a red flag in export transactions, there are some situations where a more definite license requirement is warranted for addresses that are repeatedly used by companies engaged in activity contrary to U.S. national security or foreign policy interests. This rule is intended to address those situations by enabling BIS to publish high diversion risk addresses on the Entity List, thus triggering a license requirement for all entities who use that address. The goal of this rule is to more effectively combat unlawful diversion and to incentivize a stronger awareness of export compliance among the corporate service provider industries that facilitate trade through shell companies.

To facilitate adding the addresses detailed above, BIS is revising § 744.16, which describes, among other things, the license requirements, license exceptions, and license review policy for entities added to the Entity List. This rule adds paragraph (f) to § 744.16. Under paragraph (f) (*Addresses with High Diversion Risk*), BIS may identify by address an entity (or multiple entities) on the Entity List that presents a high risk of diversion without an associated entity name. As with other entries on the Entity List, these entries will detail the license requirements, license review policies, and restrictions on the use of license exceptions; however, the entry will apply to all entities using that address, other than entities with their own separate entry at that same address, in which case the more specific entry will apply. Prior to this rule, the license requirement applied to the entity listed by name on the Entity List. BIS will include as much identifying information as possible for any such address listed on the Entity List under this policy. As a conforming change, BIS is adding reference to addresses of persons or changing references from entities to entries in the introductory text in supplements 4 and 5 to part 744.

For ease of compliance and administrative purposes, the entries that consist of an address only will be titled "Address #," where # represents a number in a sequence of address entries. This pattern will apply to each destination for which there is an address-only entry.

Beyond entries that consist of an address only, given the risk of diversion from multiple listed entities using the same address, when a party to a transaction uses the same address as (e.g., is co-located with) a listed entity, the address is a red flag and the exporter, reexporter, and transferor must undertake sufficient due diligence to verify that the entity co-located with the listed entity is not, in fact, the listed entity and is not acting on behalf of the listed entity. This is similar to red flag guidance BIS has issued on listed entities.

The final rule also makes additional changes to §§ 744.11 and 744.16 where needed to reflect the addition of paragraph (f) under § 744.11. These changes broaden the sentences that use the phrase "entities listed on the Entity List" to reflect that these provisions also apply to addresses that present a high diversion risk listed on the Entity List.

BIS estimates these changes described in section II.C will not result in any additional license application submitted to BIS annually.

D. Confirmation of the Standard Used in Connection With Actions Involving the Availability of License Exceptions and Clarification of the Scope of a Commodity Subject to the Russian and Belarusian Industry Sanctions

This final rule makes revisions to two existing provisions of the EAR. First, this final rule specifies the standard used by BIS when revising, suspending, or revoking the use of EAR license exceptions, which applies to all license exceptions, destinations, and users of such license exceptions. By making this standard explicit, BIS provides transparency to exporters, reexporters, and transferors that may seek to utilize license exceptions in various destinations. In the section below, BIS provides some examples in the Russia context and in contexts involving other destinations in which BIS either has (or may) exercise this authority to revise, suspend, or revoke the use of license exceptions to protect U.S. national security or foreign policy interests. Second, this final rule makes a clarification regarding the control status of fasteners as it relates to the Russian and Belarusian industry sector sanctions. BIS estimates these changes described in section II.D will not result in any additional license application submitted to BIS annually.

1. Specifying the standard that governs when revising, suspending, or revoking EAR license exceptions.

BIS is responsible for protecting U.S. national security and foreign policy interests under the EAR. EAR license exceptions (part 740) are authorizations to engage in activity that otherwise requires a license and play an important role in the EAR control structure. In § 740.2 (Restrictions on all License Exceptions), this final rule revises paragraph (b) to specify the standard under which BIS may revise, suspend, or revoke a license exception, in whole or in part, without notice. Specifically, this final rule adds text to confirm (and render explicit) the fact that BIS may make such revisions, suspensions, or revocations to protect U.S. national security or foreign policy interests, consistent with the policy considerations in Section 1752 of the Export Control Reform Act of 2018 (50 U.S.C. 4811). In order to protect U.S. national security and foreign policy interests, BIS has broad authority to make revisions, suspensions, or revocations that apply to specific entities (including natural persons) or take action that affects all transactions involving a particular destination. For example, BIS may revoke a license exception for a particular foreign airline

that changes its ownership structure to circumvent the national security and foreign policy objectives underlying the restrictions on the use of License Exception AVS for temporary sojourns to Russia in § 746.8 of the EAR. As another example, BIS may revoke license exception availability for a company under investigation for fraudulent use of license exceptions on export control documents to avoid scrutiny of its shipments. BIS may also revoke multiple license exceptions for transactions involving particular countries, as it did in June 2020 for Hong Kong after new security measures were imposed that undermined Hong Kong's autonomy (85 FR 45998, July 31, 2020), or as it did for Burma in March 2021 in response to that country's military coup (86 FR 13173, March 8, 2021).

2. Clarification that the exclusion for fasteners for the "parts," "components," "accessories," and "attachments" does not apply to fasteners that are specified under one of the HTS-6 codes specified in the respective supplements.

In supplement nos. 2, 4, 5, and 7, this final rule adds a sentence to clarify the scope of the exclusion for fasteners (e.g., screw, bolt, nut, nut plate, stud, insert, clip, rivet, pin) in the three supplements. Fasteners are identified in an exclusion from the scope of this control, but a clarification is needed because certain fasteners will now be described under HTS-6 Codes under supplement no. 4 with the additions made in this final rule and some of the HTS-Codes in supplement nos. 2, 4, 5, and 7 also identify certain fasteners, and are therefore included within the scope of the controls. This final rule clarifies the scope of the exclusion by adding a new third sentence to each of these three supplements to specify that the exclusion of fasteners from this control does not apply to fasteners that are designated under an HTS Code that is specified in that supplement. This final rule also adds the word 'generally' before the term fasteners in each of the three supplements to clarify that the exclusion for fasteners has limits. This final rule also adds the word 'and' before the term 'washers' to clarify that in all cases a washer, spacer, insulator, grommet, bushing, spring, wire, or solder is excluded from the scope of these three supplements regardless of the HTS Code or HTS description.

Savings Clause

For the changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a

result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on June 12, 2024, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR), provided the export, reexport, or transfer (in-country) is completed no later than on July 12, 2024.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (codified, as amended, at 50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. BIS has examined the impact of this rule as required by Executive Orders 12866, 13563, and 14094, which 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 (e.g., potential economic, environmental, public, health, and safety effects, distributive impacts, and equity). Pursuant to E.O. 12866, as amended, this final rule has not been determined to be a "significant regulatory action."

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves the following OMB-approved collections of information subject to the PRA:

- 0694–0088, "Simple Network Application Process and Multipurpose Application Form," which carries a burden hour estimate of 29.4 minutes for a manual or electronic submission;
- 0694–0096 "Five Year Records Retention Period," which carries a burden hour estimate of less than 1 minute; and
- 0607–0152 "Automated Export System (AES) Program," which carries a burden hour estimate of 3 minutes per electronic submission.

BIS estimates that these new controls on Russia and Belarus under the EAR will result in an increase of twenty-one license applications submitted annually to BIS. However, the additional burden falls within the existing estimates currently associated with these control numbers. Additional information regarding these collections of information—including all background materials—can be found at <https://www.reginfo.gov/public/do/PRAMain> by using the search function to enter either the title of the collection or the OMB Control Number.

3. This rule does not contain policies with federalism implications as that term is defined in E.O. 13132.

4. Pursuant to section 1762 of ECRA (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. While section 1762 of ECRA provides sufficient authority for such an exemption, this action is also independently exempt from these APA requirements because it involves a military or foreign affairs function of the United States (5 U.S.C. 553(a)(1)).

5. Because neither the Administrative Procedure Act nor any other law requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no Final Regulatory Flexibility Analysis is required and none has been prepared.

List of Subjects

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Parts 746 and 774

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 734, 740, 744, 746, and 774 of the Export Administration Regulations (15 CFR parts 730 through 774) are amended as follows:

PART 734—SCOPE OF THE EAR

■ 1. The authority citation for part 734 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of November 1, 2023, 88 FR 75475 (November 3, 2023).

■ 2. Supplement no. 2 to part 734 is amended by revising the third sentence of paragraph (a)(1) to read as follows:

Supplement No. 2 to Part 734—Guidelines for De Minimis Rules

(a) * * *

(1) * * * For purposes of identifying U.S.-origin controlled content, you should consult the Commerce Country Chart in supplement no. 1 to part 738 of the EAR and controls described in part 746 of the EAR (excluding U.S.-origin content that meets the criteria in § 746.7(a)(1)(v) or § 746.8(a)(12)(iii)(B)).

* * *

PART 740—LICENSE EXCEPTIONS

■ 3. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 4. Section 740.2 is amended by revising paragraph (b) to read as follows:

§ 740.2 Restrictions on all License Exceptions.

* * *

(b) All License Exceptions are subject to revision, suspension, or revocation, in whole or in part, without notice to protect U.S. national security or foreign policy interests. BIS may stop a shipment or an export, reexport, or (in-country) transaction at any stage of its progress, *e.g.*, in order to prevent an unauthorized export, reexport, or transfer (in-country). If a shipment is already en route, BIS may order the return or unloading of the shipment at any port of call.

■ 5. Section 740.19 is amended by revising paragraph (b) to read as follows:

§ 740.19 Consumer Communications Devices (CCD).

* * *

(b) *Eligible commodities and software.* Commodities and software in paragraphs (b)(1) through (8) of this section are eligible for export, reexport, or transfer (in-country) under this

section to and within Cuba, Russia, and Belarus. Commodities and software in paragraphs (b)(9) through (18) of this section are eligible for export, reexport, or transfer (in-country) to Cuba only.

(1) Consumer computers, tablets, and peripherals including microphones, speakers, and headphones designated EAR99 or classified under Export Control Classification Numbers (ECCN) 5A992.c or 4A994.b;

(2) Mobile phones, including cellular and satellite telephones, personal digital assistants, and subscriber information module (SIM) cards, accessories for such devices and similar devices classified under ECCNs 5A992.c or 5A991 or designated EAR99; drivers and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c;

(3) Monitors classified under ECCN 5A992.c or designated EAR99;

(4) Printers, including multifunctional printers, classified under ECCN 5A992.c or designated EAR99;

(5) Keyboards, mice, and similar devices designated EAR99;

(6) Batteries, chargers, carrying cases, and accessories for the equipment described in paragraphs (b)(1) through (5) of this section that are designated EAR99;

(7) Consumer “information security” equipment, “software” (except “encryption source code”), such as firewalls, virtual private network clients, antivirus, user authentication, password managers, identification verification, and peripherals classified under ECCNs 5A992.c or 5D992.c or designated EAR99;

(8) Consumer “software” (except “encryption source code”) classified under ECCNs 4D994, 5D991, or 5D992.c or designated EAR99 to be used for equipment described in paragraphs (b)(1) through (16) of this section;

(9) Consumer disk drives and solid-state storage equipment classified under ECCN 5A992 or designated EAR99;

(10) Graphics accelerators and graphics coprocessors designated EAR99;

(11) Modems, network interface cards, routers, switches, and WiFi access points, designated EAR99 or classified under ECCNs 5A992.c or 5A991; drivers, communications, and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c;

(12) Network access controllers and communications channel controllers classified under ECCN 5A991.b.4, 5A992.c, or designated EAR99;

(13) Memory devices classified under ECCN 5A992.c or designated EAR99;

(14) Digital cameras (including webcams) and memory cards classified under ECCN 5A992 or designated EAR99;

(15) Television and radio receivers, set top boxes, video decoders, and antennas, classified under ECCNs 5A991, 5A992, or designated EAR99;

(16) Recording devices classified under ECCN 5A992 or designated EAR99;

(17) Commodities described under 3A991.p or 4A994.l; and

(18) Batteries, chargers, carrying cases, and accessories for the equipment described in paragraphs (b)(8) through (17) of this section that are designated EAR99.

Note 1 to paragraph (b): In this paragraph, the term “consumer” refers to items that are:

1. Generally available to the public by being sold, without restriction, from stock at retail selling points by means of any of the following:

a. Over-the-counter transactions;

b. Mail order transactions;

c. Electronic transactions; or

d. Telephone call transactions; and

2. Designed for installation by the user without further substantial support by the supplier.

* * * * *

PART 744—CONTROL POLICY: END-USER AND END-USE BASED

■ 6. The authority citation for part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 7, 2023, 88 FR 62439 (September 11, 2023); Notice of November 1, 2023, 88 FR 75475 (November 3, 2023).

■ 7. Amend § 744.11 by revising the section introductory text, paragraphs (a) introductory text, (b) introductory text, (b)(4)(i), and (c), to read as follows:

§ 744.11 License requirements that apply to entities acting or at significant risk of acting contrary to the national security or foreign policy interests of the United States, and to addresses that present a high diversion risk.

BIS may impose foreign policy export, re-export, and transfer (in-country) license requirements, limitations on availability of license exceptions, and set license application review policy based on the criteria in this section.

Such requirements, limitations and policy are in addition to those set forth elsewhere in the EAR. License requirements, limitations on use of license exceptions, and license application review policies will be imposed under this section by adding an entity or an address that presents a high diversion risk (*see* § 744.16(f) of this part) to the Entity List (supplement no. 4 to this part) with a reference to this section and by stating on the Entity List the license requirements and license application review policies that apply to that entity or address, or by informing an exporter, re-exporter, or transferor pursuant to paragraph (c) of this section that a specific entity or address is subject to a license requirement, limitations on use of license exceptions and license application review policies as specified in a specific notice provided to an exporter, re-exporter, or transferor. BIS may remove an entity from the Entity List if it is no longer engaged in the activities described in paragraph (b) of this section and is unlikely to engage in such activities in the future, or if it is no longer at significant risk of acting contrary to the national security or foreign policy interests of the United States as described therein. BIS may remove an address that presents a high diversion risk from the Entity List if the address is determined to no longer be a high diversion risk, for example if measures are undertaken to educate companies operating at those addresses on export compliance, or to effectively screen clients for diversion risk. BIS may modify the license exception limitations and license application review policies that apply to a particular entity or address that presents a high diversion risk to implement the policies of this section. BIS will implement the provisions of this section in accordance with the decisions of the End-User Review Committee or, if appropriate in a particular case, in accordance with the decisions of the body to which the End-User Review Committee decision is escalated. The End-User Review Committee will follow the procedures set forth in supplement no. 5 to this part.

(a) *License requirement, availability of license exceptions, and license application review policy.* A license is required, to the extent specified on the Entity List, to export, reexport, or transfer (in-country) any item subject to the EAR when an entity that is listed on the Entity List, or any entity using an address identified on the Entity List as presenting a high risk of diversion to activities of concern, is a party to the

transaction as described in § 748.5(c) through (f) of the EAR unless otherwise authorized or excluded in this section. License exceptions may not be used unless authorized in the Entity List entry for the entity that is party to the transaction or for an address that presents a high diversion risk that is used by a party to the transaction. Applications for licenses required by this section will be evaluated as stated in the relevant Entity List entry, in addition to any other applicable review policy stated elsewhere in the EAR.

* * * * *

(b) *Criteria for revising the Entity List.* Entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entity or party to the transaction that is operating at an address that presents a high diversion risk has been involved, is involved, or poses a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such entities or conducting operations at an address that presents a high diversion risk may be added to the Entity List pursuant to this section. An entity or address that presents a high diversion risk may pose a significant risk through certain circumstances that may be outside of its own control or in the case of addresses with high diversion risk, outside the control of certain parties to the transaction operating at such address that presents a high diversion risk. Such circumstances that may place an entity or address that presents a high diversion risk include situations involving a sustained lack of cooperation by a host government authority, for example, by preventing an end-use check from being conducted, that effectively prevents BIS from determining compliance with the EAR. This section may not be used to place any U.S. person, as defined in § 772.1 of the EAR, on the Entity List. Paragraphs (b)(1) through (5) of this section provide an illustrative list of activities that could be or represent a significant risk of being contrary to the national security or foreign policy interests of the United States, including the foreign policy interest of the protection of human rights throughout the world.

* * * * *

(4) * * *

(i) The entity or persons that own or control an address that presents a high diversion risk precluding access to; refusing to provide information about; or providing false or misleading information about parties to the transaction or the item to be checked.

The conduct in this example includes: expressly refusing to permit a check; providing false or misleading information; or engaging in dilatory or evasive conduct that effectively prevents the check from occurring or makes the check inaccurate or useless. A nexus between the conduct of the party or address that presents a high diversion risk to be listed and the failure to produce a complete, accurate and useful check is required, even though an express refusal by the party to be listed is not required; or

* * * * *

(c) *Additional prohibition on persons informed by BIS.* BIS may inform persons, either individually by specific notice or through amendment to the EAR, that a license is required for:

(1) A specific export, reexport, or transfer (in-country) because there is an unacceptable risk that the export, reexport, or transfer (in-country) is intended to circumvent the license requirement imposed on an entity or address that presents a high diversion risk listed in supplement no. 4 to this part; or

(2) The export, reexport, or transfer (in-country) of specified items to a certain party because there is an unacceptable risk that the party is acting as an agent, front, or shell company for an entity listed in supplement no. 4 to this part, or is otherwise assisting that listed entity in circumventing the license requirement set forth in that entity's entry in supplement no. 4 to this part; or

(3) The export, reexport, or transfer (in-country) of specified items to a certain party or address that presents a high diversion risk because there is reasonable cause to believe, based on specific and articulable facts, that the entity has been involved, is involved, or poses a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States, including the foreign policy interest of the protection of human rights throughout the world, and those acting on behalf of such entity or that an address that presents a high diversion risk of being used to divert items subject to the EAR to end-uses or end-users inconsistent with U.S. foreign policy or national security interests. Specific notice will be given only by, or at the direction of, the Principal Deputy Assistant Secretary for Strategic Trade and Technology Security or the Deputy Assistant Secretary for Strategic Trade. When such notice is provided orally, it will be followed by written notice within two working days signed by the

Principal Deputy Assistant Secretary for Strategic Trade and Technology Security or the Principal Deputy Assistant Secretary's or Deputy Assistant Secretary's designee. The specific notice will include the license requirement, limitations on use of license exceptions, and license application review policy with which that exporter, re-exporter, or transferor must comply pursuant to this paragraph (c)(3). The ERC may add such entities or addresses that present a high diversion risk to the Entity List in supplement no. 4 to this part.

■ 7. Section 744.16 is amended by:

- a. Revising the introductory text;
- b. Revising paragraphs (a), (b), (c)(1), (e) introductory text; and
- c. Adding paragraph (f).

The addition and revisions read as follows:

§ 744.16 Entity List.

The Entity List (supplement no. 4 to this part) identifies persons or addresses of persons reasonably believed to be involved, or to pose a significant risk of being or becoming involved, in activities contrary to the national security or foreign policy interests of the United States. The entries are added to the Entity List pursuant to sections of part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

* * * * *

(a) *License requirements.* In addition to the license requirements for items specified on the CCL, you may not, without a license from BIS, export, reexport, or transfer (in-country) any items included in the License Requirement column of an entry on the Entity List (supplement no. 4 to this part) when an entity associated with that entry or when any entity using an address of high diversion risk associated with that entry is a party to a transaction as described in § 748.5(c) through (f) of the EAR. The specific license requirement for each listed entity or address with high diversion risk is identified in the license requirement column on the Entity List in supplement no. 4 to this part. A license is not required for the release of certain "technology" or "software" when such a release is for a "standards-related activity," as described in §§ 744.11(a)(1) and 772.1 of the EAR.

(b) *License exceptions.* No license exceptions are available for exports, reexports or transfers (in-country) to listed entities or addresses that present a high diversion risk of specified items, except license exceptions for items

listed in § 740.2(a)(5) of the EAR destined to listed Indian or Pakistani entities to ensure the safety of civil aviation and safe operation of commercial passenger aircraft, and in the case of entities added to the Entity List pursuant to § 744.20, to the extent specified on the Entity List.

(c) * * *

(1) *General review policy.* The license review policy for each listed entity or address that presents a high diversion risk is identified in the License Review Policy column on the Entity List.

* * * * *

(e) *Removal or modification requests.* Any entity listed on the Entity List or the owner or operator of any address that presents a high diversion risk listed on the Entity List may request that its listing be removed or modified. All such requests, including reasons therefor, must be in writing and sent to: Chair, End-User Review Committee, Bureau of Industry and Security, U.S. Department of Commerce, 14th Street and Pennsylvania Avenue NW, Room 3886, Washington, DC 20230.

* * * * *

(f) *Addresses that present a high diversion risk.* In limited circumstances, such as when multiple entities on the Entity List use the same address, or the name of an entity at a particular address is unknown to BIS, BIS may determine that such an address presents a high risk of diversion and publish the address on the Entity List without an associated entity name. These entries will apply license requirements, license review policies, and restrictions on the use of license exceptions for all entities using that address. When submitting a license application, the applicant should name the specific entity on the application. In the license application field for additional information, the applicant should state that the address is on the Entity List.

■ 9. Amend supplement no. 4 to part 744 by:

- a. Revising the introductory text;
- b. Under CHINA, PEOPLE'S REPUBLIC OF by adding, in alphabetical order, entries for "Address 01"; "Address 02"; "Address 03"; "Address 04"; "Address 05"; "Address 06"; "Address 07"; "Address 08"; "Advantage Trading Company Limited"; "Duling Technology (HK) Limited"; and "FY International Trading Company"; and "Shenzhen Daotong Intelligent Aviation Technology Co., Ltd.";
- c. Under CYPRUS, revising the entry for "Rosneft Trade Limited";
- d. Under RUSSIA, by:
- i. Revising the entries for "Achim Development, OOO"; "CJSC

VANKORNEFT”; “Daltransgaz, OAO”; “Druzhba, AO”; “Gaz-Oil, OOO”; “Gazprom Dobycha Irkutsk, OOO”; “Gazprom Dobycha Krasnodar, OOO”; “Gazprom Dobycha Kuznetsk, OOO”; “Gazprom Dobycha Nadym, OOO”; “Gazprom Dobycha Noyabrsk, OOO”; “Gazprom Dobycha Urengoi, OOO”; “Gazprom Dobycha Yamburg, OOO”; “Gazprom Energo, OOO”; “Gazprom Flot, OOO”; “Gazprom Gaznadzor, OOO”; “Gazprom Gazobezopasnost, OOO”; “Gazprom Geologorazvedka, OOO”; “Gazprom Inform, OOO”; “Gazprom Invest, OOO”; “Gazprom Kapital, OOO”; “Gazprom Komplektatsiya, OOO”; “Gazprom Mezhrregiongaz, OOO”; “Gazprom Neft”; “Gazprom, OAO”; “Gazprom Pererabotka, OOO”; “Gazprom Personal, OOO”; “Gazprom Promgaz, AO”; “Gazprom Russkaya, OOO”; “Gazprom Sotsinvest, OOO”; “Gazprom Svyaz, OOO”; “Gazprom Svyaz, OOO”; “Gazprom Telekom, OOO”; “Gazprom Transgaz Kazan, OOO”; “Gazprom Transgaz Krasnodar, OOO”; “Gazprom Transgaz Makhachkala, OOO”; “Gazprom Transgaz Nizhni Novgorod, OOO”; “Gazprom Transgaz Samara, OOO”; “Gazprom Transgaz Sankt-Peterburg, OOO”; “Gazprom Transgaz

Saratov”; “Gazprom Transgaz Stavropol, OOO”; “Gazprom Transgaz Surgut, OOO”; “Gazprom Transgaz Tomsk, OOO”; “Gazprom Transgaz Ufa, OOO”; “Gazprom Transgaz Ukhta, OOO”; “Gazprom Transgaz Volgograd, OOO”; “Gazprom Transgaz Yugorsk, OOO”; “Gazprom Tsentrremont, OOO”; “Gazprom Vniigaz, OOO”; “Kaliningradnefteprodukt OOO”; “Kamchatgazprom, OAO”; “Kinef OOO”; “Kirishiavtoservis OOO”; “Krasnoyarskgazprom, PAO”; “Lazurnaya OOO”; and “Lengiproneftekhim OOO”; ■ ii. Adding, in alphabetical order, entry for “LLC Volgogradpromproyekt”; ■ iii. Revising the entries for “Lukoil, OAO”; “Media-Invest OOO”; “Neft-Aktiv LLC”; “Niigazekonomika, OOO”; “Novgorodnefteprodukt OOO”; “OJSC Achinsk Refinery”; “OJSC Angarsk Petrochemical Company”; “OJSC Kuybyshev Refinery”; “OJSC Novokuybyshev Refinery”; “OJSC Orenburgneft”; “OJSC RN Holding”; “OJSC Samotlorneftegaz”; “OJSC Syzran Refinery”; “PJSC Verkhnechonskneftegaz”; “Pskovnefteprodukt OOO”; “RN-Komsomolsky Refinery LLC”; “RN-Yuganskneftegaz LLC”; “Rosneft”; “SNGB AO”; “SO Tvernefteprodukt

OOO”; “Sovkhos Chervishevski PAO”; “Strakhovove Obshchestvo Surgutneftegaz OOO”; “Surgutmebel OOO”; “Surgutneftegas”; “Vostokgazprom, OAO”; “Yamalgazinvest, ZAO”; and “Yuzhno-Kirinskoye Field, in the Sea of Okhotsk”; and

■ e. Under SWITZERLAND, revising the entry for “Rosneft Trading S.A.”.

The revisions read as follows:

Supplement No. 4 to Part 744—Entity List

This supplement lists certain entities or addresses subject to license requirements for specified items under parts 744 and 746 of the EAR. License requirements for these entities include exports, reexports, and transfers (in-country) unless otherwise stated. A license is required, to the extent specified on the Entity List, to export, reexport, or transfer (in-country) any item subject to the EAR when an entity or a party to the transaction is operating at an address that is listed on the Entity List under an address entry is a party to the transaction as described in § 748.5(c) through (f) of the EAR. See § 744.11 for licensing requirements in the context of a “standards-related activity.” This list is revised and updated on a periodic basis in this supplement by adding new or amended notifications and deleting notifications no longer in effect.

Country	Entity	License requirement	License review policy	Federal Register citation
CHINA, PEOPLE'S REPUBLIC OF.				
	Address 01, Unit D, 16/F One Capital Place, 18 Luard Rd, Wan Chai, Hong Kong.	For items on the CCL and listed in supplement no. 7 to part 746 of the EAR.	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Address 02, Unit 04, 7/F Bright Way Tower, No. 33 Mong Kok Road, Kowloon, Hong Kong.	For items on the CCL and listed in supplement no. 7 to part 746 of the EAR.	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Address 03, Room 19C Lockhart Centre 301–307, Lockhart Rd. Wan Chai, Hong Kong.	For items on the CCL and listed in supplement no. 7 to part 746 of the EAR.	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Address 04, Room 803, Chevalier House 45–51, Chatham Road South, Tsim Sha Tsui, Hong Kong.	For items on the CCL and listed in supplement no. 7 to part 746 of the EAR.	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Address 05, Flat/RM 2309, 23/F, Ho King Commercial Centre, 2–16 Fa Yuen Street, Mong Kok, Kowloon, Hong Kong.	For items on the CCL and listed in supplement no. 7 to part 746 of the EAR.	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Address 06, Office 4, 16/F Ho King Commercial Centre, 2–16 Fayuen Street, Hong Kong.	For items on the CCL and listed in supplement no. 7 to part 746 of the EAR.	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Address 07, Room 1318–19, 13F, Hollywood Plaza, 610 Nathan Road, Mong Kok, Kowloon, Hong Kong.	For items on the CCL and listed in supplement no. 7 to part 746 of the EAR.	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Address 08, Room 1318–20, 13F, Hollywood Plaza, 610 Nathan Road, Mong Kok Kowloon, Hong Kong.	For items on the CCL and listed in supplement no. 7 to part 746 of the EAR.	Presumption of denial.	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Advantage Trading Company Limited a.k.a., the following one alias:—Jin Ying Trading Co., Ltd. No. 6 Kin Tai Street, Shop 185 G/F, Hand Wai Industrial Centre, Tuen Mun, New Territories, Hong Kong.	For all items subject to the EAR. (See §§ 744.8(b), 744.11, 734.9(g), ³ 746.8(a)(3), and 744.21(b) of the EAR).	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].

Country	Entity	License requirement	License review policy	Federal Register citation
	* Duling Technology (HK) Limited, 2–16 Fayuen Street, Room 4, 16th Floor, Ho King Commercial Centre, Mongkok, Kowloon, Hong Kong.	* For all items subject to the EAR (See §§ 744.8(b), 744.11, 734.9(g), ³ 746.8(a)(3), and 744.21(b) of the EAR).	* Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	* 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	* FY International Trading Company, a.k.a., the following one alias:—FYIT. Cac Kitt Building, Room 21B7, Shenzhen Guangdong China; and No. 48 Street, Office No. 6, 12th Floor, Wealth Commercial Centre, Kowloon, Hong Kong; and 707 to 713 Nathan Road, Flat Room B, 26th Floor, Silvercorp International Tower, Mong Kok, Kowloon, Hong Kong; and 426 Shanghai Street, Flat 2002C, 20F, Multifield Commercial Centre, Mongkok, Kowloon, Hong Kong; and No. 16 Shing Yip Street, Workshop 603F, Block A, East Sun Industrial Centre, Kowloon, Hong Kong; and Flat F 10 Floor Hung Cheong Industrial Centre Phase I 12Tsing Yeung, Tuen Mun, N.T. Hong Kong.	* For all items subject to the EAR (See §§ 744.8(b), 744.11, 734.9(g), ³ 746.8(a)(3), and 744.21(b) of the EAR).	* Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	* 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	* Shenzhen Daotong Intelligent Aviation Technology Co., Ltd., a.k.a., the following two aliases: —Autel Robotics; and —Daotong Intelligence. 6th Floor, No. 1, Chuangxiangdi, Yanxiang Intelligent Valley, No. 11 Gaoxin West Road, Guangming New District, Shenzhen, China; and Building C1 & B1, Nanshan Zhiyuan, No.1001, Xueyuan Avenue, Xili Street, Nanshan District, Shenzhen, China; and Unit 701–702, 7/F, Grandtech Center, 8 On Ping Street, Shatin, N.T., Hong Kong; and Unit 06, Floor 4, 501, 7th Floor, No. 8 Xibinhe Road, Yongdingmen, Dongcheng District, Beijing, China; and Room 405, No. 5, Jixiang 3rd Road, Yixin Community, Pingdi Street, Longgang District, Shenzhen, China; and No. 11303, Unit 1, Building 3, Moore Center, northwest corner of Keji 6th Road, Fenghui South Road, High-tech Zone, Xi'an City, Shaanxi Province, China; and No. 701 on the east side and 701 on the west side of the electronics factory in Building 3, Yanxiang Technology Industrial Park, Gaoxin Road, Dongzhou Community, Guangming Street, Guangming District, Shenzhen, China.	* For all items subject to the EAR. (See § 744.11 of the EAR).	* Presumption of denial.	* 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
CYPRUS	* Rosneft Trade Limited, f.k.a., TNK Trade Limited. Elenion Building 5 Themistokli Dervi, 2nd floor, Lefkosia, Nicosia 1066, Cyprus.	* For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	* See § 746.8(b)(2) of the EAR.	* 80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
RUSSIA	* Achim Development, OOO, a.k.a., the following two aliases: —Achim Development; and —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Achim Development'. d.7 ul.Promyshlennaya, Novy Urengoi, Yamalo-Nenetski a.o. 629306, Russia.	* For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	* See § 746.8(b)(2) of the EAR.	* 81 FR 61601 preview citation details, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	* CJSC VANKORNEFT, a.k.a., the following two aliases: —Vankorneft; and —ZAO Vankorneft. Dobrovolcheskoy Brigady St., 15, Krasnoyarsk Territory 660077, Russia.	* For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	* See § 746.8(b)(2) of the EAR.	* 80 FR 52968 preview citation details, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	* Daltransgaz, OAO, a.k.a., the following two aliases: —Daltransgaz; and —Otkrytoe Aktsionernoe Obshchestvo 'Daltransgaz'. d. 1 ul.Solnechnaya S. Ilinka, Khabarovski Raion Khabarovski krai 680509, Russia.	* For all items subject to the EAR when used in projects specified in § 746.8(a)(4)5 of the EAR.	* See § 746.8(b)(2) of the EAR.	* 81 FR 61601 preview citation details, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].

Country	Entity	License requirement	License review policy	Federal Register citation
	Druzhba, AO, a.k.a., the following two aliases: —Aksionernoe Obshchestvo 'Druzhba'; <i>and</i> —Druzhba. Rogozinino, Moscow 143397, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gaz-Oil, OOO (f.k.a., Zakrytoe Aksionernoe Obshchestvo Gaz Oil), a.k.a., the following two aliases: —Gaz-Oil; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gaz-Oil'. d.10 B ul.Nametkina, Moscow 117420, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Dobycha Irkutsk, OOO (f.k.a., Otkrytoe Aksionernoe Obshchestvo Irkutskgazprom), a.k.a., the following two aliases: —Gazprom Dobycha Irkutsk; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Dobycha Irkutsk'. d.14 ul.Nizhnaya Naberezhnaya, Irkutsk, Irkutskaya obl 664011, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Dobycha Krasnodar, OOO, a.k.a., the following two aliases: —Gazprom Dobycha Krasnodar; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Dobycha Krasnodar'. d.53 ul.Shosse Neftyanikov, Krasnodar, Krasnodarskiy kraj 350051, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Dobycha Kuznetsk, OOO, a.k.a., the following two aliases: —Gazprom Dobycha Kuznetsk; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Dobycha Kuznetsk'. d.4 prospekt Oktyabrskiy, Kemerovo, Kemerovskaya obl 650066, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Dobycha Nadym, OOO, a.k.a., the following two aliases: —Gazprom Dobycha Nadym; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Dobycha Nadym'. d.1 ul.Zvereva, Nadym, Yamalo-Nenetskiy a.o. 629730, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Dobycha Noyabrsk, OOO, a.k.a., the following two aliases: —Gazprom Dobycha Noyabrsk; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Dobycha Noyabrsk'. d.20 ul. Respubliki, Noyabrsk, Yamalo-Nenetskiy a.o. 629802, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Dobycha Urengoi, OOO, a.k.a., the following two aliases: —Gazprom Dobycha Urengoi; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Dobycha Urengoi'. d.8 ul.Zhelezodorozhnaya, Novy Urengoi, Yamalo-Nenetskiy a.o. 629307, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Dobycha Yamburg, OOO, a.k.a., the following two aliases: —Gazprom Dobycha Yamburg; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Dobycha Yamburg'. d.9 ul. Geologorazvedchikov, Novy Urengoi, Yamalo-Nenetskiy a.o. 629306, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Energo, OOO, a.k.a., the following two aliases: —Gazprom Energo; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Energo'. 8 Korp. 1 ul.Stroitelei, Moscow 117939, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Flot, OOO (f.k.a., Obshchestvo S Ogranichennoi Otvetstvennostyu Gazflot), a.k.a., the following two aliases: —Gazprom Flot; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Flot'. d. 12 A ul.Nametkina, Moscow 117420, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Gaznadzor, OOO, a.k.a., the following two aliases: —Gazprom Gaznadzor; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Gaznadzor'. 41 str. 1 prospekt Vernadskogo, Moscow 119415, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Gazobezopasnost, OOO, a.k.a., the following two aliases: —Gazprom Gazobezopasnost; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Gazobezopasnost'. d. 8 korp. 1 ul.Stroitelei, Moscow 119311, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].

Country	Entity	License requirement	License review policy	Federal Register citation
	Gazprom Geologorazvedka, OOO (f.k.a., Obshchestvo S Ogranichennoi Otvetstvennostyu Gazprom Dobycha Krasnoyarsk), a.k.a., the following two aliases: —Gazprom Geologorazvedka; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Geologorazvedka'. d.70 ul.Gertsena, Tyumen, Tyumenskaya obl. 625000, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Inform, OOO (f.k.a., Zakrytoe Aktsionernoe Obshchestvo Informgazinvest), a.k.a., the following two aliases: —Gazprom Inform; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Inform'. d. 13 str. 3 ul.Bolshaya Cheremushkinskaya, Moscow 117447, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Invest, OOO, a.k.a., the following two aliases: —Gazprom Invest; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Invest'. d. 6 litera D ul.Startovaya, St. Petersburg 196210, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Kapital, OOO (f.k.a., Obshchestvo S Ogranichennoi Otvetstvennostyu Kap Infin), a.k.a., the following two aliases: —Gazprom Kapital; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Kapital'. Sosenskoe Pos, Pos. Gazoprovod, D. 101 Korp. 9, Moscow 142770, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Komplektatsiya, OOO, a.k.a., the following two aliases: —Gazprom Komplektatsiya; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Komplektatsiya'. 8 Korp. 1 ul.Stroitelei, Moscow 119991, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Mezhregiongaz, OOO, a.k.a., the following two aliases: —Gazprom Mezhregiongaz; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Mezhregiongaz'. d. Dom 24 korp. Liter A nab.Admirala Lazareva, St. Petersburg 197110, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Neft (a.k.a. Gazprom Neft OAO; a.k.a. JSC Gazprom Neft; a.k.a. Open Joint-Stock Company Gazprom Neft; f.k.a. Sibirskaia Neftyanaya Kompaniya OAO) Address: Let. A. Galernaya, 5, ul, St. Petersburg 190000, Russia Alt Address: Ul. Pochtamskaya, 3–5, St. Petersburg 190000, Russia Alt Address: 3–5 Pochtamskaya St., St. Petersburg 190000, Russia Alt Address: 125 A. Profsoyuznaya Street, Moscow 117647, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	79 FR 55612, 9/17/14. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom, OAO (a.k.a. Open Joint Stock Company Gazprom; a.k.a. OAO Gazprom; a.k.a. Gazprom) Address: 16 Nametkina St., Moscow, Russia GSP–7, 117997, Russia Alt Address: 16 Nametkina ul., Moscow 117991, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	79 FR 55612, 9/17/14. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Pererabotka, OOO, a.k.a., the following two aliases: —Gazprom Pererabotka; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Pererabotka'. d.16 ul.Ostrovskogo, Surgut, Khanty-Mansiskiy Avtonomnyy okrug—Yugra a.o. 628417, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Personal, OOO, a.k.a., the following two aliases: —Gazprom Personal; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Personal'. 16, Gsp-7 ul.Nametkina, Moscow 117997, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Promgaz, AO (f.k.a., Otkrytoe Aktsionernoe Obshchestvo Gazprom Promgaz), a.k.a., the following two aliases: —Aktsionernoe Obshchestvo 'Gazprom Promgaz' <i>and</i> —Gazprom Promgaz. d. 6 ul.Nametkina, Moscow 117420, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].

Country	Entity	License requirement	License review policy	Federal Register citation
	Gazprom Russkaya, OOO (f.k.a., Obshchestvo S Ogranichennoi Otvetstvennostyu Kovyktneftegaz), a.k.a., the following two aliases: —Gazprom Russkaya; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Russkaya'. 3 korp.2 ul.Varshavskaya, St. Petersburg 196128, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Sotsinvest, OOO (f.k.a., Gazprominvestarena OOO), a.k.a., the following two aliases: —Gazprom Sotsinvest; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Sotsinvest'. d. 20 litera A nab.Aptekarskaya, St. Petersburg 197022, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Svyaz, OOO, a.k.a., the following two aliases: —Gazprom Svyaz; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Svyaz'. d.16 ul.Nametkina, Moscow 117997, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Telekom, OOO (f.k.a., Zakrytoe Aktsionernoe Obshchestvo Gaztelekom), a.k.a., the following two aliases: —Gazprom Telekom; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Telekom'. d. 62 str. 2 shosse Starokaluzhskoe, Moscow 117630, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Kazan, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Kazan; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Kazan'. d.41 ul.Adelya Kutuya, Kazan, Tatarstan resp 420073, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Krasnodar, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Krasnodar; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Krasnodar'. d.36 ul.Im Dzerzhinskogo, Krasnodar, Krasnodarski krai 350051, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Makhachkala, OOO (f.k.a., Obshchestvo S Ogranichennoi Otvetstvennostyu Gazprom Transgaz Makhachkala), a.k.a., the following two aliases: —Gazprom Transgaz Makhachkala; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Makhachkala'. ul.O.Bulacha, Makhachkala, Dagestan resp. 367030, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Nizhni Novgorod, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Nizhny Novgorod; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Nizhni Novgorod'. d.11 ul.Zvezdinka, Nizhni Novgorod, Nizhegorodskaya obl. 603950, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Samara, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Samara; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Samara'. d. 106 A str. 1 ul.Novo-Sadovaya, Samara, Samarskaya obl. 443068, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Sankt-Peterburg, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Saint Petersburg; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Sankt-Peterburg'. 3 korp.2 ul.Varshavskaya, St. Petersburg 196128, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Saratov, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Saratov; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Saratov'. d.118 A prospekt Im 50 Let Oktyabrya, Saratov, Saratovskaya obl. 410052, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Stavropol, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Stavropol; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Stavropol'. d.6 prospekt Oktyabskoi Revolyutsii, Stavropol, Stavropolski krai 355000, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].

Country	Entity	License requirement	License review policy	Federal Register citation
	Gazprom Transgaz Surgut, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Surgut; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Surgut'. d.1 ul.Universitetskaya, Surgut, Khanty-Mansiki Avtonomnyy okrug—Yugra a.o. 628406, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Tomsk, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Tomsk; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Tomsk'. d.9 prospekt Frunze, Tomsk, Tomskaya obl. 634029, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Ufa, OOO (f.k.a., Obshchestvo S Ogranichennoi Otvetstvennostyu Bashtransgaz Otkrytogo Aktsionernogo Obshchestva Gazprom), a.k.a., the following two aliases: —Gazprom Transgaz Ufa; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Ufa'. 59 ul.Rikharda Zorge, Ufa, Bashkortostan resp. 450054, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Ukhta, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Ukhta; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Ukhta'. d.39/2 prospekt Lenina, Ukhta, Komi resp 169312, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Volgograd, OOO, a.k.a., the following two aliases: —Gazprom Transgaz Volgograd; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Volgograd'. 58 ul.Raboche-Krestyanskaya, Volgograd, Volgogradskaya obl. 400074, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Transgaz Yugorsk, OOO (f.k.a., Obshchestvo S Ogranichennoi Otvetstvennostyu Tyumentransgaz), a.k.a., the following two aliases: —Gazprom Transgaz Yugorsk; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Transgaz Yugorsk'. d.15 ul.Mira, Yugorsk, Khanty-Mansiki Avtonomnyy okrug, Yugra a.o. 628260, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Tsentrremont, OOO, a.k.a., the following two aliases: —Gazprom Tsentrremont; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Gazprom Tsentrremont'. d.1 ul.Moskovskaya, Shchelkovo, Moskovskaya obl 141112, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Gazprom Vniigaz, OOO, a.k.a., the following two aliases: —Gazprom Vniigaz; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Nauchno-Issledovatel'skiy Institut Prirodnikh Gazov I Gazovykh Tekhnologii—Gazprom Vniigaz'. P Razvilka, Leninskiy Raion, Moskovskaya obl. 142717, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Kaliningradnefteprodukt OOO, a.k.a., the following three aliases: —Kaliningradnefteprodukt LLC; —Limited Liability Company Kaliningradnefteprodukt; <i>and</i> —LLC Kaliningradnefteprodukt	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	Presumption of denial.	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	22-b Komsomolskaya Ulitsa, Central District, Kaliningrad, Russia.			
	Kamchatgazprom, OAO, a.k.a., the following two aliases: —Kamchatgazprom; <i>and</i> —Otkrytoe Aktsionernoe Obshchestvo 'Kamchatgazprom'. d.19 ul.Pogranichnaya, Petropavlovsk-Kamchatski, Kamchatskiy kraj 683032, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Kinef OOO, a.k.a., the following three aliases: —Kinef, LLC; —Limited Liability Company Production Association Kirishinefteorgsintez; <i>and</i> —LLC Kinef.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	Presumption of denial.	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	d. 1 Shosse Entuziastov, Kirishi, Leningradskaya Oblast 187110, Russia.			

Country	Entity	License requirement	License review policy	Federal Register citation
	Kirishiavtoservis OOO, a.k.a., the following two aliases: —Limited Liability Company Kirishiavtoservis; <i>and</i> —LLC Kirishiavtoservis. lit A, 12 Smolenskaya Ulitsa, St. Petersburg 196084. * *	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR. * *	Presumption of denial. *	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. *
	Krasnoyarskgazprom, PAO, a.k.a., the following two aliases: —Krasnoyarskgazprom; <i>and</i> —Publichnoe Aktsionernoe Obshchestvo 'Krasnoyarskgazprom. d.1 pl.Akademika Kurchatova, Moscow 123182, Russia. * *	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR. * *	See § 746.8(b)(2) of the EAR. *	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. *
	Lazurnaya, OOO, a.k.a., the following two aliases: —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Lazurnaya'; <i>and</i> —“Lazurnaya”. d.103 prospekt Kurortny, Sochi, Krasnodarski krai 354024, Russia. Lengiproneftekhim OOO, a.k.a., the following three aliases: —Institut Po Proektirovaniyu Predpriyat Neftepererabatyvayushey I Neftekhimicheskoy Promyshlennosti, Limited Liability Company; —Limited Liability Company Oil Refining and Petrochemical Facilities Design Institute; <i>and</i> —LLC Lengiproneftekhim. d. 94, Obvodnogo Kanala, nab, St. Petersburg 196084, Russia. * *	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR. * *	See § 746.8(b)(2) of the EAR. *	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. 83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	LLC Volgogradpromproyekt, a.k.a. the following five aliases: —Obshchestvo S Ogranichennoi Otvetstvennostyu “Volgogradpromproekt”; —OOO Volgogradpromproyekt; —OOO Volgogradpromproekt; —OOO VPP; <i>and</i> —VPP. 47 Promyslovaya Street, Volgograd, Volgograd Region, 400057, Russia. Lukoil, OAO (a.k.a. Lukoil; a.k.a. Lukoil Oil Company; a.k.a. Neftyanaya Kompaniya Lukoil OOO; a.k.a. NK Lukoil OAO) Address: 11 Sretenski boulevard, Moscow 101000, Russia * *	For all items subject to the EAR. (See §§ 734.9(g), ³ 746.8(a)(3), and 744.21(b) of the EAR). * *	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e). See § 746.8(b)(2) of the EAR. *	89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. 79 FR 55612, 9/17/14. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. *
	Media-Invest OOO, a.k.a., the following two aliases: —Limited Liability Company Media-Invest; <i>and</i> —LLC Media-Invest. 17 Bld 1 Zubovskiy Blvd, Moscow 119847, Russia. * *	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR. * *	Presumption of denial. *	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. *
	Neft-Aktiv LLC, a.k.a., the following two aliases: —OOO Neft —Aktiv; <i>and</i> —RN-Aktiv OOO. Ulica Kaluzhskaya M., d., 15, str. 28, Moscow 119071, Russia. * *	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR. * *	See § 746.8(b)(2) of the EAR. *	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. *
	Niigazekonomika, OOO, a.k.a., the following two aliases: —Niigazeconomika; <i>and</i> —Obshchestvo S Ogranichennoi Otvetstvennostyu 'Nauchnoissledovatel'ski Institut Ekonomiki I Organizatsii Upravleniya V Gazovoipromyshlennosti'. d. 20 korp. 8 ul. Staraya Basmannaya, Moscow 107066, Russia. * *	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR. * *	See § 746.8(b)(2) of the EAR. *	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. *
	Novgorodnefteprodukt OOO, a.k.a., the following three aliases: —Limited Liability Company Novgorodnefteprodukt; —LLC Novgorodnefteprodukt; <i>and</i> —Novgorodnefteprodukt LLC. d. 20 Germana Ulitsa, Veliky Novgorod, Novgorodskaya Oblast 173002, Russia. * *	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR. * *	Presumption of denial. *	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024]. *

Country	Entity	License requirement	License review policy	Federal Register citation
	OJSC Achinsk Refinery, a.k.a., the following two aliases: —Achinsk Refinery; <i>and</i> —OAO Achinsk Oil Refinery VNK. Achinsk Refinery industrial area, Bolsheuluisky district, Krasnoyarsk territory 662110, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	OJSC Angarsk Petrochemical Company, a.k.a., the following one alias: —Angarsk Refinery. Angarsk, Irkutsk region 665830, Russia; <i>and</i> 6 ul. K. Marksa, Angarsk 665830, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	OJSC Kuybyshev Refinery, a.k.a., the following two aliases: —Kuibyshev Refinery; <i>and</i> —OJSC Kuibyshev Refinery. 25 Groznenskaya st., Samara 443004, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	OJSC Novokuibyshev Refinery, a.k.a., the following one alias: —Novokuibyshevsk Refinery. Novokuibyshevsk, Samara region 446207, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	OJSC Orenburgneft, a.k.a., the following two aliases: —OAO JSC Orenburgneft; <i>and</i> —Orenburgneft. Magistralnaya St., 2, Buzuluk, the Orenburg Region 461040, Russia; <i>and</i> st. Magistralnaya 2, Buzuluk 461040, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	OJSC RN Holding, a.k.a., the following one alias: —RN Holding OAO. 60 Oktyabrskaya ul., Uvat 626170, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	OJSC Samotlorneftegaz, a.k.a., the following two aliases: —Samotlorneftegaz; <i>and</i> —Samotlorneftegaz JSC. Lenina St. 4, the Tyumen Region 446009, Russia; <i>and</i> Khanty-Mansiysk, Autonomous District, Nizhnevartovsk 628606, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	OJSC Syzran Refinery, a.k.a., the following two aliases: —Open Joint-Stock Oil and Gas Company Syzran; <i>and</i> —Syzran Refinery. 1 Astrakhanskaya st., Syzran, Samara region 446009, Russia; <i>and</i> Moskvorechje street 105, Building 8, Moscow 115523, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	PJSC Verkhnechonskneftegaz, a.k.a., the following two aliases: —OJSC Verkhnechonskneftegaz; <i>and</i> —Verkhnechonskneftegaz. Baikalskaya St., 295 B, Irkutsk 664050, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Pskovnefteprodukt OOO, a.k.a., the following two aliases: —Limited Liability Company Marketing Association Pskovnefteprodukt; <i>and</i> —LLC Pskovnefteprodukt. 4 Oktyabrsky Prospekt, Pskov 180000, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	Presumption of denial.	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	RN-Komsomolsky Refinery LLC, a.k.a., the following three aliases: —Komsomolsk Refinery; —LLC RN-Komsomolsk Refinery; <i>and</i> —RN-Komsomolski NPZ OOO. 115 Leningradskaya st., Komsomolsk-on-Amur, Khabarovsk region 681007, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	RN-Yuganskneftegaz LLC, a.k.a., the following two aliases: —RN-Yuganskneftegaz OOO; <i>and</i> —Yuganskneftegaz. Lenina St., 26, Nefteyugansk, Tyumen Region, 628309, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Rosneft (a.k.a. Open Joint-Stock Company Rosneft Oil Company; a.k.a. OAO Rosneft Oil Company; a.k.a. Oil Company Rosneft; a.k.a. OJSC Rosneft Oil Company; a.k.a. Rosneft Oil Company) Address: 26/1, Sofiyaskaya Embankment, 117997, Moscow, Russia	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	79 FR 55612, 9/17/14. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	SNGB AO, a.k.a., the following three aliases: —Closed Joint Stock Company Surgutneftegasbank (ZAO SNGB); —Joint Stock Company Surgutneftegasbank; <i>and</i> —JSC BANK SNGB. 19 Kukuyvitskogo Street, Surgut 628400, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	Presumption of denial.	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].

Country	Entity	License requirement	License review policy	Federal Register citation
	SO Tvernefteprodukt OOO, a.k.a., the following two aliases: —Limited Liability Company Marketing Association Tvernefteprodukt; and —LLC MA Tvernefteprodukt.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR..	Presumption of denial.	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	6 Novotorzhskaya Ulitsa, Tver, Russia.	*	*	*
	Sovkhoz Chervishevski PAO, a.k.a., the following three aliases: —OJSC Sovkhoz Chervishevsky; —Open Joint Stock Company Sovkhoz Chervishevsky; and —Sovkhoz Chervishevsky, JSC.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	Presumption of denial.	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	d. 81 Sovetskaya Ulitsa, S. Chervichevsky, Tyumensky Rayon, Tyumensky Oblast 625519, Russia.	*	*	*
	Strakhovove Obshchestvo Surgutneftegaz OOO, a.k.a., the following three aliases: —Insurance Company Surgutneftegas, LLC; —Limited Liability Company Insurance Company Surgutneftegas; and —LLC Insurance Company Surgutneftegas.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	Presumption of denial.	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	9/1 Lermontova Ulitsa, Surgut 628418, Russia.	*	*	*
	Surgutmebel OOO, a.k.a., the following four aliases: —Limited Liability Company Syrgutmebel; —LLC Surgutmebel; —LLC Syrgutmebel; and —Surgutmebel, LLC.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	Presumption of denial.	83 FR 6952, 2/16/18. 83 FR 12479, 3/22/18. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Vostochnaya Industrial 1 Territory 2, Poselok Barsovo, Surgutsky District, Yugra, Khanty-Mansiysky Autonomos Okrug, Russia.			
	Surgutneftegas (a.k.a. Open Joint Stock Company Surgutneftegas; a.k.a. Otkrytoe Aktsionernoe Obshchestvo Surgutneftegaz; a.k.a. Surgutneftegas OAO; a.k.a. Surgutneftegas OJSC; a.k.a. Surgutneftegaz OAO)	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	79 FR 55612, 9/17/14. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Address: ul. Grigoriya Kukuyevitskogo, 1, bld. 1, Khanty-Mansiysky Autonomous Okrug—Yugra, the city of Surgut, Tyumenskaya Oblast 628415, Russia Alt Address: korp. 1 1 Grigoriya Kukuevitskogo ul., Surgut, Tyumenskaya oblast 628404, Russia. Alt Address: Street Kukuevitskogo 1, Surgut, Tyumen Region 628415, Russia			
	Vostokgazprom, OAO, a.k.a., the following two aliases: —Otkrytoe Aktsionernoe Obshchestvo 'Vostokgazprom'; and —Vostokgazprom.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	d.73 ul.Bolshaya Podgornaya, Tomsk, Tomskaya obl. 634009, Russia.	*	*	*
	Yamalgazinvest, ZAO, a.k.a., the following two aliases: —Yamalgazinvest; and —Zakrytoe Aktsionernoe Obshchestvo 'Yamalgazinvest'. d. 41 korp. 1 prospekt Vernadskogo, Moscow 117415, Russia.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	81 FR 61601, 9/7/16. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	Yuzhno-Kirinskoye Field, in the Sea of Okhotsk.	For all items subject to the EAR. (See § 746.8(a)(4) of the EAR).	Presumption of denial.	80 FR 47404, 8/7/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
	*	*	*	*
SWITZERLAND	Rosneft Trading S.A., 2, Rue Place du Lac, 1204, Geneva, Switzerland.	For all items subject to the EAR when used in projects specified in § 746.8(a)(4) of the EAR.	See § 746.8(b)(2) of the EAR.	80 FR 52968, 9/2/15. 89 FR [INSERT FR PAGE NUMBER AND June 18, 2024].
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■ 10. Supplement no. 5 is amended by revising the second paragraph to read as follows:

**Supplement No. 5 to Part 744—
Procedures for End-User Review
Committee Entity List and ‘Military End
User’ (MEU) List Decisions**

* * * * *

When determining to add an entry or modify an existing entry, to the Entity List or MEU List, the ERC will also specify the section or sections of the EAR that provide the basis for that determination. All additions and modifications to the MEU List are done pursuant to § 744.21(b). The license requirements, the license application review policy, or the availability of license exceptions for entities or address entries on the MEU List are specified in § 744.21 under paragraphs (b) to (e). In addition, for the Entity List, if the section or sections that form the basis for an addition or modification do not specify the license requirements, the license application review policy, or the availability of license exceptions, the ERC will specify the license requirements, the license application review policy and which license exceptions (if any) will be available for shipments to that entry.

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**PART 746—EMBARGOES AND OTHER
SPECIAL CONTROLS**

■ 11. The authority citation for 15 CFR part 746 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 2151 note; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Presidential Determination 2007–7, 72 FR 1899, 3 CFR, 2006 Comp., p. 325; Notice of May 8, 2024, 89 FR 40355 (May 9, 2024).

§ 746.5 [Removed and Reserved]

■ 12. Remove and reserve § 746.5.

■ 13. Section 746.8 is revised to read as follows:

§ 746.8 Sanctions against Russia and Belarus.

(a) *License requirements.* Except as described in the exclusions in paragraph (a)(12), and in addition to license requirements specified on the Commerce Control List (CCL) in supplement no. 1 to part 774 of the EAR and in other provisions of the EAR, including part 744 and other sections of part 746, a license is required as specified under paragraphs (a)(1) through (7). These license requirements

follow an order of review, which provides guidance on the relationship between the different license requirements and which ones take precedence for certain items. For purposes of paragraphs (a)(5) through (7) of this section, a license is not required for any item that is listed in supplement nos. 4, 5 or 6 to this part that is also classified under an Export Control Classification Number (ECCN) on the Commerce Control List (CCL) in supplement no. 1 to part 774 of the EAR. See paragraph (a)(1) of this section and part 742 for license requirements for exports, reexports, and transfers to or within Russia or Belarus for items classified in ECCNs, as well as part 744 for end-use and end-user controls that may apply to your transaction. Paragraphs (a)(1) and (2) of this section, are also used for determining license requirements for exports, reexports, and transfers to or within Russia or Belarus of any item that is listed in supplement nos. 4, 5, or 6 to this part and is classified in an ECCN on the CCL in supplement no. 1 to part 774 of the EAR. License requirements in paragraph (a)(4) that apply to exports, reexports, and transfers (in-country) involved in certain end-uses should be reviewed only after license requirements in paragraphs (a)(1) through (a)(3) and (a)(5) through (a)(7) are reviewed.

(1) *Items classified in any ECCN on the CCL.* A license is required to export, reexport, or transfer (in-country) to or within Russia or Belarus any item subject to the EAR and specified in any Export Control Classification Number (ECCN) on the CCL.

(2) *Russia/Belarus/Temporarily occupied Crimea region of Ukraine foreign “direct product” (FDP) rule.* A license is required to reexport, export from abroad, or transfer (in-country) to any destination any foreign-produced item subject to the EAR under the Russia/Belarus/Temporarily occupied Crimea region of Ukraine under the FDP rule described in § 734.9(f) of the EAR.

(3) *Russia/Belarus-Military End User FDP rule.* A license is required to reexport, export from abroad, or transfer (in-country) to or within any destination any foreign-produced item subject to the EAR under § 734.9(g) of the EAR.

Note 1 to paragraph (a)(3). A ‘military end user’ for purposes of this paragraph is any entity listed on the Entity List in supplement no. 4 to part 744 of the EAR with a Footnote 3 designation.

(4) *Oil and Gas.* (i) *Certain exploration or production of oil or gas.* A license is required to export, reexport, or transfer (in-country) any item subject to the EAR listed in supplement no. 2

to this part and items specified in ECCNs 0A998, 1C992, 3A229, 3A231, 3A232, 6A991, 8A992, and 8D999 when you “know” that the item will be used directly or indirectly in exploration for, or production of, oil or gas in Russian deepwater (greater than 500 feet) or Arctic offshore locations or shale formations in Russia or Belarus, or are unable to determine whether the item will be used in such projects. Such items include, but are not limited to, drilling rigs, parts for horizontal drilling, drilling and completion equipment, subsea processing equipment, Arctic-capable marine equipment, wireline and down hole motors and equipment, drill pipe and casing, software for hydraulic fracturing, high pressure pumps, seismic acquisition equipment, remotely operated vehicles, compressors, expanders, valves, and risers.

(ii) *Additional prohibition on those informed by BIS.* BIS may inform persons, either individually by specific notice or through amendment to the EAR, that a license is required for a specific export, reexport, or transfer (in-country) or for the export, reexport, or transfer (in-country) of specified items to a certain end-user or end-use, because there is an unacceptable risk of use in, or diversion to, the activities specified in this section in Russia or Belarus. Specific notice is to be given only by, or at the direction of, the Principal Deputy Assistant Secretary for Strategic Trade and Technology Security or the Deputy Assistant Secretary for Strategic Trade. When such notice is provided orally, it will be followed by a written notice within two working days signed by either the Principal Deputy Assistant Secretary for Strategic Trade and Technology Security or the Deputy Assistant Secretary for Strategic Trade. However, the absence of any such notification does not excuse persons from compliance with the license requirements of this section.

(5) *Industrial Goods.* A license is required to export, reexport, or transfer (in-country) any item subject to the EAR listed in supplement no. 4 to this part to or within Russia or Belarus.

(6) *Itemized Items.* A license is required to export, reexport, or transfer (in-country) any item subject to the EAR listed in supplement no. 6 to this part to or within Russia or Belarus.

(7) *Luxury goods.* A license is required to export, reexport, or transfer (in-country) any item subject to the EAR listed in supplement no. 5 to this part to or within Russia or Belarus.

Note 2 to paragraph (a)(7): For purposes of paragraph (a)(7) of this section, a ‘luxury

good' means any item that is identified in supplement no. 5 to this part.

(8) through (11) [RESERVED]

(12) *Exclusions from license requirements and scope of U.S.-origin controlled content.* Paragraphs (a)(12)(i), (ii), and (iii)(A) of this section exclude certain exports, reexports, and transfers (in-country) from the scope of the license requirements of this section. Paragraph (a)(12)(iii)(B) excludes certain items from the scope of U.S.-origin content for purposes of *de minimis* calculations from certain destinations.

(i) *Deemed exports and deemed reexports.* The license requirements in paragraph (a) do not apply to deemed exports or reexports. However, the exclusion for deemed exports and deemed reexports is limited to the license requirements specified only in this section of the EAR. Any deemed export or deemed reexport to a Russian or Belarusian national must be made in accordance with all other applicable EAR license requirements, such as CCL-based license requirements. For example, the release of NS1 controlled technology to a Russian or Belarusian national in the United States or in a third country would require a CCL-based deemed export or deemed reexport license (as applicable). Consequently, authorization (in the form of a deemed export or deemed reexport license, or license exception eligibility) would be required under the EAR notwithstanding the exclusion in this paragraph (b).

(ii) *Mass market encryption commodities and software.* Commodities specified under ECCN 5A991, and commodities and software classified under ECCNs 5A992.c or 5D992.c that have been 'classified in accordance with § 740.17,' do not require a license to or within Russia or Belarus for the following civil end-users:

(A) Wholly owned U.S. subsidiaries, branches, or sales offices;

(B) Joint ventures between two or more U.S. companies, including the wholly owned subsidiaries, branches, or sales offices of such joint ventures;

(C) Joint ventures between U.S. companies and companies headquartered in countries from Country Group A:5 and A:6 in supplement no. 1 to part 740 of the EAR, including the wholly owned subsidiaries, branches, or sales offices of such joint ventures;

(D) Wholly owned subsidiaries, branches, or sales offices of companies headquartered in countries from Country Group A:5 and A:6 in supplement no. 1 to part 740; or

(E) Joint ventures between two or more companies headquartered in Country Group A:5 and A:6 in supplement no. 1 to part 740, including the wholly owned subsidiaries, branches, or sales offices of such joint ventures.

(iii) *Global Export Control Coalition (GECC).* The countries listed in supplement no. 3 to this part have committed to implementing substantially similar export controls on Russia, Belarus, and the temporarily occupied Crimea region of Ukraine under their domestic laws. Therefore, exports or reexports from the countries listed in supplement no. 3 to this part or transfers (in-country) within the countries listed in this supplement are not subject to the following license requirements in paragraph (a) of this section unless a limit to the exclusion is described in the Scope column in supplement no. 3 to this part:

(A) *Foreign direct product rules.* The license requirement described in paragraphs (a)(2) and (3) of this section;

(B) *De minimis.* For purposes of determining U.S.-origin controlled content under supplement no. 2 to part 734 of the EAR, when making a *de minimis* calculation for reexports and exports from abroad to Russia or Belarus, the license requirements in paragraphs (a)(1) and (a)(4) through (7) of this section are not used to determine controlled U.S.-origin content in a foreign-made item, provided the criteria of paragraphs (a)(12)(B)(1) and (2) of this section are met:

(1) The U.S.-origin content is described in an Anti-Terrorism (AT)-only ECCN or is designated EAR99. For purposes of this paragraph, AT-only items mean any ECCN that only specifies either only AT in the reason for control paragraph of the ECCN or is classified under ECCN 9A991; and

(2) The foreign made item will be reexported or exported from abroad from a destination described in supplement no. 3 to this part.

(b) *Licensing policy.* (1) License applications required under paragraph (a)(3) of this section will be reviewed under a policy of denial in all cases.

(2) Applications for the export, reexport, or transfer (in-country) of any item pursuant to paragraph (a)(4) of this section that require a license for Russia or Belarus will be reviewed under a policy of denial when for use directly or indirectly for exploration or production from deepwater (greater than 500 feet), Arctic offshore, or shale projects in Russia or Belarus that have the potential to produce oil or gas.

(3) Applications for the export, reexport, or transfer (in-country) of any

item pursuant to paragraphs (a)(1), (2), and (5) through (7) of this section will be reviewed under a policy of denial. However, the following types of license applications submitted pursuant to paragraphs (a)(1), (2), and (5) through (7) of this section will be reviewed on a case-by-case basis to determine whether the transaction in question would benefit the Russian or Belarusian government or defense sector:

(i) Applications for export, reexport, or transfer (in-country) of items that may be necessary for health and safety reasons, including the safety of flight, maritime safety, and civil nuclear safety;

(ii) Applications for the disposition of items by companies not headquartered in Country Group D:1, D:5, E:1, or E:2 in supplement no. 1 to part 740 that are winding down or closing all operations in Russia or Belarus;

(iii) Applications for items that meet humanitarian needs, including applications for items that are predominantly agricultural or medical in nature;

(iv) Applications for government-to-government activities or to support government space cooperation;

(v) Replacement licenses for exports and reexports to and transfers within Russia and Belarus of items described in HTS-6 Codes or items described in supplement no. 6 to part 746 that were added to the EAR and made subject to license requirements after the validation date of the BIS license.

(vi) Applications for items destined to:

(A) Wholly owned U.S. subsidiaries, branches, or sales offices;

(B) Foreign subsidiaries, branches, or sales offices of U.S. companies that are joint ventures with other U.S. companies;

(C) Joint ventures of U.S. companies with companies headquartered in countries from Country Group A:5 and A:6 in supplement no. 1 to part 740 of the EAR;

(D) The wholly owned subsidiaries, branches, or sales offices of companies headquartered in countries from Country Group A:5 and A:6 in supplement no. 1 to part 740; or

(E) Joint ventures of companies headquartered in Country Groups A:5 and A:6 with other companies headquartered in Country Groups A:5 and A:6; and

(vii) Applications for companies headquartered in Country Groups A:5 and A:6 to support civil telecommunications infrastructure.

Note 3 to paragraph (b): See also § 750.7(c)(1)(xi) of the EAR for the divestiture of items within Russia or Belarus or the transfer of items within Russia or Belarus for

the purpose of reexporting such items from Russia or Belarus. For purposes of § 750.7(c)(1)(xi), divestiture means the action or process of selling off subsidiary business interests or investments involving items subject to the EAR.

(c) *License exceptions.* Consistent with § 740.2(b), BIS may revise, suspend, or revoke License Exception availability under this section consistent with U.S. national security and foreign policy interests, including on a case-by-case basis, to prevent Russian or Belarusian persons from circumventing the restrictions in this section.

(1) No license exceptions may overcome the license requirements in paragraph (a)(3) of this section, except as specified in the entry for a Footnote 3 entity on the Entity List in supplement no. 4 to part 744 of the EAR.

(2) No license exceptions may overcome the license requirements in paragraphs (a)(1), (2), and (4) through (7) of this section except the following:

(i) License Exception TMP for items for use by the news media as set forth in § 740.9(a)(9) of the EAR may overcome the license requirements in paragraphs (a)(1), (2), (7) of this section.

(ii) License Exception GOV (§ 740.11(b) of the EAR) may overcome the license requirements in paragraphs (a)(1), (2), and (4) through (7) of this section.

(iii) License Exception TSU for software updates for civil end-users that are wholly-owned U.S. subsidiaries, branches, or sales offices; foreign subsidiaries, branches, or sales offices of U.S. companies that are joint ventures with other U.S. companies; joint ventures of U.S. companies with companies headquartered in countries from Country Group A:5 and A:6 in supplement no. 1 to part 740 of the EAR countries; the wholly-owned subsidiaries, branches, or sales offices of companies headquartered in countries from Country Group A:5 and A:6 in supplement no. 1 to part 740; or joint ventures of companies headquartered in Country Group A:5 and A:6 with other companies headquartered in Country Groups A:5 and A:6 (§ 740.13(c) of the EAR) may overcome the license requirements in paragraphs (a)(1), (2), and (7) of this section.

(iv) License Exception BAG, excluding firearms and ammunition (§ 740.14, excluding paragraph (e), of the EAR) may overcome the license requirements in paragraphs (a)(1) and (2) of this section.

(v) License Exception AVS, excluding any aircraft registered in, owned or controlled by, or under charter or lease by Russia or Belarus or a national of Russia or Belarus (§ 740.15(a) and (b) of

the EAR) may overcome the license requirements in paragraphs (a)(1) and (2) of this section.

(vi) License Exception encryption commodities, software, and technology (ENC) for civil end-users that are wholly-owned U.S. subsidiaries, branches, or sales offices; foreign subsidiaries, branches, or sales offices of U.S. companies that are joint ventures with other U.S. companies; joint ventures of U.S. companies with companies headquartered in countries from Country Group A:5 and A:6 in supplement no. 1 to part 740 of the EAR countries; the wholly-owned subsidiaries, branches, or sales offices of companies headquartered in countries from Country Group A:5 and A:6 in supplement no. 1 to part 740; or joint ventures of companies headquartered in Country Groups A:5 and A:6 (§§ 740.13(c) and 740.17 of the EAR) may overcome the license requirements in paragraphs (a)(1) and (2) of this section.

(vii) License Exception CCD (§ 740.19 of the EAR) may overcome the license requirements in paragraphs (a)(1), (2), and (4) through (7) of this section.

(viii) License Exception MED (§ 740.23 of the EAR) may overcome the license requirements in paragraphs (a)(5) through (7) of this section.

(d) *License Applications.* License applications submitted to BIS under this section may include the phrase “§ 746.8” and identify the paragraph (a) license requirement(s) from this section that are applicable. You should include a description such as “paragraph (a)(1) or any of the other paragraph (a) paragraphs that may be applicable to a license application” in Block 9 (Special Purpose) of your license application as described in supplement no. 1 to part 748 of the EAR.

■ 14. Effective September 16, 2024, amend § 746.8 by:

- a. In paragraph (a) introductory text first and last sentences;
- b. Adding paragraph (a)(8);
- c. Revising paragraph (a)(12)(ii) introductory text;
- d. Adding paragraph (a)(12)(iv);
- e. Revising paragraph (b)(3) introductory text; and
- f. Revising paragraph (c)(1).

The addition and revisions read as follows:

§ 746.8 Sanctions against Russia and Belarus.

(a) *License requirements.* Except as described in the exclusions in paragraph (a)(12), and in addition to license requirements specified on the Commerce Control List (CCL) in

supplement no. 1 to part 774 of the EAR and in other provisions of the EAR, including part 744 and other sections of part 746, a license is required as specified under paragraphs (a)(1) through (8) of this section. * * * License requirements in paragraph (a)(4) of this section that apply to exports, reexports, and transfers (in-country) involved in certain end-users should be reviewed only after license requirements in paragraphs (a)(1) through (3) and (5) through (8) of this section are reviewed.

* * * * *

(8) *EAR99 designated software.* (i) A license is required to export, reexport, or transfer (in-country) to or within Russia or Belarus any “software” subject to the EAR and described in paragraph (a)(8)(ii) of this section.

(ii) The following types of software subject to the EAR are in the scope of paragraph (a)(8): Enterprise resource planning (ERP); customer relationship management (CRM); business intelligence (BI); supply chain management (SCM); enterprise data warehouse (EDW); computerized maintenance management system (CMMS); project management software, product lifecycle management (PLM); building information modelling (BIM); computer aided design (CAD); computer-aided manufacturing (CAM); and engineering to order (ETO). The scope of paragraph (a)(8) also includes software updates of software identified in this paragraph that are subject to the EAR and designated as EAR99.

* * * * *

(12) * * *

(ii) *Mass market encryption commodities and software, and software designated EAR99.* Commodities specified under ECCN 5A991, and commodities and software classified under ECCNs 5A992.c or 5D992.c that have been ‘classified in accordance with § 740.17,’ as well as software designated EAR99 and identified in paragraph (a)(8)(ii) of this section do not require a license to export, reexport, or transfer (in-country) to or within Russia or Belarus for the following civil end-users:

* * * * *

(iv) *Software designated EAR99.* Software that is subject to the EAR and designated EAR99 is excluded from the license requirement in paragraph (a)(8) when destined to entities engaged exclusively in the agriculture or medical industries.

(b) * * *

(3) Applications for the export, reexport, or transfer (in-country) of any item pursuant to paragraphs (a)(1), (2),

and (a)(5) through (8) of this section will be reviewed under a policy of denial. However, the following types of license applications submitted pursuant to paragraphs (a)(1), (2), and (4) through (8) will be reviewed on a case-by-case basis to determine whether the transaction in question would benefit the Russian or Belarusian government or defense sector:

* * * * *

(c) * * *

(1) No license exceptions may overcome the license requirements in paragraph (a)(3) of this section, except as specified in the entry for a Footnote 3 entity on the Entity List in supplement no. 4 to part 744 of the EAR, or in paragraph (a)(8) of this section.

* * * * *

§ 746.10 [Removed and reserved]

■ 15. Remove and reserve § 746.10.

■ 16. Supplement no. 2 to part 746 is amended by revising the heading, paragraph (a) and first sentence of paragraph (b) to read as follows:

Supplement No. 2 to Part 746—Russian and Belarusian Industry Sector Sanction List Pursuant to § 746.8(a)(4)

(a) The source for the Harmonized Tariff Schedule (HTS)-6 codes and descriptions in this list comes from the United States International Trade Commission (USITC's) Harmonized Tariff Schedule of the United States (2023). The items described in supplement no. 2 to part 746 include any modified or designed "components," "parts," "accessories," and "attachments" therefor regardless of the HTS Code or HTS Description of the "components," "parts," "accessories," and "attachments," apart from any "part" or minor "component" that is a fastener (e.g., screw, bolt, nut, nut plate, stud, insert, clip, rivet, pin), washer, spacer, insulator, grommet, bushing, spring, wire, or solder. The exclusion of fasteners from this control does not apply to fasteners that are designated under an HTS Code under this supplement. Although generally fasteners (e.g., screws, bolts, nuts, nut plates, studs, inserts, clips, rivets, pins), and washers, spacers, insulator, grommets, bushings, springs, wires, and solders are excluded from the scope of this supplement, certain part 744 license requirements for Russia and Belarus extend to all items "subject to the EAR," and would therefore not exclude these items from the license requirements under that part (e.g., § 744.21 of the EAR and the Entity List license requirements, which in most cases extend to all items "subject to the EAR"). This supplement includes two columns consisting of the HTS Codes and HTS Descriptions to assist exporters, reexporters, and transferors in identifying the products in this supplement. For information on HTS codes in general, you may contact a local import specialist at U.S. Customs and Border Protection at the nearest port. HTS-6 codes 730424, 731100, 761300, 841350, 841360,

841382, 841392, 842139, 843049, 843139, 843143, 847989, and 870520 are listed in both this supplement and supplement no. 4 to this part, so exporters, reexporters, and transferors must comply with the license requirements under both § 746.8(a)(4) and (5) as applicable.

(b) The items identified in the HTS-6 Code column of this supplement are subject to the license requirement under § 746.8(a)(4). The other column—HTS Description—is intended to assist exporters with their Automated Export System (AES) filing responsibilities.

* * *

* * * * *

■ 17. Supplement no. 3 to part 746 is amended by revising the first sentence of the introductory text to read as follows:

Supplement No. 3 to Part 746—Countries Excluded From Certain License Requirements of §§ 746.6, 746.7, and 746.8

Countries listed in this supplement have committed to implementing substantially similar export controls on Russia and Belarus under their domestic laws and are consequently excluded from certain requirements in §§ 746.6 and 746.8 of the EAR, as described in §§ 746.6(a)(4) and 746.8(a)(12)(iii). * * *

* * * * *

■ 18. Supplement no. 4 to part 746 is amended by:

■ a. Revising the heading, paragraphs (a) and (b); and

■ b. Adding in numerical order the following entries to the table: "250200," "250300," "250410," "250490," "250510," "250590," "250610," "250620," "250700," "251110," "251120," "251310," "251320," "251400," "251611," "251612," "251620," "251690," "251710," "251720," "251730," "251741," "251749," "251810," "251990," "252020," "252310," "252321," "252329," "252330," "252390," "252410," "252490," "252800," "252910," "252921," "252922," "252930," "253010," "253090," "260111," "260112," "260120," "260200," "260300," "260400," "260500," "260600," "260700," "260800," "260900," "261000," "261100," "261220," "261310," "261390," "261400," "261510," "261590," "261610," "261690," "261710," "261790," "261800," "261900," "262011," "262019," "262021," "262029," "262030," "262040," "262060," "262091," "262099," "262110," "262190," "270500," "270600," "270710," "270740," "270750," "270791," "270799," "270810," "270900," "271012," "271020," "271091," "271099," "271111," "271112," "271113," "271114," "271119,"

"271121," "271129," "271220," "271311," "271312," "271320," "271390," "271410," "271490," "272010," "2720120," "2720150," "272021," "2720219," "2720221," "2720229," "2720230," "2720241," "2720249," "2720250," "2720260," "2720270," "2720280," "2720291," "2720293," "2720299," "2720310," "2720390," "2720410," "2720421," "2720429," "2720430," "2720441," "2720449," "2720450," "2720510," "2720521," "2720529," "2720610," "2720690," "2721410," "2721420," "2721430," "2721491," "2721499," "2721510," "2721590," "2721710," "2721720," "2721730," "2721790," "2722100," "2722211," "2722219," "2722220," "2722240," "2722300," "2722710," "2722720," "2722790," "2722920," "2730110," "2730210," "2730230," "2730240," "2730290," "2730300," "2730431," "2730439," "2730441," "2730449," "2730451," "2730459," "2730490," "2730531," "2730590," "2730621," "2730629," "2730630," "2730640," "2730661," "2730669," "2730690," "2730711," "2730719," "2730721," "2730723," "2730729," "2730791," "2730792," "2730793," "2730799," "2731210," "2731290," "2731300," "2731414," "2731419," "2731420," "2731431," "2731439," "2731441," "2731442," "2731449," "2731450," "2731511," "2731512," "2731519," "2731520," "2731581," "2731582," "2731589," "2731590," "2731600," "2731700," "2731811," "2731812," "2731813," "2731814," "2731815," "2731816," "2731819," "2731821," "2731822," "2731823," "2731829," "2731940," "2731990," "2732010," "2732090," "2732111," "2732112," "2732119," "2732181," "2732182," "2732189," "2732190," "2732211," "2732219," "2732310," "2732391," "2732392," "2732393," "2732394," "2732399," "2732410," "2732421," "2732490," "2732510," "2732591," "2732599," "2732611," "2732619," "2732620," "2740100," "2740200," "2740311," "2740312," "2740313," "2740319," "2740321," "2740322," "2740329," "2740400," "2740500," "2740610," "2740620," "2741011," "2741012," "2741021," "2741022," "2741110," "2741121," "2741122," "2741210," "2741220," "2741300," "2741510," "2741529," "2741533," "2741539," "2741810," "2741820," "2741920," "2741980," "2750110," "2750120," "2750210," "2750220," "2750300," "2750400," "2760110," "2760120," "2760200," "2760310," "2760320," "2760410," "2760421," "2760429," "2760611," "2760612," "2760691," "2760711," "2760719," "2760810,"

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 “820160,” “820190,” “820210,”
 “820231,” “820239,” “820240,”
 “820291,” “820299,” “820310,”
 “820320,” “820330,” “820340,”
 “820412,” “820420,” “820510,”
 “820520,” “820530,” “820540,”
 “820551,” “820560,” “820570,”
 “820590,” “820600,” “820720,”
 “820730,” “820740,” “820750,”
 “820770,” “820780,” “820900,”
 “821000,” “821110,” “821191,”
 “821192,” “821193,” “821194,”
 “821195,” “821210,” “821220,”
 “821290,” “821300,” “821410,”
 “821420,” “821490,” “821510,”
 “821520,” “821591,” “821599,”
 “830110,” “830130,” “830140,”
 “830150,” “830160,” “830210,”
 “830220,” “830241,” “830242,”
 “830249,” “830250,” “830260,”
 “830300,” “830400,” “830510,”
 “830520,” “830590,” “830610,”
 “830630,” “830810,” “830820,”
 “830890,” “831000,” “831110,”
 “831120,” “831130,” “831190,”
 “860120,” “860310,” “860390,”
 “860500,” “860711,” “860712,”
 “860719,” “860721,” “860729,”
 “860730,” “860791,” “860799,”
 “860800,” “860900,” “870110,”
 “870129,” “870191,” “870192,”
 “870193,” “870194,” “870195,”
 “870210,” “870220,” “870230,”
 “870240,” “870290,” “870790,”

“870810,” “870821,” “870822,”
 “870829,” “870830,” “870840,”
 “870850,” “870870,” “870880,”
 “870891,” “870892,” “870893,”
 “870894,” “870895,” “870919,”
 “871000,” “871110,” “871200,”
 “871491,” “871492,” “871493,”
 “871494,” “871495,” “871496,”
 “871499,” “871610,” “871631,”
 “871640,” “871680,” “890120,”
 “890130,” “890190,” “890200,”
 “890400,” “890510,” “890610,”
 “890690,” “890710,” “890790,”
 “890800,” “930200,” “930310,”
 “930320,” “930330,” “930390,”
 “930400,” “930510,” “930520,”
 “930599,” “930621,” “930629,”
 “930630,” “930690,” “930700,”
 “960350,” and “960390.”

The revisions and additions read as follows:

Supplement No. 4 to Part 746—Russian and Belarusian Industry Sector Sanctions Pursuant to § 746.8(a)(5)

(a) The source for the Harmonized Tariff Schedule (HTS)-6 codes and descriptions in this list is the United States International Trade Commission (USITC)’s Harmonized Tariff Schedule of the United States (2023). The items described in supplement no. 4 to part 746 include any modified or designed “components,” “parts,” “accessories,” and “attachments” thereof regardless of the HTS Code or HTS Description of the “components,” “parts,” “accessories,” and “attachments,” apart from any “part” or minor “component” that is a fastener (e.g., screw, bolt, nut, nut plate, stud, insert, clip, rivet, pin), washer, spacer, insulator, grommet, bushing, spring, wire, or solder. The exclusion of fasteners from this control does not apply to fasteners that are designated under an HTS Code under this supplement. Although generally fasteners (e.g., screws, bolts, nuts, nut plates, studs, inserts, clips, rivets, pins), and washers, spacers, insulators, grommets, bushings, springs, wires, and solders are excluded from the scope of this supplement, certain part 744 license requirements for Russia and Belarus apply to all items “subject to the EAR,” and would therefore not exclude these items from the license requirements under that part (e.g., § 744.21 and the Entity List license requirements, which in most cases apply to all items “subject to the EAR.”). This supplement includes two columns consisting of the HTS Codes and HTS Descriptions to assist exporters, reexporters, and transferors

in identifying the products in this supplement. For information on HTS codes in general, you may contact a local import specialist at U.S. Customs and Border Protection at the nearest port. HTS-6 codes 730424, 731100, 761300, 841350, 841360, 841382, 841392, 842139, 843049, 843139, 843143, 847989, and 870520 are listed in both this supplement and supplement no. 2 to this part, so exporters, reexporters, and transferors must comply with the license requirements under both § 746.8(a)(4) and (5) as applicable. HTS-6 Codes 590500, 840710, 840721, 840729, 840731, 840732, 840733, 840734, 840790, 840810, 840820, 840890, 840910, 840991, 840999, 841111, 841112, 841121, 841122, 841181, 841182, 841191, 841199, 841229, 841290, 841451, 841459, 841460, 841510, 841810, 841821, 841829, 841830, 841840, 841981, 842211, 842310, 842860, 843139, 844312, 844331, 844332, 844339, 845011, 845012, 845019, 845121, 845210, 847010, 847021, 847029, 847030, 847130, 847141, 847149, 847150, 847160, 847170, 847180, 847190, 847290, 847960, 848310, 848320, 848330, 848340, 848350, 848360, 848390, 850811, 850819, 850860, 850980, 851110, 851120, 851130, 851140, 851150, 851180, 851190, 851220, 851230, 851240, 851631, 851650, 851660, 851671, 851672, 851679, 851711, 851713, 851718, 851761, 851762, 851769, 851920, 851930, 851981, 851989, 852110, 852190, 852691, 852712, 852713, 852719, 852721, 852729, 852791, 852792, 852799, 852871, 852872, 852910, 853110, 854370, 854430, 870310, 870321, 870322, 870323, 870324, 870331, 870332, 870333, 870340, 870350, 870360, 870370, 870380, 870390, and 902000 are listed in both this supplement and supplement no. 5 to this part, so exporters, reexporters, and transferors must comply with the license requirements under both §§ 746.8(a)(5) and (7) as applicable.

(b) The items identified in the HTS-6 Code column of this supplement are subject to the license requirement under § 746.8(a)(5). The other column—HTS Description—is intended to assist exporters with their AES filing responsibilities. The license requirements extend to HTS Codes at the 8 and 10 digit level (HTS-8 and HTS-10 codes, respectively) when such longer HTS Codes begin with the HTS-6 Codes as their first 6 numbers. When a description mentions parts related to one or more numerical headings, this means parts related to any HS codes that begin with the digits in the range specified. For example, “headings 8524 to 8528” means any HS code, HTS code, or Schedule B which has 8524, 8525, 8526, 8527, or 8528 as the first four digits.

HTS-6 code	HTS description
250200	UNROASTED IRON PYRITES.
250300	SULFUR OF ALL KINDS, OTHER THAN SUBLIMED SULFUR, PRECIPITATED SULFUR AND COLLOIDAL SULFUR.
250410	NATURAL GRAPHITE, IN POWDER OR IN FLAKES.
250490	NATURAL GRAPHITE, EXCEPT POWDER OR FLAKES.
250510	SILICA SANDS AND QUARTZ SANDS, NATURAL.
250590	SANDS, NATURAL, EXCEPT METAL BEARING OR SILICA OR QUARTZ SANDS.
250610	QUARTZ (OTHER THAN NATURAL SANDS).
250620	QUARTZITE.
250700	KAOLIN AND OTHER KAOLINIC CLAYS, WHETHER OR NOT CALCINED.

HTS-6 code	HTS description
251110	NATURAL BARIUM SULFATE (BARYTES).
251120	NATURAL BARIUM CARBONATE (WITHERITE).
251310	PUMICE STONE.
251320	EMERY, NATURAL CORUNDUM, NATURAL GARNET AND OTHER NATURAL ABRASIVES.
251400	SLATE, WHETHER OR NOT ROUGHLY TRIMMED OR MERELY CUT, BY SAWING ETC. INTO BLOCKS OR SLABS OF RECTANGULAR OR SQUARE SHAPE.
251611	GRANITE, CRUDE OR ROUGHLY TRIMMED.
251612	GRANITE, MERELY CUT INTO BLOCKS OR SLABS OF RECTANGULAR OR SQUARE SHAPE.
251620	SANDSTONE.
251690	BASALT, PORPHYRY AND OTHER MONUMENTAL OR BUILDING STONE, NESOI, WHETHER OR NOT TRIMMED OR MERELY CUT INTO BLOCKS ETC. OF RECTANGULAR OR SQUARE SHAPE.
251710	PEBBLES, GRAVEL, BROKEN OR CRUSHED STONES FOR CONCRETE AGGREGATES, FOR ROAD METALLING OR BALLAST, SHINGLE AND FLINT, WHETHER OR NOT HEAT TREATED.
251720	MACADAM OF SLAG, DROSS OR SIMILAR INDUSTRIAL WASTE, WHETHER OR NOT INCORPORATING PEBBLES, GRAVEL, BROKEN OR CRUSHED STONES, CITED IN SUBHEADING 251710.
251730	TARRED MACADAM.
251741	MARBLE GRANULES, CHIPPINGS AND POWDER.
251749	GRANULES, CHIPPINGS AND POWDER OF MONUMENTAL OR BUILDING STONES (CALCAREOUS NESOI, ALABASTER, GRANITE, PORPHYRY, BASALT, SANDSTONE ETC.), NESOI.
251810	DOLOMITE NOT CALCINED.
251990	FUSED MAGNESIA; DEAD-BURNED (SINTERED) MAGNESIA; OTHER MAGNESIUM OXIDE NESOI, WHETHER OR NOT PURE.
252020	PLASTERS CONSISTING OF CALCINED GYPSUM OR CALCIUM SULFATE.
252310	CEMENT CLINKERS.
252321	WHITE PORTLAND CEMENT, WHETHER OR NOT ARTIFICIALLY COLORED.
252329	PORTLAND CEMENT, EXCEPT WHITE PORTLAND CEMENT.
252330	ALUMINOUS CEMENT.
252390	HYDRAULIC CEMENTS, NESOI.
252410	CROCIDOLITE ASBESTOS.
252490	ASBESTOS, EXCLUDING CROCIDOLITE.
252800	NATURAL BORATES & CONCENTRATES THEREOF, NOT INCLUDING BORATES SEPARATED FROM NATURAL BRINE; NATURAL BORIC ACID CONTAINING LT=85% H3BO3 CALC ON DRY WGT.
252910	FELDSPAR.
252921	FLUORSPAR, CONTAINING BY WEIGHT 97% OR LESS OF CALCIUM FLUORIDE.
252922	FLUORSPAR, CONTAINING BY WEIGHT MORE THAN 97% OF CALCIUM FLUORIDE.
252930	LEUCITE; NEPHELINE AND NEPHELINE SYENITE.
253010	VERMICULITE, PERLITE AND CHLORITES, UNEXPANDED.
253090	MINERAL SUBSTANCES, NESOI.
260111	IRON ORE CONCENTRATES (OTHER THAN ROASTED IRON PYRITES) AND NON-AGGLOMERATED IRON ORES.
260112	AGGLOMERATED IRON ORES.
260120	ROASTED IRON PYRITES.
260200	MANGANESE ORES AND CONCENTRATES, INCLUDING FERRUGINOUS MANGANESE ORES AND CONCENTRATES WITH A MANGANESE CONTENT OF 20% OR MORE, BASED ON DRY WEIGHT.
260300	COPPER ORES AND CONCENTRATES.
260400	NICKEL ORES AND CONCENTRATES.
260500	COBALT ORES AND CONCENTRATES.
260600	ALUMINUM ORES AND CONCENTRATES.
260700	LEAD ORES AND CONCENTRATES.
260800	ZINC ORES AND CONCENTRATES.
260900	TIN ORES AND CONCENTRATES.
261000	CHROMIUM ORES AND CONCENTRATES.
261100	TUNGSTEN ORES AND CONCENTRATES.
261220	THORIUM ORES AND CONCENTRATES.
261310	MOLYBDENUM ORES AND CONCENTRATES, ROASTED.
261390	MOLYBDENUM ORES AND CONCENTRATES, NOT ROASTED.
261400	TITANIUM ORES AND CONCENTRATES.
261510	ZIRCONIUM ORES AND CONCENTRATES.
261590	NIOBIUM, TANTALUM AND VANADIUM ORES AND CONCENTRATES.
261610	SILVER ORES AND CONCENTRATES.

HTS-6 code	HTS description
261690	PRECIOUS METAL ORES AND CONCENTRATES, OTHER THAN SILVER.
261710	ANTIMONY ORES AND CONCENTRATES.
261790	ORES AND CONCENTRATES, NESOI.
261800	GRANULATED SLAG (SLAG SAND) FROM IRON OR STEEL MANUFACTURE.
261900	SLAG, DROSS (OTHER THAN GRANULATED SLAG), SCALINGS AND OTHER WASTE FROM THE MANUFACTURE OF IRON OR STEEL.
262011	HARD ZINC SPELTER.
262019	ASH AND RESIDUE (OTHER THAN FROM THE MANUFACTURE OF IRON OR STEEL) CONTAINING MAINLY ZINC, OTHER THAN HARD ZINC SPELTER.
262021	ASHES AND RESIDUES OF LEADED GASOLINE SLUDGES AND LEADED ANTI-KNOCK COMPOUND SLUDGES.
262029	ASH AND RESIDUES CONTAINING MAINLY LEAD, NESOI.
262030	ASH AND RESIDUES NESOI, CONTAINING MAINLY COPPER.
262040	ASH AND RESIDUES NESOI, CONTAINING MAINLY ALUMINUM.
262060	ASH & RESIDUES CONTAINING ARSENIC, MERCURY, THALLIUM OR THEIR MIXTURES, USED FOR EXTRACTION OF THOSE METALS.
262091	ASH & RESIDUES OF ANTIMONY, BERYLLIUM, CADMIUM, CHROMIUM OR THEIR MIXTURES, NESOI.
262099	ASH AND RESIDUES NESOI, CONTAINING METALS OR METALLIC COMPOUNDS NESOI.
262110	ASH AND RESIDUES FROM THE INCINERATION OF MUNICIPAL WASTE.
262190	ASH AND SLAG, INCLUDING SEAWEED ASH (KELP), NESOI.
*	*
270500	COAL GAS, WATER GAS, PRODUCER GAS AND SIMILAR GASES, EXCEPT PETROLEUM GASES AND OTHER GASEOUS HYDROCARBONS.
270600	MINERAL TARS, INCLUDING RECONSTITUTED TARS.
270710	BENZENE.
*	*
270740	NAPHTHALENE.
270750	AROMATIC HYDROCARBONS NESOI, OF WHICH 65% OR MORE BY VOLUME (INCLUDING LOSSES) DISTILLS AT 250 DEGREES CENTIGRADE BY THE ASTM D 86 METHOD.
270791	CREOSOTE OILS.
270799	OILS AND PRODUCTS OF THE DISTILLATION OF HIGH TEMPERATURE COAL TAR, NESOI; SIMILAR PRODUCTS WHICH HAVE A PREDOMINATE (WT.) AROMATIC CONSTITUENT, NESOI.
270810	PITCH FROM COAL AND OTHER MINERAL TARS.
*	*
270900	PETROLEUM OILS AND OILS FROM BITUMINOUS MINERALS, CRUDE.
271012	LIGHT OILS AND PREPARATIONS CONTAINING GT=70% BY WEIGHT PETROLEUM OILS OR OILS FROM BITUMINOUS MINERALS, NOT CONTAINING BIODIESEL, NOT WASTE OILS.
*	*
271020	PETROLEUM OILS AND PREPARATIONS CONTAINING BIODIESEL, CONTAINING BY WEIGHT GT=70% PETROLEUM OILS OR OILS OF BITUMINOUS MINERALS, OTHER THAN WASTE OILS.
271091	WASTE OILS CONTAINING POLYCHLORINATED BIPHENYLS (PBC), POLYCHLORINATED TERPHENYLS (PCT) OR POLYBROMINATED BIPHENYLS (PBB).
271099	WASTE OILS, NESOI.
271111	NATURAL GAS, LIQUEFIED.
271112	PROPANE, LIQUEFIED.
271113	BUTANES, LIQUEFIED.
271114	ETHYLENE, PROPYLENE, BUTYLENE AND BUTADIENE, LIQUEFIED.
271119	PETROLEUM GASES AND OTHER GASEOUS HYDROCARBONS, LIQUEFIED, NESOI.
271121	NATURAL GAS, GASEOUS.
271129	PETROLEUM GASES AND OTHER GASEOUS HYDROCARBONS IN A GASEOUS STATE, NESOI (OTHER THAN NATURAL GAS).
*	*
271220	PARAFFIN WAX CONTAINING BY WEIGHT LESS THAN 0.75% OIL.
*	*
271311	PETROLEUM COKE, NOT CALCINED.
271312	PETROLEUM COKE, CALCINED.
271320	PETROLEUM BITUMEN.
271390	RESIDUES OF PETROLEUM OILS OR OF OILS OBTAINED FROM BITUMINOUS MINERALS, NESOI.
271410	BITUMINOUS OR OIL SHALE AND TAR SANDS.
271490	BITUMEN AND ASPHALT, NATURAL; ASPHALTITES AND ASPHALTIC ROCKS.
*	*
720110	NONALLOY PIG IRON CONTAINING 0.5% (WT.) OR LESS PHOSPHORUS, IN PRIMARY FORMS.
720120	NONALLOY PIG IRON CONTAINING MORE THAN 0.5% (WT.) PHOSPHORUS, IN PRIMARY FORMS.
720150	ALLOY PIG IRON; SPIEGELEISEN, IN PRIMARY FORMS.
720211	FERROMANGANESE, CONTAINING MORE THAN 2% (WT.) CARBON.
720219	FERROMANGANESE, CONTAINING 2% (WT.) OR LESS CARBON.
720221	FERROSILICON, CONTAINING MORE THAN 55% (WT.) SILICON.
720229	FERROSILICON, CONTAINING 55% (WT.) OR LESS SILICON.

HTS-6 code	HTS description
720230	FERROSILICON MANGANESE.
720241	FERROCHROMIUM, CONTAINING MORE THAN 4% (WT.) CARBON.
720249	FERROCHROMIUM, CONTAINING 4% (WT.) OR LESS CARBON.
720250	FERROSILICON CHROMIUM.
720260	FERRONICKEL.
720270	FERROMOLYBDENUM.
720280	FERROTUNGSTEN AND FERROSILICON TUNGSTEN.
720291	FERROTITANIUM AND FERROSILICON TITANIUM.
*	*
720293	FERRONIUBIUM.
720299	FERROALLOYS, NESOI.
720310	FERROUS PRODUCTS OBTAINED BY DIRECT REDUCTION OF IRON ORE.
720390	SPONGY FERROUS PRODUCTS NESOI, IN LUMPS, PELLETS OR SIMILAR FORMS; IRON WITH MINIMUM PURITY OF 99.94% (WT.), IN LUMPS, PELLETS OR SIMILAR FORMS.
720410	CAST IRON WASTE AND SCRAP.
720421	STAINLESS STEEL WASTE AND SCRAP.
720429	ALLOY STEEL WASTE AND SCRAP, OTHER THAN STAINLESS.
720430	TINNED IRON OR STEEL WASTE AND SCRAP.
720441	FERROUS WASTE AND SCRAP NESOI, TURNINGS, SHAVINGS, CHIPS, MILLING WASTE, SAWDUST, FILINGS, TRIMMINGS AND STAMPINGS, WHETHER OR NOT IN BUNDLES.
720449	FERROUS WASTE AND SCRAP, NESOI.
720450	REMELTING SCRAP INGOTS OF IRON OR STEEL.
720510	IRON OR STEEL GRANULES.
720521	ALLOY STEEL POWDERS.
720529	IRON OR NONALLOY STEEL POWDERS.
720610	IRON AND NONALLOY STEEL INGOTS.
720690	IRON AND NONALLOY STEEL IN PRIMARY FORMS, OTHER THAN INGOTS.
*	*
721410	BARS AND RODS OF IRON OR NONALLOY STEEL, FORGED.
721420	BARS AND RODS OF IRON OR NONALLOY STEEL, HOT-WORKED NESOI, CONCRETE REINFORCING.
721430	BARS AND RODS OF FREE-CUTTING NONALLOY STEEL, HOT-WORKED NESOI.
721491	BARS AND RODS OF IRON OR NONALLOY STEEL, NOT FURTHER WORKED THAN HOT-ROLLED, HOT-DRAWN OR HOT-EXTRUDED BUT INCL TWISTED, RECTANGULAR CROSS SECTN, NESOI.
721499	BARS AND RODS OF IRON OR NONALLOY STEEL, NOT FURTHER WORKED THAN HOT-ROLLED, HOT-DRAWN OR HOT-EXTRUDED, BUT INCLUDING TWISTED AFTER ROLLING, N.E.S.O.I.
721510	BARS AND RODS OF FREE-CUTTING NONALLOY STEEL, COLD-FORMED OR COLD-FINISHED.
*	*
721590	BARS AND RODS OF IRON OR NONALLOY STEEL, NESOI.
*	*
721710	WIRE OF IRON OR NONALLOY STEEL, NOT PLATED OR COATED, WHETHER OR NOT POLISHED.
721720	WIRE OF IRON OR NONALLOY STEEL, PLATED OR COATED WITH ZINC.
721730	WIRE OF IRON OR NONALLOY STEEL, PLATED OR COATED WITH BASE METAL OTHER THAN ZINC.
721790	WIRE OF IRON OR NONALLOY STEEL LESS THAN 0.25 PERCENT CARBON, NESOI.
*	*
722100	BARS AND RODS OF STAINLESS STEEL, HOT-ROLLED, IN IRREGULARLY WOUND COILS.
722211	OTHER BARS AND RODS OF STAINLESS STEEL, HOT-ROLLED, CIRCULAR CROSS-SECTION.
722219	OTHER BARS AND RODS OF STAINLESS STEEL, HOT-ROLLED, OTHER THAN CIRCULAR CROSS-SECTION.
722220	BARS AND RODS OF STAINLESS STEEL, COLD-FORMED OR COLD-FINISHED.
*	*
722240	ANGLES, SHAPES AND SECTIONS OF STAINLESS STEEL.
722300	WIRE OF STAINLESS STEEL.
*	*
722710	BARS AND RODS OF HIGH-SPEED STEEL, HOT-ROLLED, IN IRREGULARLY WOUND COILS.
722720	BARS AND RODS OF SILICO-MANGANESE STEEL, HOT-ROLLED, IN IRREGULARLY WOUND COILS.
722790	BARS AND RODS OF ALLOY STEEL (OTHER THAN STAINLESS), HOT-ROLLED, IN IRREGULARLY WOUND COILS, NESOI.
*	*
722920	WIRE OF SILICO-MANGANESE STEEL.
*	*
730110	SHEET PILING OF IRON OR STEEL, WHETHER OR NOT DRILLED, PUNCHED OR MADE FROM ASSEMBLED ELEMENTS.
*	*
730210	RAILWAY OR TRAMWAY RAILS OF IRON OR STEEL.

HTS-6 code	HTS description
730230	RAILWAY OR TRAMWAY TRACK SWITCH BLADES, CROSSING FROGS, POINT RODS AND OTHER CROSSING PIECES OF IRON OR STEEL.
730240	RAILWAY OR TRAMWAY TRACK FISH-PLATES AND SOLE PLATES OF IRON OR STEEL.
730290	RAILWAY OR TRAMWAY TRACK CONSTRUCTION MATERIAL OF IRON OR STEEL NESOI.
730300	TUBES, PIPES AND HOLLOW PROFILES OF CAST IRON.
*	*
730431	TUBES, PIPES AND HOLLOW PROFILES, SEAMLESS NESOI, OF CIRCULAR CROSS SECTION OF IRON OR NONALLOY STEEL, COLD-DRAWN OR COLD-ROLLED.
730439	TUBES, PIPES AND HOLLOW PROFILES, SEAMLESS NESOI, OF CIRCULAR CROSS SECTION OF IRON OR NONALLOY STEEL, NOT COLD-DRAWN OR COLD-ROLLED.
730441	TUBES, PIPES AND HOLLOW PROFILES, SEAMLESS NESOI, OF CIRCULAR CROSS SECTION OF STAINLESS STEEL, COLD-DRAWN OR COLD-ROLLED.
730449	TUBES, PIPES AND HOLLOW PROFILES, SEAMLESS NESOI, OF CIRCULAR CROSS SECTION OF STAINLESS STEEL, NOT COLD-DRAWN OR COLD-ROLLED.
730451	TUBES, PIPES AND HOLLOW PROFILES, SEAMLESS NESOI, OF CIRCULAR CROSS SECTION OF ALLOY STEEL (OTHER THAN STAINLESS), COLD-DRAWN OR COLD-ROLLED.
730459	TUBES, PIPES AND HOLLOW PROFILES, SEAMLESS NESOI, OF CIRCULAR CROSS SECTION OF ALLOY STEEL (OTHER THAN STAINLESS), NOT COLD-DRAWN OR COLD-ROLLED.
730490	TUBES, PIPES AND HOLLOW PROFILES, SEAMLESS NESOI, OF IRON (OTHER THAN CAST IRON) OR STEEL.
730531	PIPES AND TUBES NESOI, EXTERNAL DIAMETER OVER 406.4 MM (16 IN.), OF IRON OR STEEL, LONGITUDINALLY WELDED.
*	*
730590	PIPES AND TUBES NESOI, EXTERNAL DIAMETER OVER 406.4 MM (16 IN.), OF IRON OR STEEL, RIVETED OR SIMILARLY CLOSED NESOI.
730621	CASING OR TUBING FOR OIL OR GAS DRILLING, WELDED OF STAINLESS STEEL, NESOI.
730629	CASING OR TUBING FOR OIL OR GAS DRILLING, OF IRON OR STEEL, NESOI.
730630	PIPES, TUBES AND HOLLOW PROFILES NESOI, WELDED, OF CIRCULAR CROSS SECTION, OF IRON OR NONALLOY STEEL.
730640	PIPES, TUBES AND HOLLOW PROFILES NESOI, WELDED, OF CIRCULAR CROSS SECTION, OF STAINLESS STEEL.
*	*
730661	TUBES, PIPES AND HOLLOW PROFILES, OF IRON OR STEEL, WELDED, OF A SQUARE OR RECTANGULAR CROSS-SECTION, NESOI.
730669	TUBES, PIPES AND HOLLOW PROFILES, OF IRON OR STEEL, WELDED, OF NON-CIRCULAR CROSS-SECTION, NESOI.
730690	PIPES, TUBES AND HOLLOW PROFILES NESOI, OF IRON OR STEEL, RIVETED OR SIMILARLY CLOSED.
730711	PIPE OR TUBE FITTINGS, CAST, OF NONMALLEABLE IRON.
730719	PIPE OR TUBE FITTINGS, CAST, OF IRON NESOI OR STEEL.
730721	PIPE OR TUBE FITTINGS, NESOI, STAINLESS STEEL FLANGES.
*	*
730723	PIPE OR TUBE FITTINGS, NESOI, STAINLESS STEEL BUTT WELDING FITTINGS.
730729	PIPE OR TUBE FITTINGS, NESOI, STAINLESS STEEL FITTINGS NESOI.
730791	PIPE OR TUBE FITTINGS, NESOI, IRON OR NONSTAINLESS STEEL FLANGES.
730792	PIPE OR TUBE FITTINGS, NESOI, IRON OR NONSTAINLESS STEEL THREADED ELBOWS, BENDS AND SLEEVES.
730793	PIPE OR TUBE FITTINGS, NESOI, IRON OR NONSTAINLESS STEEL BUTT WELDING FITTINGS.
730799	PIPE OR TUBE FITTINGS, NESOI, IRON OR NONSTAINLESS STEEL FITTINGS NESOI.
*	*
731210	STRANDED WIRE, ROPES AND CABLES, NOT ELECTRICALLY INSULATED, OF IRON OR STEEL.
731290	PLAITED BANDS, SLINGS AND THE LIKE (OTHER THAN STRANDED WIRE, ROPES OR CABLES), NOT ELECTRICALLY INSULATED, OF IRON OR STEEL.
731300	BARBED WIRE, TWISTED HOOP OR SINGLE FLAT WIRE, BARBED OR NOT, AND LOOSELY TWISTED DOUBLE WIRE, OF A KIND USED FOR FENCING, OF IRON OR STEEL.
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731414	OTHER PRODUCTS OF WOVEN STAINLESS STEEL CLOTH.
731419	WOVEN PRODUCTS OF IRON OR STEEL, NESOI.
731420	GRILL, NETTING AND FENCING OF IRON OR STEEL WIRE, WELDED AT THE INTERSECTION, MAXIMUM CROSS-SECTION OF 3 MM OR MORE AND MESH SIZE OF 100 CM2 OR MORE.
731431	OTHER GRILL, NETTING AND FENCING WELDED AT THE INTERSECTION OF GALVANIZED STEEL.
731439	OTHER GRILL, NETTING AND FENCING WELDED AT THE INTERSECTION OF IRON OR STEEL OTHER THAN GALVANIZED STEEL.
731441	GRILL, NETTING AND FENCING OF IRON OR STEEL WIRE NESOI, PLATED OR COATED WITH ZINC.
731442	GRILL, NETTING AND FENCING OF IRON OR STEEL WIRE NESOI, COATED WITH PLASTICS.
731449	GRILL, NETTING AND FENCING OF IRON OR STEEL WIRE NESOI.
731450	EXPANDED METAL OF IRON OR STEEL.
731511	ROLLER CHAIN OF IRON OR STEEL.
731512	ARTICULATED LINK CHAIN OTHER THAN ROLLER CHAIN, OF IRON OR STEEL.
731519	PARTS OF ARTICULATED LINK CHAIN OF IRON OR STEEL.
731520	SKID CHAIN OF IRON OR STEEL.
731581	STUD LINK CHAIN OF IRON OR STEEL.

HTS-6 code	HTS description
731582	CHAIN NESOI, WELDED LINK OF IRON OR STEEL.
731589	CHAIN OF IRON OR STEEL, NESOI.
731590	PARTS OF CHAIN NESOI, OF IRON OR STEEL.
731600	ANCHORS, GRAPNELS AND PARTS THEREOF, OF IRON OR STEEL.
731700	NAILS, TACKS, DRAWING PINS, STAPLES (OTHER THAN IN STRIPS), AND SIMILAR ARTICLES, OF IRON OR STEEL, EXCLUDING SUCH ARTICLES WITH HEADS OF COPPER.
731811	COACH SCREWS, THREADED, OF IRON OR STEEL.
731812	WOOD SCREWS OTHER THAN COACH SCREWS, THREADED, OF IRON OR STEEL.
731813	SCREW HOOKS AND SCREW RINGS, THREADED, OF IRON OR STEEL.
731814	SELF-TAPPING SCREWS, THREADED, OF IRON OR STEEL.
731815	THREADED SCREWS AND BOLTS NESOI, WITH OR WITHOUT THEIR NUTS OR WASHERS, OF IRON OR STEEL.
731816	NUTS, THREADED, OF IRON OR STEEL.
731819	THREADED ARTICLES OF IRON OR STEEL NESOI.
731821	SPRING WASHERS AND OTHER LOCK WASHERS, OF IRON OR STEEL.
731822	WASHERS, OTHER THAN LOCK WASHERS, OF IRON OR STEEL.
731823	RIVETS OF IRON OR STEEL.
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731829	NONTHREADED ARTICLES (FASTENERS) NESOI, OF IRON OR STEEL.
731940	SAFETY PINS AND OTHER PINS OF IRON OR STEEL.
731990	KNITTING NEEDLES, BODKINS, CROCHET HOOKS, EMBROIDERY STILETTOS AND SIMILAR ARTICLES FOR USE IN THE HAND, OF IRON OR STEEL, NESOI.
732010	LEAF SPRINGS AND LEAVES THEREFOR, OF IRON OR STEEL.
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732090	SPRINGS NESOI, OF IRON OR STEEL.
732111	COOKING APPLIANCES AND PLATE WARMERS, FOR GAS FUEL OR FOR BOTH GAS AND OTHER FUELS, OF IRON OR STEEL.
732112	COOKING APPLIANCES AND PLATE WARMERS FOR LIQUID FUEL, OF IRON OR STEEL.
732119	COOKING APPLIANCES AND PLATE WARMERS, NONELECTRIC, OF IRON OR STEEL, NESOI.
732181	NONELECTRIC DOMESTIC APPLIANCES NESOI, FOR GAS FUEL OR BOTH GAS AND OTHER FUELS, OF IRON OR STEEL.
732182	NONELECTRIC DOMESTIC APPLIANCES NESOI, FOR LIQUID FUEL, OF IRON OR STEEL.
732189	NONELECTRIC DOMESTIC APPLIANCES, OF IRON OR STEEL, NESOI.
732190	PARTS OF NONELECTRIC DOMESTIC COOKING APPLIANCES AND PLATE WARMERS AND SIMILAR NONELECTRIC DOMESTIC APPLIANCES, OF IRON OR STEEL.
732211	RADIATORS FOR CENTRAL HEATING AND PARTS THEREOF, OF CAST IRON.
732219	RADIATORS FOR CENTRAL HEATING AND PARTS THEREOF, OF IRON OR STEEL, EXCEPT CAST IRON.
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732310	IRON OR STEEL WOOL; POT SCOURERS AND SCOURING OR POLISHING PADS, GLOVES AND THE LIKE, OF IRON OR STEEL.
732391	TABLE, KITCHEN OR OTHER HOUSEHOLD ARTICLES AND PARTS THEREOF, OF CAST IRON, NOT ENAMELED.
732392	TABLE, KITCHEN OR OTHER HOUSEHOLD ARTICLES AND PARTS THEREOF, OF CAST IRON, ENAMELED.
732393	TABLE, KITCHEN OR OTHER HOUSEHOLD ARTICLES AND PARTS THEREOF, OF STAINLESS STEEL.
732394	TABLE, KITCHEN OR OTHER HOUSEHOLD ARTICLES AND PARTS THEREOF, OF IRON (NOT CAST) AND STEEL (NOT STAINLESS), ENAMELED.
732399	TABLE, KITCHEN OR OTHER HOUSEHOLD ARTICLES AND PARTS THEREOF, OF IRON (NOT CAST) AND STEEL (NOT STAINLESS), NOT ENAMELED.
732410	SINKS AND WASH BASINS OF STAINLESS STEEL.
732421	BATHS OF CAST IRON, WHETHER OR NOT ENAMELED.
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732490	SANITARY WARE AND PARTS THEREOF NESOI, OF IRON OR STEEL (OTHER THAN STAINLESS STEEL SINKS OR WASH BASINS AND BATHS OF IRON OR STEEL).
732510	ARTICLES NESOI, OF NONMALLEABLE CAST IRON.
732591	GRINDING BALLS AND SIMILAR ARTICLES FOR MILLS, CAST, OF IRON OR STEEL, OTHER THAN NONMALLEABLE CAST IRON.
732599	CAST ARTICLES NESOI, OF IRON OR STEEL.
732611	GRINDING BALLS AND SIMILAR ARTICLES FOR MILLS, FORGED OR STAMPED, BUT NOT FURTHER WORKED, OF IRON OR STEEL.
732619	ARTICLES NESOI, FORGED OR STAMPED, BUT NOT FURTHER WORKED, OF IRON OR STEEL.
732620	ARTICLES OF IRON OR STEEL WIRE, NESOI.
740100	COPPER MATTES; CEMENT COPPER (PRECIPITATED COPPER).
740200	UNREFINED COPPER; COPPER ANODES FOR ELECTROLYTIC REFINING.
740311	REFINED COPPER CATHODES AND SECTIONS OF CATHODES.
740312	REFINED COPPER WIRE BARS, UNWROUGHT.
740313	REFINED COPPER BILLETS, UNWROUGHT.
740319	REFINED COPPER, UNWROUGHT, NESOI.
740321	COPPER-ZINC BASE ALLOYS (BRASS), UNWROUGHT.
740322	COPPER-TIN BASE ALLOYS (BRONZE), UNWROUGHT.
740329	COPPER ALLOYS, UNWROUGHT, NESOI.
740400	COPPER WASTE AND SCRAP.
740500	MASTER ALLOYS OF COPPER.

HTS-6 code	HTS description
740610	COPPER POWDERS OF NON-LAMELLAR STRUCTURE.
740620	COPPER POWDERS OF LAMELLAR STRUCTURE; FLAKES.
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741011	COPPER FOIL, NOT BACKED, OF REFINED COPPER, NOT OVER 0.15 MM THICK.
741012	COPPER ALLOY FOIL, NOT BACKED, NOT OVER 0.15 MM THICK.
741021	COPPER FOIL, BACKED, OF REFINED COPPER, NOT OVER 0.15 MM THICK.
741022	COPPER FOIL, BACKED, OF COPPER ALLOYS, NOT OVER 0.15 MM THICK.
741110	TUBES AND PIPES OF REFINED COPPER.
741121	TUBES AND PIPES OF COPPER-ZINC BASE ALLOYS (BRASS).
741122	TUBES AND PIPES OF COPPER-NICKEL BASE ALLOYS (CUPRO-NICKEL) OR COPPER-NICKEL-ZINC BASE ALLOYS (NICKEL-SILVER).
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741210	TUBE OR PIPE FITTINGS OF REFINED COPPER.
741220	TUBE OR PIPE FITTINGS OF COPPER ALLOYS.
741300	STRANDED WIRE, CABLES, PLAIED BANDS AND SIMILAR ARTICLES, OF COPPER, NOT ELECTRICALLY INSULATED.
741510	NAILS, TACKS, DRAWING PINS, STAPLES (OTHER THAN IN STRIPS) AND SIMILAR ARTICLES OF COPPER OR OF IRON OR STEEL WITH HEADS OF COPPER.
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741529	RIVETS, COTTERS, COTTER PINS AND SIMILAR ARTICLES OF COPPER (NOT THREADED), NESOI.
741533	THREADED SCREWS, BOLTS, AND NUTS OF COPPER OR IRON OR STEEL WITH HEADS OF COPPER.
741539	THREADED FASTENERS NESOI, OF COPPER.
741810	COPPER TABLE, KITCHEN OR OTHER HOUSEHOLD ARTICLES AND PARTS THEREOF; POT SCOURERS OR POLISHING PADS, GLOVES AND THE LIKE, OF COPPER.
741820	SANITARY WARE AND PARTS THEREOF, OF COPPER.
741920	ARTICLES OF COPPER, NESOI, CAST, MOLDED, STAMPED OR FORGED, BUT NOT FURTHER WORKED.
741980	ARTICLES OF COPPER, NESOI.
750110	NICKEL MATTES.
750120	NICKEL OXIDE SINTERS AND OTHER INTERMEDIATE PRODUCTS OF NICKEL METALLURGY.
750210	NICKEL, NOT ALLOYED, UNWROUGHT.
750220	NICKLE ALLOYS, UNWROUGHT.
750300	NICKEL WASTE AND SCRAP.
750400	NICKLE POWDERS AND FLAKES.
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760110	ALUMINUM, NOT ALLOYED, UNWROUGHT.
760120	ALUMINUM ALLOYS, UNWROUGHT.
760200	ALUMINUM WASTE AND SCRAP.
760310	ALUMINUM POWDERS OF NONLAMELLAR STRUCTURE.
760320	ALUMINUM POWDERS OF LAMELLAR STRUCTURE; FLAKES.
760410	ALUMINUM BARS, RODS AND PROFILES, NOT ALLOYED.
760421	ALUMINUM ALLOY HOLLOW PROFILES.
760429	ALUMINUM ALLOY BARS, RODS AND PROFILES, OTHER THAN HOLLOW PROFILES.
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760611	ALUMINUM NONALLOYED RECTANGULAR (INCLUDING SQUARE) PLATES, SHEETS AND STRIP, OVER 0.2 MM THICK.
760612	ALUMINUM ALLOY RECTANGULAR (INCLUDING SQUARE) PLATES, SHEETS AND STRIP, OVER 0.2 MM THICK.
760691	ALUMINUM NONALLOYED PLATES, SHEETS OR STRIP, OVER 0.2 MM THICK, NESOI (OTHER THAN RECTANGULAR OR SQUARE SHAPES).
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760711	ALUMINUM FOIL, NOT OVER 0.2 MM THICK, NOT BACKED, ROLLED BUT NOT FURTHER WORKED.
760719	ALUMINUM FOIL, NOT OVER 0.2 MM THICK, NOT BACKED, NESOI.
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760810	ALUMINUM TUBES AND PIPES, NOT ALLOYED.
760820	ALUMINUM ALLOY TUBES AND PIPES.
760900	ALUMINUM TUBE OR PIPE FITTINGS (INCLUDING COUPLINGS, ELBOWS, AND SLEEVES).
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761410	STRANDED WIRE, CABLES, PLAIED BANDS AND SIMILAR ARTICLES OF ALUMINUM, NOT ELECTRICALLY INSULATED, WITH A STEEL CORE.
761490	STRANDED WIRE, CABLES, PLAIED BANDS AND SIMILAR ARTICLES OF ALUMINUM, NOT ELECTRICALLY INSULATED, NESOI.
761510	ALUMINUM TABLE, KITCHEN OR OTHER HOUSEHOLD ARTICLES AND PARTS THEREOF; POT SCOURERS, SCOURING OR POLISHING PADS, GLOVES AND THE LIKE, OF ALUMINUM ETC.
761520	ALUMINUM SANITARY WARE AND PARTS THEREOF.
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761691	CLOTH, GRILL, NETTING AND FENCING OF ALUMINUM WIRE.

HTS-6 code	HTS description
761699	ARTICLES OF ALUMINUM, N.E.S.O.I.
780110	REFINED LEAD, UNWROUGHT.
780191	LEAD, OTHER THAN REFINED, CONTAINING ANTIMONY BY WEIGHT AS THE PRINCIPAL OTHER ELEMENT, UNWROUGHT.
780199	LEAD, OTHER THAN REFINED, NESOI, UNWROUGHT.
780200	LEAD WASTE AND SCRAP.
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780600	ARTICLES OF LEAD, NESOI.
790111	ZINC, NOT ALLOYED, CONTAINING 99.9% OR MORE BY WEIGHT OF ZINC, UNWROUGHT.
790112	ZINC, NOT ALLOYED, CONTAINING UNDER 99.99% ZINC BY WEIGHT. UNWROUGHT.
790120	ZINC ALLOYS, UNWROUGHT.
790200	ZINC WASTE AND SCRAP.
790310	ZINC DUST.
790390	ZINC POWDERS AND FLAKES.
790400	ZINC BARS, RODS, PROFILES AND WIRE.
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790700	ARTICLES OF ZINC, N.E.S.O.I.
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800200	TIN WASTE AND SCRAP.
*	*
810194	TUNGSTEN, UNWROUGHT, INCLUDING BARS AND RODS OBTAINED SIMPLY BY SINTERING.
810196	TUNGSTEN WIRE.
810197	TUNGSTEN WASTE AND SCRAP.
810199	TUNGSTEN, WROUGHT, NESOI.
*	*
810320	UNWROUGHT TANTALUM, INCLUDING BARS AND RODS OBTAINED SIMPLY BY SINTERING; POWDERS.
810330	TANTALUM WASTE AND SCRAP.
810391	TANTALUM AND ARTICLES THEREOF, NESOI.
810399	TANTALUM AND ARTICLES THEREOF, NESOI.
810411	MAGNESIUM, CONTAINING 99.8% OR MORE MAGNESIUM BY WEIGHT, UNWROUGHT.
810419	MAGNESIUM, CONTAINING UNDER 99.8% MAGNESIUM BY WEIGHT, UNWROUGHT.
810420	MAGNESIUM WASTE AND SCRAP.
810430	MAGNESIUM RASPIINGS, TURNINGS AND GRANULES, GRADED ACCORDING TO SIZE; MAGNESIUM POWDERS.
810490	MAGNESIUM AND ARTICLES THEREOF, NESOI.
810520	COBALT MATTES AND OTHER INTERMEDIATE PRODUCTS OF COBALT METALLURGY; COBALT, UNWROUGHT; COBALT POWDERS.
810530	COBALT WASTE AND SCRAP.
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810610	BISMUTH AND ARTICLES THEREOF, INCLUDING WASTE AND SCRAP.
810690	BISMUTH AND ARTICLES THEREOF, INCLUDING WASTE AND SCRAP.
810820	UNWROUGHT TITANIUM; POWDERS.
810830	TITANIUM WASTE AND SCRAP.
810890	TITANIUM AND ARTICLES THEREOF, NESOI.
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811010	UNWROUGHT ANTIMONY; POWDERS.
811020	ANTIMONY WASTE AND SCRAP.
811090	ANTIMONY AND ARTICLES THEREOF, NESOI.
811100	MANGANESE AND ARTICLES THEREOF, INCLUDING WASTE AND SCRAP.
811212	UNWROUGHT BERYLLIUM; BERYLLIUM POWDERS, NESOI.
811213	BERYLLIUM WASTE AND SCRAP.
811219	BERYLLIUM AND ARTICLES THEREOF, NESOI.
811221	UNWROUGHT CHROMIUM; POWDERS.
811222	CHROMIUM WASTE AND SCRAP.
811229	CHROMIUM AND ARTICLES THEREOF, NESOI.
811231	GALLIUM, HAFNIUM, INDIUM, NIOBIUM (COLUMBIUM), RHENIUM & ARTICLES OF THESE METALS, INCLUDING WASTE & SCRAP.
811239	GALLIUM, HAFNIUM, INDIUM, NIOBIUM (COLUMBIUM), RHENIUM AND THALLIUM AND ARTICLES THEREOF, NESOI.
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811251	UNWROUGHT THALLIUM; POWDERS.
811252	THALLIUM WASTE AND SCRAP.
811259	THALLIUM AND ARTICLES THEREOF, NESOI.
811261	UNWROUGHT CADMIUM; WASTE AND SCRAP.
811269	UNWROUGHT CADMIUM; POWDERS.
811292	GALLIUM, HAFNIUM, INDIUM, NIOBIUM (COLUMBIUM), RHENIUM & ARTICLES OF THESE METALS, INCLUDING WASTE & SCRAP.
811299	GALLIUM, HAFNIUM, INDIUM, NIOBIUM (COLUMBIUM), RHENIUM AND THALLIUM AND ARTICLES THEREOF, NESOI.

HTS-6 code	HTS description
811300	CERMETS AND ARTICLES THEREOF, INCLUDING WASTE AND SCRAP.
820110	SPADES AND SHOVELS AND PARTS THEREOF, OF BASE METAL.
820130	MATTOCKS, PICKS, HOES AND RAKES, AND PARTS THEREOF OF BASE METAL.
820140	AXES, BILL HOOKS AND SIMILAR HEWING TOOLS, AND PARTS THEREOF, OF BASE METAL.
820150	ONE-HANDED SECATEURS AND SIMILAR ONE-HANDED PRUNERS AND SHEARS (INCLUDING POULTRY SHEARS), AND PARTS THEREOF, OF BASE METAL.
820160	HEDGE SHEARS, TWO-HANDED PRUNING SHEARS AND SIMILAR TWO-HANDED SHEARS, AND PARTS THEREOF, OF BASE METAL.
820190	HANDTOOLS NESOI, OF A KIND USED IN AGRICULTURE, HORTICULTURE OR FORESTRY, AND PARTS THEREOF, OF BASE METAL.
820210	HANDSAWS AND PARTS THEREOF (EXCEPT BLADES) OF BASE METAL.
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820231	CIRCULAR SAW BLADES OF BASE METAL, WITH WORKING PART OF STEEL, AND PARTS THEREOF.
820239	CIRCULAR SAW BLADES OF BASE METAL WITH WORKING PART OF MATERIAL OTHER THAN STEEL, AND PARTS.
820240	CHAIN SAW BLADES (LENGTHS OR CUT TO SIZE), AND PARTS THEREOF, OF BASE METAL.
820291	STRAIGHT SAW BLADES FOR WORKING METAL, OF BASE METAL.
820299	SAW BLADES NESOI, AND PARTS OF SAW BLADES NESOI, OF BASE METAL.
820310	FILES, RASPS AND SIMILAR TOOLS, OF BASE METAL.
820320	PLIERS (INCLUDING CUTTING PLIERS), PINCERS, TWEEZERS, AND SIMILAR TOOLS, AND PARTS THEREOF, OF BASE METAL.
820330	METAL CUTTING SHEARS AND SIMILAR TOOLS, AND PARTS THEREOF, OF BASE METAL.
820340	PIPE CUTTERS, BOLT CUTTERS, PERFORATING PUNCHES AND SIMILAR TOOLS, AND PARTS THEREOF, OF BASE METAL.
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820412	SPANNERS AND WRENCHES, HAND-OPERATED, ADJUSTABLE, AND PARTS THEREOF, OF BASE METAL.
820420	SOCKET WRENCHES WITH OR WITHOUT HANDLES, DRIVES AND EXTENSIONS, AND PARTS THEREOF, OF BASE METAL.
820510	DRILLING, THREADING OR TAPPING TOOLS, AND PARTS THEREOF, OF BASE METAL.
820520	HAMMERS AND SLEDGE HAMMERS AND PARTS THEREOF, OF BASE METAL.
820530	PLANES, CHISELS, GOUGES AND SIMILAR CUTTING TOOLS FOR WOOD WORKING, AND PARTS THEREOF, OF BASE METAL.
820540	SCREWDRIVERS, AND PARTS THEREOF, OF BASE METAL.
820551	HOUSEHOLD HANDTOOLS NESOI, AND PARTS THEREOF, OF BASE METAL.
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820560	BLOW TORCHES AND SIMILAR SELF-CONTAINED TORCHES, AND PARTS THEREOF, OF BASE METAL.
820570	VICES, CLAMPS AND THE LIKE, AND PARTS THEREOF, OF BASE METAL.
820590	HANDTOOLS, INCLUDING SETS OF ARTICLES OF TWO OR MORE SUBHEADINGS OF 8205, NESOI.
820600	TOOLS OF TWO OR MORE OF THE HEADINGS 8202 TO 8205 (SAWS, FILES, PLIERS, WRENCHES ETC. AND HANDTOOLS ETC. NESOI) PUT UP IN SETS FOR RETAIL SALE.
820720	DIES FOR DRAWING OR EXTRUDING METAL, AND PARTS THEREOF, OF BASE METAL.
820730	TOOLS FOR PRESSING, STAMPING OR PUNCHING, AND PARTS THEREOF, OF BASE METAL.
820740	TOOLS FOR TAPPING OR THREADING, AND PARTS THEREOF, OF BASE METAL.
820750	TOOLS FOR DRILLING, OTHER THAN ROCK DRILLING, AND PARTS THEREOF, OF BASE METAL.
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820770	TOOLS FOR MILLING, AND PARTS THEREOF, OF BASE METAL.
820780	TOOLS FOR TURNING, OF BASE METAL.
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820900	PLATES, STICKS, TIPS AND THE LIKE FOR TOOLS, UNMOUNTED, OF CERMETS.
821000	HAND-OPERATED MECHANICAL APPLIANCES, WEIGHING NOT OVER 10 KG, FOR PREPARING, CONDITIONING OR SERVING FOOD OR DRINK, AND BASE METAL PARTS THEREOF.
821110	SETS OF ASSORTED KNIVES AND BLADES, OTHER THAN KNIVES FOR MACHINES OR MECHANICAL APPLIANCES AND BLADES THEREFOR OF HEADING 8208.
821191	TABLE KNIVES HAVING FIXED BLADES, AND PARTS THEREOF, OF BASE METAL.
821192	KNIVES, OTHER THAN TABLE KNIVES, HAVING FIXED BLADES, AND PARTS THEREOF, OF BASE METAL.
821193	KNIVES HAVING OTHER THAN FIXED BLADES, AND PARTS THEREOF (EXCEPT BLADES), OF BASE METAL.
821194	BLADES FOR KNIVES, NESOI.
821195	HANDLES OF BASE METAL FOR KNIVES WITH CUTTING BLADES, OTHER THAN THOSE OF 8208.
821210	RAZORS.
821220	SAFETY RAZOR BLADES, INCLUDING BLADE BLANKS IN STRIPS.
821290	PARTS FOR RAZORS NESOI, OF BASE METAL.
821300	SCISSORS, TAILORS' SHEARS AND SIMILAR SHEARS, AND BLADES AND OTHER BASE METAL PARTS THEREOF.
821410	PAPER KNIVES, LETTER OPENERS, ERASING KNIVES, PENCIL SHARPENERS (NONMECHANICAL), BLADES, AND PARTS THEREOF, OF BASE METAL.
821420	MANICURE OR PEDICURE SETS AND INSTRUMENTS (INCLUDING NAIL FILES) AND BASE METAL PARTS THEREOF.
821490	ARTICLES OF CUTLERY NESOI, AND PARTS THEREOF, OF BASE METAL.
821510	SETS OF ASSORTED KITCHENWARE OR TABLEWARE OF BASE METAL, CONTAINING AT LEAST ONE ARTICLE PLATED WITH PRECIOUS METAL.
821520	SETS OF ASSORTED KITCHENWARE OR TABLEWARE OF BASE METAL, CONTAINING NO ARTICLES PLATED WITH PRECIOUS METAL.

HTS-6 code	HTS description
821591	SPOONS, FORKS, LADLES, CAKE-SERVERS, SUGAR TONGS AND LIKE KITCHEN OR TABLEWARE OF BASE METAL (NO SETS), AND PARTS THEREOF, PLATED WITH PRECIOUS METAL.
821599	SPOONS, FORKS, LADLES, CAKE-SERVERS, SUGAR TONGS AND LIKE KITCHEN OR TABLEWARE OF UNPLATED BASE METAL (NO SETS), AND PARTS THEREOF, NESOI.
830110	PADLOCKS OF BASE METAL.
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830130	LOCKS OF A KIND USED FOR FURNITURE, OF BASE METAL.
830140	LOCKS (KEY, COMBINATION OR ELECTRICALLY OPERATED), EXCEPT FOR MOTOR VEHICLES OR FURNITURE, OF BASE METAL.
830150	CLASPS AND FRAMES WITH CLASPS, INCORPORATING LOCKS, OF BASE METAL.
830160	PARTS OF LOCKS, OF BASE METAL.
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830210	HINGES, AND PARTS THEREOF, OF BASE METAL.
830220	CASTORS, AND PARTS THEREOF, OF BASE METAL.
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830241	MOUNTINGS, FITTINGS AND SIMILAR ARTICLES NESOI (EXCEPT HINGES AND CASTORS), AND PARTS THEREOF, SUITABLE FOR BUILDINGS, OF BASE METAL.
830242	MOUNTINGS, FITTINGS AND SIMILAR ARTICLES NESOI (EXCEPT HINGES AND CASTORS), AND PARTS THEREOF, SUITABLE FOR FURNITURE, OF BASE METAL.
830249	MOUNTINGS, FITTINGS AND SIMILAR ARTICLES, AND PARTS THEREOF, NESOI, OF BASE METAL.
830250	HAT-RACKS, HAT PEGS, BRACKETS AND SIMILAR FIXTURES, AND PARTS THEREOF, OF BASE METAL.
830260	AUTOMATIC DOOR CLOSURES, AND PARTS THEREOF, OF BASE METAL.
830300	ARMORED OR REINFORCED SAFES, STRONG-BOXES, DOORS AND SAFE DEPOSIT LOCKERS FOR STRONG-ROOMS, CASH OR DEED BOXES ETC., AND PARTS THEREOF, OF BASE METAL.
830400	DESK-TOP FILING OR CARD-INDEX CABINETS, PAPER TRAYS, PAPER RESTS, PEN TRAYS AND SIMILAR DESK ETC. ITEMS (NO FURNITURE) AND THEIR PARTS, OF BASE METAL.
830510	FITTINGS FOR LOOSELEAF BINDERS OR FILES, OF BASE METAL.
830520	STAPLES IN STRIPS, OF BASE METAL.
830590	LETTER CLIPS, LETTER CORNERS, PAPER CLIPS, INDEXING TAGS AND SIMILAR OFFICE ARTICLES, AND PARTS THEREOF, OF BASE METAL.
830610	BELLS, GONGS AND THE LIKE, AND PARTS THEREOF, OF BASE METAL.
830630	PHOTOGRAPH, PICTURE OR SIMILAR FRAMES AND MIRRORS, AND PARTS THEREOF, OF BASE METAL.
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830810	HOOKS, EYES AND EYELETS, OF BASE METAL.
830820	TUBULAR OR BIFURCATED RIVETS, OF BASE METAL.
830890	CLASPS, FRAMES WITH CLASPS, BUCKLES, BUCKLE CLASPS, AND PARTS THEREOF, NESOI, OF BASE METAL.
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831000	SIGN PLATES, NAME PLATES, ADDRESS PLATES AND SIMILAR PLATES, NUMBERS, LETTERS AND OTHER SYMBOLS (NOT ILLUMINATED), AND PARTS THEREOF, OF BASE METAL.
831110	COATED ELECTRODES OF BASE METAL, FOR ELECTRIC ARC-WELDING.
831120	CORED WIRE OF BASE METAL, FOR ELECTRIC ARC-WELDING.
831130	COATED RODS AND CORED WIRE, OF BASE METAL, FOR SOLDERING, BRAZING OR WELDING BY FLAME.
831190	TUBES, PLATES ETC. OF BASE METAL OR METAL CARBIDES WITH FLUX MATERIAL FOR WELDING ETC.; WIRE AND RODS OF AGGLOMERATED BASE METAL POWDER; PARTS THEREOF.
*	*
860120	RAIL LOCOMOTIVES POWERED BY ELECTRIC ACCUMULATORS (BATTERIES).
*	*
860310	SELF-PROPELLED RAILWAY OR TRAMWAY COACHES, VANS AND TRUCKS (EXCEPT RAILWAY OR TRAMWAY MAINTENANCE OR SERVICE VEHICLES), POWERED EXTERNALLY, ELECTRIC.
860390	SELF-PROPELLED RAILWAY OR TRAMWAY COACHES, VANS AND TRUCKS (EXCEPT RAILWAY OR TRAMWAY MAINTENANCE OR SERVICE VEHICLES), NESOI.
*	*
860500	RAILWAY OR TRAMWAY PASSENGER COACHES, LUGGAGE VANS, POST OFFICE COACHES AND OTHER SPECIAL PURPOSE RAIL OR TRAMWAY COACHES, NOT SELF-PROPELLED, NESOI.
*	*
860711	TRUCK ASSEMBLIES FOR SELF-PROPELLED RAILWAY OR TRAMWAY LOCOMOTIVES OR ROLLING STOCK.
860712	TRUCK ASSEMBLIES, NESOI, FOR RAILWAY OR TRAMWAY ROLLING STOCK.
860719	TRUCK AXLES AND WHEELS AND PARTS THEREOF, INCLUDING PARTS OF TRUCK ASSEMBLIES, FOR RAILWAY OR TRAMWAY VEHICLES.
860721	AIRBRAKES AND PARTS THEREOF, FOR RAILWAY OR TRAMWAY VEHICLES.
860729	BRAKES (EXCEPT AIRBRAKES) AND PARTS THEREOF, FOR RAILWAY OR TRAMWAY VEHICLES.
860730	HOOKS AND OTHER COUPLING DEVICES, BUFFERS AND PARTS THEREOF, FOR RAILWAY OR TRAMWAY VEHICLES.
860791	PARTS OF RAILWAY OR TRAMWAY LOCOMOTIVES, NESOI.
860799	PARTS OF RAILWAY OR TRAMWAY VEHICLES, OTHER THAN LOCOMOTIVES, NESOI.

HTS-6 code	HTS description
860800	RAIL TRACK FIXTURES; MECHANICAL SIGNALING, SAFETY OR TRAFFIC CONTROL EQUIPMENT FOR RAIL, ROAD, WATERWAY, PARKING, AIRFIELD ETC. AREAS; PARTS THEREOF.
860900	CONTAINERS (INCLUDING CONTAINERS FOR THE TRANSPORT OF FLUIDS) SPECIALLY DESIGNED AND EQUIPPED FOR CARRIAGE BY ONE OR MORE MODES OF TRANSPORT.
870110	TRACTORS, PEDESTRIAN CONTROLLED TYPE (OTHER THAN TRACTORS OF THE TYPE USED ON RAILWAY STATION PLATFORMS).
*	*
870129	ROAD TRACTORS FOR SEMI-TRAILERS.
*	*
870191	TRACTORS (OTHER THAN TRACTORS OF HEADING 8709), NOT EXCEEDING 18KW.
870192	TRACTORS (OTHER THAN TRACTORS OF HEADING 8709), EXCEEDING 18 KW BUT NOT EXCEEDING 37 KW.
870193	TRACTORS (OTHER THAN TRACTORS OF HEADING 8709), EXCEEDING 37 KW BUT NOT EXCEEDING 75 KW.
870194	TRACTORS (OTHER THAN TRACTORS OF HEADING 8709), EXCEEDING 75 KW BUT NOT EXCEEDING 130 KW.
870195	TRACTORS (OTHER THAN TRACTORS OF HEADING 8709) EXCEEDING 130 KW.
870210	MOTOR VEHICLES FOR THE TRANSPORT OF TEN OR MORE PERSONS, WITH A COMPRESSION-IGNITION INTERNAL COMBUSTION PISTON ENGINE (DIESEL OR SEMI-DIESEL).
870220	MOTOR VEHICLES FOR TRANSPORT OF 10 OR MORE WITH BOTH COMPRESSION-IGNITION INTERNAL COMBUSTION PISTON ENG (DIESEL OR SEMI-DIESEL) AND ELECTRIC MOTOR.
870230	MOTOR VEHICLES FOR TRANSPORT OF 10 OR MORE WITH BOTH SPARK-IGNITION RECIPROCATING PISTON AND ELECTRIC MOTOR.
870240	MOTOR VEHICLES FOR TRANSPORT OF 10 OR MORE WITH ONLY ELECTRIC MOTOR FOR PROPULSION.
870290	MOTOR VEHICLES FOR THE TRANSPORT OF TEN OR MORE PERSONS, NESOI.
*	*
870790	BODIES (INCLUDING CABS) FOR ROAD TRACTORS FOR SEMI-TRAILERS, MOTOR VEHICLES FOR PUBLIC-TRANSPORT OF PASSENGERS, GOODS TRANSPORT AND SPECIAL PURPOSE.
870810	BUMPERS AND PARTS THEREOF FOR MOTOR VEHICLES.
870821	SAFETY SEAT BELTS FOR MOTOR VEHICLES.
870822	LAMINATED SAFETY GLASS, OF SIZE AND SHAPE SUITABLE FOR INCORPORATION IN VEHICLES, AIRCRAFT, SPACECRAFT OR VESSELS.
870829	PARTS AND ACCESSORIES OF BODIES (INCLUDING CABS) FOR MOTOR VEHICLES, NESOI.
870830	BRAKES AND SERVO-BRAKES; PARTS THEREOF.
870840	GEAR BOXES FOR MOTOR VEHICLES.
870850	DRIVE AXLES WITH DIFFERENTIAL FOR MOTOR VEHICLES.
870870	ROAD WHEELS AND PARTS AND ACCESSORIES THEREOF FOR MOTOR VEHICLES.
870880	SUSPENSION SHOCK ABSORBERS FOR MOTOR VEHICLES.
870891	RADIATORS FOR MOTOR VEHICLES.
870892	MUFFLERS AND EXHAUST PIPES FOR MOTOR VEHICLES.
870893	CLUTCHES AND PARTS THEREOF FOR MOTOR VEHICLES.
870894	STEERING WHEELS, STEERING COLUMNS AND STEERING BOXES FOR MOTOR VEHICLES.
870895	SAFETY AIRBAGS WITH INFLATOR SYSTEM; PARTS THEREOF.
*	*
870919	WORKS TRUCKS (NOT LIFTING OR HANDLING) USED IN FACTORIES ETC. AND TRACTORS USED ON RAILWAY STATION PLATFORMS, NOT ELECTRICAL.
*	*
871000	TANKS AND OTHER ARMORED FIGHTING VEHICLES, MOTORIZED, WHETHER OR NOT FITTED WITH WEAPONS, AND PARTS OF SUCH VEHICLES.
871110	MOTORCYCLES AND CYCLES WITH AN AUXILIARY MOTOR, WITH RECIPROCATING INTERNAL COMBUSTION PISTON ENGINE, CYLINDER CAPACITY NOT OVER 50 CC.
871200	BICYCLES AND OTHER CYCLES (INCLUDING DELIVERY TRICYCLES), NOT MOTORIZED.
871491	FRAMES AND FORKS, AND PARTS THEREOF FOR BICYCLES AND OTHER CYCLES NESOI.
871492	WHEEL RIMS AND SPOKES FOR BICYCLES AND OTHER CYCLES NESOI.
871493	HUBS (OTHER THAN COASTER BRAKING HUBS AND HUB BRAKES) AND FREE-WHEEL SPROCKET-WHEELS FOR BICYCLES AND OTHER CYCLES NESOI.
871494	BRAKES, INCLUDING COASTER BRAKING HUBS AND HUB BRAKES AND PARTS THERE OF, FOR BICYCLES AND OTHER CYCLES NESOI.
871495	SADDLES FOR BICYCLES AND OTHER CYCLES NESOI.
871496	PEDALS AND CRANK-GEAR, AND PARTS THEREOF FOR BICYCLES AND OTHER CYCLES NESOI.
871499	PARTS AND ACCESSORIES NESOI, FOR BICYCLES AND OTHER CYCLES NESOI.
871610	TRAILERS AND SEMI-TRAILERS FOR HOUSING OR CAMPING.
*	*
871631	TANKER TRAILERS AND TANKER SEMI-TRAILERS.
*	*
871640	TRAILERS AND SEMI-TRAILERS, NESOI.
871680	VEHICLES (OTHER THAN TRAILERS AND SEMI-TRAILERS), NOT MECHANICALLY PROPELLED, NESOI.
*	*
890120	TANKERS FOR THE TRANSPORT OF GOODS.

HTS-6 code	HTS description
890130	REFRIGERATED VESSELS, OTHER THAN TANKERS.
890190	VESSELS NESOI, FOR THE TRANSPORT OF GOODS, AND OTHER VESSELS NESOI, FOR THE TRANSPORT OF BOTH PERSONS AND GOODS.
890200	FISHING VESSELS; FACTORY SHIPS AND OTHER VESSELS FOR PROCESSING OR PRESERVING FISHERY PRODUCTS.
*	*
890400	TUGS AND PUSHER CRAFT VESSELS.
890510	DREDGERS (VESSELS).
890610	WARSHIPS (INCLUDING SUBMARINES, TROOPSHIPS ETC.).
890690	VESSELS (OTHER THAN WARSHIPS) INCLUDING LIFEBOATS, OTHER THAN ROW BOATS, NESOI.
890710	INFLATABLE RAFTS.
890790	FLOATING STRUCTURES (FOR EXAMPLE, TANKS, COFFERDAMS, LANDING-STAGES, BUOYS AND BEACONS), EXCEPT INFLATABLE RAFTS.
890800	VESSELS AND FLOATING STRUCTURES FOR BREAKING UP (SCRAPPING).
*	*
930200	REVOLVERS AND PISTOLS, DESIGNED TO FIRE LIVE AMMUNITION.
930310	MUZZLE-LOADING FIREARMS.
930320	SPORTING, HUNTING OR TARGET-SHOOTING SHOTGUNS, INCLUDING COMBINATION SHOTGUN-RIFLES, EXCEPT MUZZLE-LOADING FIREARMS.
930330	SPORTING, HUNTING OR TARGET-SHOOTING RIFLES, EXCEPT MUZZLE-LOADING FIREARMS AND COMBINATION SHOTGUN-RIFLES.
930390	DEVICES DESIGNED TO PROJECT ONLY SIGNAL FLARES; PISTOLS AND REVOLVERS FOR FIRING BLANK AMMUNITION; CAPTIVE-BOLT HUMANE KILLERS; LINE-THROWING GUNS.
930400	ARMS NESOI (INCLUDING SPRING, AIR OR GAS GUNS AND PISTOLS, BUT EXCLUDING SWORDS, BAYONETS AND SIMILAR ARMS).
930510	PARTS AND ACCESSORIES OF REVOLVERS OR PISTOLS.
930520	PARTS AND ACCESSORIES OF SHOTGUNS OR RIFLES OF HEADING 9303.
930599	PARTS AND ACCESSORIES OF ARTICLES OF HEADINGS 9303 TO 9304, NESOI.
930621	SHOTGUN CARTRIDGES.
930629	AIR GUN PELLETS AND PARTS OF SHOTGUN CARTRIDGES.
930630	CARTRIDGES AND PARTS THEREOF, NESOI.
930690	BOMBS, GRENADES, TORPEDOES, MINES, MISSILES AND SIMILAR MUNITIONS OF WAR AND PARTS THEREOF; OTHER AMMUNITION AND PROJECTILES AND PARTS THEREOF, NESOI.
930700	SWORDS, CUTLASSES, BAYONETS, LANCES AND SIMILAR ARMS AND PARTS THEREOF AND SCABBARDS AND SHEATHS THEREFOR.
*	*
960350	BRUSHES NESOI, CONSTITUTING PARTS OF MACHINES, APPLIANCES OR VEHICLES.
960390	HAND-OPERATED MECHANICAL (NOT MOTORIZED) FLOOR SWEEPERS, MOPS AND FEATHER DUSTERS; PREPARED KNOTS AND TUFTS FOR BROOM OR BRUSH MAKING, NESOI.

■ 19. Supplement no. 5 to part 746 is amended by revising the heading, paragraph (a), and first sentence of paragraph (b) to read as follows:

Supplement No. 5 to Part 746—“Luxury Goods’ Sanctions for Russia and Belarus Pursuant to § 746.8(a)(7)”

(a) The source for the Harmonized Tariff Schedule (HTS)-6 codes and descriptions in this list is the United States International Trade Commission (USITC)’s Harmonized Tariff Schedule of the United States (2023). The items described in supplement no. 5 to part 746 include any modified or designed “components,” “parts,” “accessories,” and “attachments” therefor regardless of the HTS Code or HTS Description of the “components,” “parts,” “accessories,” and “attachments,” apart from any “part” or minor “component” that is a fastener (e.g., screw, bolt, nut, nut plate, stud, insert, clip, rivet, pin), washer, spacer, insulator, grommet, bushing, spring, wire, or solder. The exclusion of fasteners from this control does not apply to fasteners that are designated under an HTS Code under this supplement. Although generally fasteners

(e.g., screws, bolts, nuts, nut plates, studs, inserts, clips, rivets, pins), and washers, spacers, insulators, grommets, bushings, springs, wires, and solder are excluded from the scope of this supplement, see part 744 of the EAR for license requirements for Russia and Belarus that apply to all items “subject to the EAR,” e.g., § 744.21 and the Entity List license requirements, which in most cases extend to all items “subject to the EAR.” This supplement includes two columns consisting of the HTS Code and HTS Description and Per Unit Wholesale Price in the U.S. if applicable to assist exporters, reexporters, and transferors in identifying the products in this supplement. For information on HTS codes in general, you may contact a local import specialist at U.S. Customs and Border Protection at the nearest port. HTS-6 Codes 590500, 840710, 840721, 840729, 840731, 840732, 840733, 840734, 840790, 840810, 840820, 840890, 840910, 840991, 840999, 841111, 841112, 841121, 841122, 841181, 841182, 841191, 841199, 841229, 841290, 841451, 841459, 841460, 841510, 841810, 841821, 841829, 841830, 841840, 841981, 842211, 842310, 842860, 843139, 844312, 844331, 844332, 844339, 845011, 845012, 845019, 845121, 845210, 847010, 847021,

847029, 847030, 847130, 847141, 847149, 847150, 847160, 847170, 847180, 847190, 847290, 847960, 848310, 848320, 848330, 848340, 848350, 848360, 848390, 850811, 850819, 850860, 850980, 851110, 851120, 851130, 851140, 851150, 851180, 851190, 851220, 851230, 851240, 851631, 851650, 851660, 851671, 851672, 851679, 851711, 851713, 851718, 851761, 851762, 851769, 851920, 851930, 851981, 851989, 852110, 852190, 852691, 852712, 852713, 852719, 852721, 852729, 852791, 852792, 852799, 852871, 852872, 852910, 853110, 854370, 854430, 870310, 870321, 870322, 870323, 870324, 870331, 870332, 870333, 870340, 870350, 870360, 870370, 870380, 870390, and 902000 are listed in both this supplement and supplement no. 4 to this part, so exporters, reexporters, and transferors must comply with the license requirements under both §§ 746.8(a)(5) and (7) as applicable.

(b) The items identified in the HTS-6 Code column of this supplement are subject to the license requirement under § 746.8(a)(7).

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- 20. Supplement no. 6 to part 746 is amended by:
- a. Revising the heading; and
 - b. Adding paragraph (h), to read as follows:

Supplement No. 6 to Part 746—Russian and Belarusian Industry Sector Sanctions Pursuant to § 746.8(a)(6)

* * * * *

(h) Riot Control Agents which are isomers of CS (o-Chlorobenzylidenemalononitrile or o-Chlorobenzalmononitrile) (CAS 2698–41–1); CN (Phenylacetyl chloride or w-Chloroacetophenone) (CAS 532–27–4); or Oleoresin Capsicum (CAS 8023–77–6) as follows:

- (1) 8-Methyl-N-vanillyl-trans-6-nonenamide (Capsaicin) (CAS 404–86–4);
- (2) 8-Methyl-N-vanillylnonamide (Dihydrocapsaicin) (CAS 19408–84–5);
- (3) N-Vanillylnonamide (Pseudocapsaicin, PAVA) (CAS 2444–46–4);
- (4) N-Vanillyl-9-methyldec-7-(E)-enamide (Homocapsaicin) (CAS 58493–48–4);
- (5) N-Vanillyl-9-methyldecanamide (Homodihydrocapsaicin) (CAS 20279–06–5);
- (6) N-Vanillyl-7-methyloctanamide (Nordihydrocapsaicin) (CAS 28789–35–7);
- (7) 2'-chloroacetophenone (CAS 2142–68–9);
- (8) 3'-chloroacetophenone (CAS 99–02–5);
- (9) α-chlorobenzylidenemalononitrile (CAS 18270–61–6); and
- (10) Cis-4-acetylaminodicyclohexylmethane (CAS 37794–87–9).

- 21. Supplement no. 7 to part 746 is amended by revising paragraph (a) to read as follows:

Supplement No. 7 to Part 746—Items That Require a License Under § 746.6 When Destined to the Temporarily Occupied Crimea Region of Ukraine, Under § 746.7 When Destined to Iran, and Under § 746.8 When Destined to Russia or Belarus

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(a) The source for the Harmonized Tariff Schedule (HTS)-6 codes and descriptions in this list is the United States International Trade Commission (USITC)'s Harmonized Tariff Schedule of the United States (2023). The items described in this supplement include any modified or designed "components," "parts," "accessories," and "attachments" therefor regardless of the HTS Code or HTS Description of the "components," "parts," "accessories," and "attachments," apart from any "part" or minor "component" that is a fastener (e.g., screw, bolt, nut, nut plate, stud, insert, clip, rivet, pin), washer, spacer, insulator, grommet, bushing, spring, wire, or solder. The exclusion of fasteners from this control does not apply to fasteners that are designated under an HTS Code under this supplement. Although generally fasteners (e.g., screws, bolts, nuts, nut plates, studs, inserts, clips, rivets, pins), and washers, spacers, insulators, grommets, bushings, springs, wires, and solder are excluded from the scope of this supplement, see part 744 of

the EAR for license requirements for Russia and Belarus that apply to all items "subject to the EAR," e.g., § 744.21 of the EAR and the Entity List license requirements, which in most cases extend to all items "subject to the EAR." This supplement includes two columns consisting of the HTS Code and HTS Description to assist exporters, reexporters, and transferors in identifying the products in this supplement. For information on HTS codes in general, you may contact a local import specialist at U.S. Customs and Border Protection at the nearest port.

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PART 774—THE COMMERCE CONTROL LIST

- 22. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

- 23. Supplement no. 1 to part 774 is amended by revising ECCNs 0A998, 1C992, 3A229, 3A231, 3A232, 6A991, 8A992, and 8D999 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

0A998 Oil and gas exploration equipment, software, and data, as follows (see List of Items Controlled).

License Requirements

Reason for Control: Foreign policy

Control(s)	Country chart
Russian industry sector sanction applies to entire entry.	See § 746.8 for specific license requirements and license review policy.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: N/A

Related Definitions: N/A

Items:

- a. Oil and gas exploration data, e.g., seismic analysis data.
- b. Hydraulic fracturing items, as follows:
 - b.1. Hydraulic fracturing design and analysis software and data.
 - b.2. Hydraulic fracturing 'proppant,' 'fracking fluid,' and chemical additives therefor.

Technical Note: A 'proppant' is a solid material, typically treated sand or man-made ceramic materials, designed to keep an induced hydraulic fracture open, during or following a fracturing treatment. It is added to a 'fracking fluid' which may vary in

composition depending on the type of fracturing used, and can be gel, foam or slickwater-based.

- b.3. High pressure pumps.

* * * * *

1C992 Commercial charges and devices containing energetic materials, n.e.s. and nitrogen trifluoride in a gaseous state (see List of Items Controlled).

License Requirements

Reason for Control: AT, RS, foreign policy

Control(s)	Country chart (see Supp. No. 1 to part 738)
AT applies to entire entry. RS applies to entire entry.	AT Column 1. A license is required for items controlled by this entry for export or reexport to Iraq and transfer within Iraq for regional stability reasons. The Commerce Country Chart is not designed to determine RS license requirements for this entry. See §§ 742.6 and 746.3 of the EAR for additional information.
Russian industry sector sanctions apply to entire entry.	See § 746.8 for specific license requirements and license review policy.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) Commercial charges and devices "subject to the EAR," contain energetic materials described on the USML that exceed the quantities noted or that are not covered by this entry are controlled under ECCN 1C608. (2) Nitrogen trifluoride when not in a gaseous state is controlled under ECCN 1C608.

Related Definitions: (1) Items controlled by this entry ECCN 1C992 are those materials not controlled by ECCN 1C608 and not "subject to the ITAR." (2) For purposes of this entry, the term "controlled materials" means controlled energetic materials (see ECCNs 1C011, 1C111, 1C239, and 1C608; see also 22 CFR 121.1, Category V). (3) The individual energetic materials described on the USML, even when compounded with other materials, remain "subject to the ITAR" when not incorporated into explosive devices or charges. (4) Commercial prefabricated slurries and emulsions containing greater than 35% of energetic materials described on the USML are "subject to the ITAR." (5) For purposes of this entry, the mass of aluminum powder, potassium perchlorate, and any of the substances listed in the note to the USML (see 22 CFR 121.12) (such as

ammonium pictrate, black powder, etc.) contained in commercial explosive devices and in the charges are omitted when determining the total mass of controlled material.				
<i>Items:</i>				
a. Shaped charges “specially designed” for oil well operations, utilizing one charge functioning along a single axis, that upon detonation produce a hole, and	NP applies to entire entry.	NP Column 1.	NP applies to entire entry.	NP Column 1.
a.1. Contain any formulation of controlled materials;	AT applies to entire entry.	AT Column 1.	AT applies to entire entry.	AT Column 1.
a.2. Have only a uniform shaped conical liner with an included angle of 90 degrees or less;	Russian industry sector sanctions apply to entire entry.	See § 746.8 for specific license requirements and license review policy.	Russian industry sector sanctions apply to entire entry.	See § 746.8 for specific license requirements and license review policy.
a.3. Contain more than 0.010 kg but less than or equal to 0.090 kg of controlled materials; and	List Based License Exceptions (See Part 740 for a Description of All License Exceptions)		List Based License Exceptions (See Part 740 for a Description of All License Exceptions)	
a.4. Have a diameter not exceeding 4.5 inches;	LVS: N/A		LVS: N/A	
b. Shaped charges “specially designed” for oil well operations containing less than or equal to 0.010 kg of controlled materials;	GBS: N/A		GBS: N/A	
c. Detonation cord or shock tubes containing less than or equal to 0.064 kg per meter (300 grains per foot) of controlled materials;	List of Items Controlled		List of Items Controlled	
d. Cartridge power devices, that contain less than or equal to 0.70 kg of controlled materials in the deflagration material;	<i>Related Controls:</i> (1) See ECCNs 3E001 and 1E001 (“development” and “production”) and 3E201 and 1E201 (“use”) for technology for items controlled under this entry. (2) See 1A007.a for explosive detonator firing sets designed to drive explosive detonators controlled by 1A007.b. (3) High explosives and related equipment for military use are “subject to the ITAR” (see 22 CFR parts 120 through 130).		<i>Related Controls:</i> See ECCNs 3E001 (“development” and “production”) and 3E201 (“use”) for technology for items controlled under this entry.	
e. Detonators (electric or nonelectric) and assemblies thereof, that contain less than or equal to 0.01 kg of controlled materials;	<i>Related Definitions:</i> N/A		<i>Related Definitions:</i> N/A	
f. Igniters, that contain less than or equal to 0.01 kg of controlled materials;	<i>ECCN Controls:</i> (1) Optically driven firing sets include both those employing laser initiation and laser charging. (2) Explosively driven firing sets include both explosive ferroelectric and explosive ferromagnetic firing set types. (3) 3A229.b includes xenon flash-lamp drivers.		<i>Items:</i>	
g. Oil well cartridges, that contain less than or equal to 0.015 kg of controlled energetic materials;	<i>Items:</i>		a. Designed for operation without an external vacuum system; and	
h. Commercial cast or pressed boosters containing less than or equal to 1.0 kg of controlled materials;	a. Detonator firing sets (initiation systems, firesets), including electronically-charged, explosively-driven and optically-driven firing sets designed to drive multiple controlled detonators controlled by 3A232;		b. Utilizing electrostatic acceleration to induce:	
i. Commercial prefabricated slurries and emulsions containing less than or equal to 10.0 kg and less than or equal to thirty-five percent by weight of materials described on the USML;	b. Modular electrical pulse generators (pulsers) having all of the following characteristics:		b.1. A tritium-deuterium nuclear reaction; or	
j. Cutters and severing tools containing less than or equal to 3.5 kg of controlled materials;	b.1. Designed for portable, mobile, or ruggedized use;		b.2. A deuterium-deuterium nuclear reaction and capable of an output of 3×10^9 neutrons/s or greater.	
k. Pyrotechnic devices when designed exclusively for commercial purposes (e.g., theatrical stages, motion picture special effects, and fireworks displays) and containing less than or equal to 3.0 kg of controlled materials; or	b.2. Capable of delivering their energy in less than 15 μ s into loads of less than 40 Ω (ohms);		3A232 Detonators and multipoint initiation systems, as follows (see List of Items Controlled).	
l. Other commercial explosive devices and charges not controlled by 1C992.a through .k containing less than or equal to 1.0 kg of controlled materials.	b.3. Having an output greater than 100 A;		License Requirements	
Note: 1C992.l includes automotive safety devices; extinguishing systems; cartridges for riveting guns; explosive charges for agricultural, oil and gas operations, sporting goods, commercial mining, or public works purposes; and delay tubes used in the assembly of commercial explosive devices.	b.4. No dimension greater than 30 cm;		<i>Reason for Control:</i> AT, RS, foreign policy	
m. Nitrogen trifluoride (NF ₃) in a gaseous state.	b.5. Weight less than 30 kg; and			
* * * * *	b.6. Specified for use over an extended temperature range 223 K (– 50 °C) to 373 K (100 °C) or specified as suitable for aerospace applications.			
3A229 Firing sets and equivalent high-current pulse generators for detonators controlled by 3A232 (see List of Items Controlled).	c. Micro-firing units having all of the following characteristics:		<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
	c.1. No dimension greater than 35 mm;		NP applies to entire entry.	NP Column 1.
	c.2. Voltage rating of equal to or greater than 1 kV; and		AT applies to entire entry.	AT Column 1.
	c.3. Capacitance of equal to or greater than 100 nF.		Russian industry sector sanctions apply to entire entry.	See § 746.8 for specific license requirements and license review policy.
	* * * * *			
3A231 Neutron generator systems, including tubes, having both of the characteristics described in this ECCN (see List of Items Controlled).			List Based License Exceptions (See Part 740 for a Description of All License Exceptions)	
			LVS: N/A	
			GBS: N/A	
			List of Items Controlled	
			<i>Related Controls:</i> (1) See ECCNs 0A604 and 1A007 for electrically driven explosive detonators. (2) See ECCNs 3E001 (“development” and “production”) and 3E201 (“use”) for technology for items controlled under this entry. (3) High explosives and related equipment for military use are “subject to the ITAR” (see 22 CFR parts 120 through 130).	
			<i>Related Definitions:</i> N/A	
			<i>ECCN Controls:</i> This entry does not control detonators using only primary explosives, such as lead azide.	
			<i>Items:</i>	
			a. [Reserved]	
			b. Arrangements using single or multiple detonators designed to nearly simultaneously	
License Requirements	License Requirements			
<i>Reason for Control:</i> NP, AT, foreign policy	<i>Reason for Control:</i> NP, AT, foreign policy			

initiate an explosive surface over an area greater than 5,000 mm² from a single firing signal with an initiation timing spread over the surface of less than 2.5 µs.

Technical Note: The word initiator is sometimes used in place of the word detonator.

* * * * *

6A991 Marine or terrestrial acoustic equipment, n.e.s., capable of detecting or locating underwater objects or features or positioning surface vessels or underwater vehicles; and “specially designed” “parts” and “components,” n.e.s.

License Requirements

Reason for Control: AT, foreign policy

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
AT applies to entire entry.	AT Column 2.
Russian industry sector sanctions apply to entire entry.	See § 746.8 for specific license requirements and license review policy.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A

List of Items Controlled

Related Controls: N/A

Related Definitions: N/A

Items: The list of items controlled is contained in the ECCN heading.

* * * * *

8A992 Vessels, marine systems or equipment, not controlled by 8A001 or 8A002, and “specially designed” “parts” and “components” therefor, and marine boilers and “parts,” “components,” “accessories,” and “attachments” therefor (see List of Items Controlled).

License Requirements

Reason for Control: AT, Foreign policy

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
AT applies to entire entry.	AT Column 1.
Russian industry sector sanctions apply to entire entry.	See § 746.8 for specific license requirements and license review policy.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A

List of Items Controlled

Related Controls: 1. See also 8A002. 2.

Marine gas turbine engines are not controlled in paragraph .g of this entry. See ECCN 9A619 for possible controls on marine gas turbine engines specially designed for a military use. See ECCN 9A002 for possible controls on marine gas turbine engines not specially designed for a military use. Marine gas turbine engines subject to the EAR that are not controlled in ECCNs 9A002 or 9A619 are designated EAR99.

Related Definitions: N/A

Items:

a. Underwater vision systems, as follows:

a.1. Television systems (comprising camera, lights, monitoring and signal transmission equipment) having a limiting resolution when measured in air of more than 500 lines and “specially designed” or modified for remote operation with a submersible vehicle; or

a.2. Underwater television cameras having a limiting resolution when measured in air of more than 700 lines;

Technical Note: Limiting resolution in television is a measure of horizontal resolution usually expressed in terms of the maximum number of lines per picture height discriminated on a test chart, using IEEE Standard 208/1960 or any equivalent standard.

b. Photographic still cameras “specially designed” or modified for underwater use, having a film format of 35 mm or larger, and having autofocus or remote focusing “specially designed” for underwater use;

c. Stroboscopic light systems, “specially designed” or modified for underwater use, capable of a light output energy of more than 300 J per flash;

d. Other underwater camera equipment, n.e.s.;

e. Other submersible systems, n.e.s.;

f. Vessels, n.e.s., including inflatable boats, and “specially designed” “parts” and “components” therefor, n.e.s.;

g. Marine engines (both inboard and outboard) and submarine engines, n.e.s.; and “specially designed” “parts” and “components” therefor, n.e.s.;

h. Other self-contained underwater breathing apparatus (scuba gear) and related equipment, n.e.s.;

i. Life jackets, inflation cartridges, compasses, wetsuits, masks, fins, weight belts, and dive computers;

j. Underwater lights and propulsion equipment;

k. Air compressors and filtration systems “specially designed” for filling air cylinders.

l. Marine boilers designed to have any of the following characteristics:

l.1. Heat release rate (at maximum rating) equal to or in excess of 190,000 BTU per hour per cubic foot of furnace volume; or

l.2. Ratio of steam generated in pounds per hour (at maximum rating) to the dry weight of the boiler in pounds equal to or in excess of 0.83.

m. Major “components,” “accessories,” and “attachments” for marine boilers described in 8A992.l.

* * * * *

8D999 “Software” “specially designed” for the operation of unmanned submersible vehicles used in the oil and gas industry.

License Requirements

Reason for Control: Foreign policy

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
Russian industry sector sanctions apply to entire entry.	See § 746.8 for specific license requirements and license review policy.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

List of Items Controlled

Related Controls: N/A

Related Definitions: N/A

Items: The list of items controlled is contained in the ECCN heading.

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2024–13148 Filed 6–12–24; 10:30 am]

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Part IV

Consumer Financial Protection Bureau

12 CFR Part 1022

Prohibition on Creditors and Consumer Reporting Agencies Concerning
Medical Information (Regulation V); Proposed Rule

CONSUMER FINANCIAL PROTECTION BUREAU**12 CFR Part 1022****[Docket No. CFPB–2024–0023]****RIN 3170–AA54****Prohibition on Creditors and Consumer Reporting Agencies Concerning Medical Information (Regulation V)****AGENCY:** Consumer Financial Protection Bureau.**ACTION:** Proposed rule; request for public comment.

SUMMARY: The Consumer Financial Protection Bureau (CFPB) is seeking public comment on a proposed rule amending Regulation V, which implements the Fair Credit Reporting Act (FCRA), concerning medical information. The CFPB is proposing to remove a regulatory exception in Regulation V from the limitation in the FCRA on creditors obtaining or using information on medical debts for credit eligibility determinations. The proposed rule would also provide that a consumer reporting agency generally may not furnish to a creditor a consumer report containing information on medical debt that the creditor is prohibited from using.

DATES: Comments must be received on or before August 12, 2024.**ADDRESSES:** You may submit comments, identified by Docket No. CFPB–2024–0023 or RIN 3170–AA54, by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. A brief summary of this document will be available at <https://www.regulations.gov/docket/CFPB-2024-0023>.

- **Email:** 2024-NPRM-MEDICAL-DEBT@cfpb.gov. Include Docket No. CFPB–2024–2023 or RIN 3170–AA54 in the subject line of the message.

- **Mail/Hand Delivery/Courier:** Comment Intake—2024 NPRM FCRA Medical Debt Information, c/o Legal Division Docket Manager, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.

Instructions: The CFPB encourages the early submission of comments. All submissions should include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. Because paper mail is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments

received will be posted without change to <https://www.regulations.gov>.

All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Proprietary information or sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: George Karithanom, Regulatory Implementation & Guidance Program Analyst, Office of Regulations, at 202–435–7700 or <https://reginquiries.consumerfinance.gov/>. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov.

SUPPLEMENTARY INFORMATION:**I. Background****A. Rulemaking Goals**

Information about a person's medical history and health is sacrosanct and among the most intimate and sensitive categories of data. Recognizing the uniquely sensitive nature of such information, Congress acted to limit the use and sharing of medical information in the financial system.¹ Congress did so in order to “establish strong privacy protections for consumers’ sensitive medical information,” in line with the overarching privacy protection purpose of the Fair Credit Reporting Act (FCRA).² As part of these protections, Congress restricted a creditor's ability to obtain or use a consumer's medical information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit.³ A number of concerns have been raised about whether a regulatory exception that permits creditors to consider sensitive medical information about a consumer's debts and certain other types of medical information is consistent with the congressional intent to restrict the use of medical information for inappropriate purposes.

For tens of millions of consumers, medical debt is an unexpected and unwanted expense that can lead to financial hardships. The CFPB is proposing this rule to address concerns that information about medical debt is not necessary and appropriate for credit

underwriting and, as a result, does not warrant an exception to the medical information privacy protections established by Congress.

Due to the complexity of medical billing, information about medical debt is often plagued with inaccuracies and errors. Third-party reimbursement processes, and debt collectors' practices for providing (or furnishing) information on consumers' debts to consumer reporting agencies, can contribute to the prevalence of errors and consumer confusion about their medical bills.⁴ This can uniquely affect not just the accuracy of the information a creditor may consider about a medical debt, but also a consumer's understanding of whether, when, or in what amount, a medical bill must be paid. Many consumers do not find out about an erroneous medical bill in collections until applying for a mortgage or car loan and being denied for the loan based on their consumer report.⁵

Research has shown that medical debt has limited predictive value for credit underwriting purposes. Questions about the reliability of information about medical debt, as compared to information about other types of consumer debt, have been raised based on research performed by the CFPB and others.⁶ Medical debt may be less predictive of whether a consumer will pay a future loan, because medical debts can occur and are collected through unique circumstances and practices. For example, consumers often have limited ability to control the timing and types of medical services that are required.

Because consumer reports can operate as a gatekeeper to significant life and economic decisions, medical debt can be used as leverage by debt collectors to coerce consumers to pay medical bills they may not owe.⁷ In such

⁴ See Consumer Fin. Prot. Bureau, *Consumer credit reports: A study of medical and non-medical collections*, at 15–16, 38–49 (Dec. 2014), https://files.consumerfinance.gov/f/201412_cfpb_reports_consumer-credit-medical-and-non-medical-collections.pdf (discussing billing and collection practices for medical debt generally, in discussion of medical collections tradelines on consumer reports).

⁵ This document uses the term “consumer report” which has the meaning provided in section 603(d) of the FCRA, 15 U.S.C. 1681a(d). “Consumer report” is also commonly referred to as “credit report.”

⁶ See, e.g., Kenneth P. Brevoort & Michelle Kambara, Consumer Fin. Prot. Bureau, *Data point: Medical debt and credit scores* (May 2014), https://files.consumerfinance.gov/f/201405_cfpb_report_data-point_medical-debt-credit-scores.pdf. See also Mark Rukavina, *Medical Debt and Its Relevance When Assessing Creditworthiness*, 46 Suffolk U. L. Rev. 967 (2013), https://bpb-us-e1.wpmucdn.com/sites.suffolk.edu/dist/3/1172/files/2014/01/Rukavina_Lead.pdf.

⁷ See, e.g., Consumer Fin. Prot. Bureau, *Fair Debt Collection Practices Act: CFPB Annual Report 2023*,

¹ Fair and Accurate Credit Transactions Act of 2003 (FACT Act), Public Law 108–159, 117 Stat. 1952, 1999 (2003).

² 15 U.S.C. 1681 *et seq.*, 1681a(4); 149 Cong. Rec. H8122–02, H8122 (daily ed. Sept. 10, 2003) (statement of Rep. Kanjorsky).

³ 15 U.S.C. 1681b(g)(2).

circumstances, consumers are forced to choose between challenging inaccurate medical bills, often while recovering from a serious illness, or paying the inaccurate bill due to a frequently short review period.

Market participants, including in the consumer reporting industry and those most financially incentivized to assess the predictive value of medical debt, have reduced their reliance on medical debt in recognition of its limited utility. Consumer reporting agencies have removed certain medical debts from consumer reports.⁸ Major credit scoring companies have accorded less weight to, or excluded entirely, medical debt information in their newer models.⁹ Similarly, some creditors have adjusted how their underwriting standards treat medical debt information.¹⁰

Based on the totality of this information, the CFPB is proposing changes to how creditors and consumer reporting agencies treat medical

information concerning a consumer's medical debt to ensure the use of such information is consistent with the congressional intent to safeguard consumers' privacy and restrict the use of medical information for inappropriate purposes.

B. Summary of the Proposed Rule

Congress, through the Fair and Accurate Credit Transactions Act of 2003 (FACT Act), amended the FCRA to restrict creditors' ability to obtain or use medical information in connection with credit eligibility determinations (creditor prohibition).¹¹ In doing so, Congress recognized that a consumer's medical information is particularly sensitive, warranting heightened privacy protections. However, in 2005, the Federal financial agencies and the National Credit Union Administration (Agencies) issued a regulatory exception (financial information exception) to this statutory prohibition, permitting consumers' medical financial information to be obtained and used by creditors in connection with credit eligibility determinations if certain conditions were met.¹² And while Congress did permit the Agencies to create exceptions, Congress mandated that the Agencies determine that any exception be necessary and appropriate, and consistent with the congressional intent to restrict the use of medical information for inappropriate purposes.¹³

When the Agencies issued the financial information exception to the statutory prohibition, they did so without providing evidence or reasoning to support their main conclusion that an exception from a congressionally created legal requirement was warranted.

Given the developments over the past decade in its understanding of how consumer medical debt differs from other types of consumer debt and its uses in credit underwriting, the CFPB, now with primary regulatory authority over the FCRA, has preliminarily determined that the financial information exception to the creditor prohibition is neither warranted nor consistent with the FACT Act's purpose of protecting the privacy of consumers' medical information. The CFPB is proposing targeted amendments to Regulation V as follows:

- Remove the financial information exception which broadly permits creditors to obtain and use medical financial information (including

information about medical debt) in connection with credit eligibility determinations, while retaining select elements of the exception related to income, benefits, and loan purpose; and

- Limit the circumstances under which consumer reporting agencies are permitted to furnish medical debt information to creditors in connection with credit eligibility determinations.

These amendments would apply to any person that participates as a creditor in a transaction, except for a person excluded from coverage by section 1029 of the Consumer Financial Protection Act of 2010 (CFPA)¹⁴ (*i.e.*, certain auto dealers). The term creditor has the same meaning as in section 702 of the Equal Credit Opportunity Act (ECOA).¹⁵ The amendments would also apply to a consumer reporting agency as defined in section 603(f) of the FCRA.¹⁶

Under the proposed rule, a creditor would no longer be able to obtain or use medical information related to debts, expenses, assets, or collateral, in connection with a credit eligibility determination, unless a specific exception otherwise applies to the creditor's consideration of the medical information. And a consumer reporting agency generally would be prohibited from furnishing to a creditor a consumer report containing medical debt information in connection with a credit eligibility determination.

As a result of these changes, consumers' sensitive medical information would be protected, and consumers would no longer be unfairly penalized in the credit market for having medical debt. Consumers with and without medical debt would have equal access to credit at comparable terms and debt collectors would have less leverage over consumers to pressure consumers into paying medical debts that they may not owe.

¹⁴ Public Law 111–203, 124 Stat. 1955, 2004 (2010).

¹⁵ ECOA is codified at 15 U.S.C. 1691 *et seq.*; ECOA section 702 is codified at 15 U.S.C. 1691a(e). The term creditor means any person who regularly extends, renews, or continues credit; any person who regularly arranges for the extension, renewal, or continuation of credit; or any assignee of an original creditor who participates in the decision to extend, renew, or continue credit.

¹⁶ 15 U.S.C. 1681a(f). The term consumer reporting agency means any person which, for monetary fees, dues, or on a cooperative nonprofit basis, regularly engages in whole or in part in the practice of assembling or evaluating consumer credit information or other information on consumers for the purpose of furnishing consumer reports to third parties, and which uses any means or facility of interstate commerce for the purpose of preparing or furnishing consumer reports.

at 2–5 (Nov. 2023), https://files.consumerfinance.gov/f/documents/cfpb_fdcpa-annual-report_2023-11.pdf (describing consumer medical collection complaints received by the CFPB).

⁸ See, e.g., Business Wire, *Equifax, Experian, and TransUnion Support U.S. Consumers With Changes to Medical Collection Debt Reporting* (Mar. 18, 2022), <https://www.businesswire.com/news/home/20220318005244/en/Equifax-Experian-and-TransUnion-Support-U.S.-Consumers-With-Changes-to-Medical-Collection-Debt-Reporting>.

⁹ See AnnaMaria Andriotis, *Major Credit-Score Provider to Exclude Medical Debts*, Wall St. J. (Aug. 10, 2022), <https://www.wsj.com/articles/major-credit-score-provider-to-exclude-medical-debts-11660102729> (VantageScore CEO quoted as saying that having medical debt is not necessarily reflective of a consumer's ability to pay back a loan); Ethan Dornhelm, *The Impact of Medical Debt on FICO Scores*, FICO Blog (July 13, 2015), <https://www.fico.com/blogs/impact-medical-debt-fico-scores>.

¹⁰ See, e.g., Fed. Nat'l Mortg. Ass'n, *Single Family Selling Guide*, B3–2–03 (2021), <https://selling-guide.fanniemae.com/#Public.20Records.2C.20Foreclosures.2C.20and.20Collection.20Accounts> (noting that “[c]ollection accounts reported as medical collections are not used in the DU [Desk Underwriter] risk assessment”); Fed. Home Loan Mortg. Corp., *The Single-Family Seller/Service Guide*, 5201.1 (2022), <https://guide.freddiemac.com/app/guide/section/5201.1>; U.S. Dep't of Hous. & Urban Dev., *Single Family Housing Policy Handbook*, 4000.1 (2021), <https://www.hud.gov/sites/dfiles/OCHCO/documents/4000.1hsg-112021.pdf>. See also The White House, *Fact Sheet: The Biden Administration Announces New Actions to Lessen the Burden of Medical Debt and Increase Consumer Protection* (Apr. 11, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/11/fact-sheet-the-biden-administration-announces-new-actions-to-lessen-the-burden-of-medical-debt-and-increase-consumer-protection/> (announcing changes to certain Federal government underwriting standards to remove medical debt from evaluations of whether a consumer will repay a loan, including those for the U.S. Department of Agriculture's rural housing service loans and the Small Business Administration's loan programs and the Federal Housing Finance Authority's review of credit models).

¹¹ Public Law 108–159, 117 Stat. 1952 (2003).

¹² 70 FR 70664 (Nov. 22, 2005).

¹³ 15 U.S.C. 1681b(g)(5).

C. Unique Characteristics of Medical Debt in the United States

A significant number of Americans have medical debt.¹⁷ According to one nationally representative survey, in 2022 around 41 percent of adults stated that they had some kind of medical debt, including debt that they were unable to pay, that was on credit cards, that was being paid over time, directly to a provider, or that they owed to family members, or to a bank, collection agency, or other lender.¹⁸

Several characteristics of medical debt pose special risks to consumers and distinguish it from other types of debt.¹⁹ The need for medical care can be unexpected,²⁰ and medical debt often results from bills for a one-time or short-term medical expense due to an unforeseen event such as an accident or sudden illness.²¹ Consumers are rarely informed of the costs of medical treatment in advance, and because of price opacity and an often immediate

need for medical care, consumers have little or no ability to “shop around.”²² Americans that live in rural communities may also experience limited choices when trying to access health care,²³ which may impact the amount of their medical debt in ways that are not reflective of their other debts.

There are significant concerns with the accuracy of medical bills. For example, 43 percent of all adults and 53 percent of adults with medical debt in a nationally representative survey believed they had received a medical or dental bill that included an error.²⁴ While the survey found that most of these adults had taken some action to dispute the mistake, 51 percent reported that they either did not dispute the bill or were unable to successfully resolve their dispute. This may be because medical billing and collections can be complicated and confusing since a consumer may have difficulty determining whether the amount is covered by insurance or a hospital's financial assistance program (if applicable) and, if so, whether and to what extent the amount was already paid or reduced.²⁵ Also some health care providers and debt collectors exploit these complications and charge inflated or unearned bills.²⁶

²² Consumer Fin. Prot. Bureau, *Bulletin 2022–01: Medical Debt Collection and Consumer Reporting Requirements in Connection with the No Surprises Act*, 87 FR 3025 (Jan. 20, 2022), <https://www.govinfo.gov/content/pkg/FR-2022-01-20/pdf/2022-01012.pdf>. See also Consumer Fin. Prot. Bureau, *Complaint Bulletin: Medical billing and collection issues described in consumer complaints*, at 7–8 (Apr. 20, 2022), <https://www.consumerfinance.gov/data-research/research-reports/complaint-bulletin-medical-billing-and-collection-issues-described-in-consumer-complaints/> (detailing consumer complaints received by the CFPB).

²³ See, e.g., U.S. Gov't Acct. Off., *Health Care Capsule: Accessing Health Care in Rural America* (May 2023), <https://www.gao.gov/assets/gao-23-106651.pdf> (generally describing health care access challenges for rural populations).

²⁴ See, e.g., Karen Pollitz & Kaye Pestaina, Kaiser Fam. Found., *Could Consumer Assistance Be Helpful to People Facing Medical Debt?* (July 14, 2022), <https://www.kff.org/policy-watch/could-consumer-assistance-be-helpful-to-people-facing-medical-debt/> (analyzing results of 2022 Kaiser Family Foundation Health Care Debt Survey).

²⁵ See, e.g., Consumer Fin. Prot. Bureau, *Medical Debt Burden in the United States*, at 9–14 (Feb. 2022), https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf (describing issues with medical billing and collections practices); Consumer Fin. Prot. Bureau, *Complaint Bulletin: Medical billing and collection issues described in consumer complaints* (Apr. 2022), https://files.consumerfinance.gov/f/documents/cfpb_complaint-bulletin-medical-billing_report_2022-04.pdf.

²⁶ Press Release, U.S. Dep't of Just., *Hospital Chain Will Pay Over \$260 Million to Resolve False Billing and Kickback Allegations; One Subsidiary*

D. Medical Debt and Consumer Reporting

Information about medical debt is used in different ways in the financial system. Consumer reporting agencies play a key role in assembling and evaluating consumer credit and other information on consumers²⁷—including information about a consumer's medical debt—and in providing consumer reports to other companies for employment, housing, insurance, and other decisions.²⁸ Medical debt information on a consumer report can increase the cost and reduce the availability of credit, and can even reduce access to employment and housing.²⁹

Generally, information about a medical debt on a consumer report appears as a collection tradeline. After a medical debt has been placed by the creditor in collections status because the debt has been unpaid for a period of time, the medical debt may be furnished as a collections tradeline to consumer reporting agencies by a debt collector, including a debt collector who collects

Agrees to Plead Guilty (Sept. 25, 2018), <https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-260-million-resolve-false-billing-and-kickback-allegations-one>; Press Release, U.S. Atty's Off. for C.D. Cal., *Prime Healthcare Services and its CEO Agree to Pay \$65 Million to Settle Medicare Overbilling Allegations at 14 California Hospitals* (Aug. 3, 2018), <https://www.justice.gov/usao-cdca/pr/prime-healthcare-services-and-its-ceo-agree-pay-65-million-settle-medicare-overbilling>; Press Release, Off. of Pub. Affairs, U.S. Dep't of Just., *Clinical Laboratory and Its Owner Agree to Pay an Additional \$5.7 Million to Resolve Outstanding Judgement for Billing Medicare for Inflated Mileage-Based Lab Technician Travel Allowance Fees* (Aug. 1, 2023), <https://www.justice.gov/opa/pr/clinical-laboratory-and-its-owner-agree-pay-additional-57-million-resolve-outstanding>; Press Release, Off. of Pub. Affairs, U.S. Dep't of Just., *Physician Partners of America to Pay \$24.5 Million to Settle Allegations of Unnecessary Testing, Improper Remuneration to Physicians and a False Statement in Connection with COVID–19 Relief Funds* (Apr. 12, 2022), <https://www.justice.gov/opa/pr/physician-partners-america-pay-245-million-settle-allegations-unnecessary-testing-improper>; Erica Zucco, *Providence will refund medical bills for thousands of patients after agreement with attorney general*, King 5 News (Feb. 1, 2024), <https://www.king5.com/article/news/health/providence-forgive-137-million-medical-payments-refund-20m-patients-after-agreement/281-3063dd66-ab54-413a-893a-73463f213a5b>; Off. of the Att'y Gen. of Va., *Common Health Care Fraud Schemes*, <https://www.oag.state.va.us/contact-us/frequently-asked-questions?id=511> (last visited May 21, 2024).

²⁷ See 15 U.S.C. 1681(a)(3).

²⁸ See Consumer Fin. Prot. Bureau, *Medical Debt Burden in the United States*, at 26 n.117 (Feb. 2022), https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf.

²⁹ See Consumer Fin. Prot. Bureau, *Data Point: Consumer Credit and the Removal of Medical Collections from Credit Reports*, at 2 (Apr. 2023), https://files.consumerfinance.gov/f/documents/cfpb_consumer-credit-removal-medical-collections-from-credit-reports_2023-04.pdf.

¹⁷ For more information about medical debt in the United States, including population disparities, impacts on consumers, and COVID–19 impacts, see Consumer Fin. Prot. Bureau, *Medical Debt Burden in the United States* (Feb. 2022), https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf.

¹⁸ Lunna Lopes et al., Kaiser Fam. Found., *Health Care Debt In The U.S.: The Broad Consequences Of Medical And Dental Bills* (June 16, 2022), <https://www.kff.org/report-section/kff-health-care-debt-survey-main-findings/> (reporting results of 2022 Kaiser Family Foundation Health Care Debt Survey, which polled 2,375 adults).

¹⁹ See generally Consumer Fin. Prot. Bureau, *Bulletin 2022–01: Medical Debt Collection and Consumer Reporting Requirements in Connection with the No Surprises Act*, 87 FR 3025 (Jan. 20, 2022), <https://www.govinfo.gov/content/pkg/FR-2022-01-20/pdf/2022-01012.pdf>; Consumer Fin. Prot. Bureau, *Consumer credit reports: A study of medical and non-medical collections*, at 15–16, 38–42 (Dec. 2014), https://files.consumerfinance.gov/f/201412_cfpb_reports_consumer-credit-medical-and-non-medical-collections.pdf.

²⁰ See Consumer Fin. Prot. Bureau, *Complaint Bulletin: Medical billing and collection issues described in consumer complaints*, at 7 (Apr. 2022), https://files.consumerfinance.gov/f/documents/cfpb_complaint-bulletin-medical-billing_report_2022-04.pdf (describing consumer complaints received by the CFPB about unexpected medical care).

²¹ See Lunna Lopes et al., Kaiser Fam. Found., *Health Care Debt in the U.S.: The Broad Consequences of Medical and Dental Bills* (June 16, 2022), <https://www.kff.org/report-section/kff-health-care-debt-survey-main-findings/> (reporting survey results that 7 in 10 adults with health care debt say the debt arose from bills for a one-time or short-term medical expense). But see Sara R. Collins et al., Commonwealth Fund, *Paying for It: How Health Care Costs and Medical Debt Are Making Americans Sicker and Poorer—Findings from the Commonwealth Fund 2023 Health Care Affordability Survey* (Oct. 2023), <https://www.commonwealthfund.org/publications/surveys/2023/oct/paying-for-it-costs-debt-americans-sicker-poorer-2023-affordability-survey> (about half of adults with medical debt say it is from treatment received for an ongoing condition).

on behalf of the original creditor for a fee, as well as a debt collector who purchases overdue accounts outright from the original creditor (also known as a debt buyer).³⁰ Such tradelines are referred to as medical collections or medical collections tradelines. Research by the CFPB has found that nearly all medical collections furnishing is performed by debt collectors, rather than by health care providers (as original creditors) themselves.³¹ However, a debt collector may have limited access to an original creditor's system of records, which may contribute to higher dispute rates for collections tradelines compared to other components of consumer reports.³² When debt collectors furnish to consumer reporting agencies, they generally report to one or more of the three largest nationwide consumer reporting agencies (NCRAs). Debt collections tradelines may persist on consumer reports for up to seven years;³³ however, many collections tradelines are removed well in advance of seven years.³⁴

Historically, medical debts have been the most common type of debt on consumer reports at both the consumer-report and individual collections tradeline level. The CFPB estimated that medical collections accounted for 57 percent of all collections tradelines in Q1 2022 and 58 percent in Q2 2018.³⁵ When debt collectors acting as agents or assignees of health care providers furnish information about medical collections, they must notify the consumer reporting agency that they are furnishing medical information.³⁶ The FCRA generally prohibits consumer reporting agencies from reporting to third parties the name, address, and telephone number of the health care provider for any account identified as from a medical information furnisher

that has notified the consumer reporting agency of its status, unless that information is restricted or coded such that persons other than the consumer cannot identify or infer the specific provider or the nature of the medical services provided.³⁷ Nevertheless, despite the coding of information on the consumer reports, a consumer report user could infer from the coding that certain debts relate to the provision of health care. Like with medical bills, consumers often find errors with medical collections tradeline information on their consumer reports. A CFPB analysis found that almost 6 percent of medical collections in its data were flagged as having been disputed at some point, almost three times higher than the rate of dispute flags on credit cards and seven times the rate of dispute flags on student loans.³⁸

A 2022 review of consumer complaints submitted to the CFPB found that many consumers complaining of disputed debt collection attempts reported first learning of the debt from viewing their consumer report. Consumers expressed concern with inaccurate information leading to a decrease in their credit score. Some consumers reported paying debt they did not believe they owed in order to have the tradeline removed from their consumer report.³⁹

Some of the errors in medical collections tradelines could be due to debt collection furnishing practices. Some medical debt collectors previously used debt collection furnishing to engage in a practice known as "debt parking," or "passive collection." Debt collectors would report a debt to a consumer reporting agency, then wait for the consumer to notice the tradeline when, for example, applying for credit. The consumer may then pay the debt, possibly without raising any dispute as to any errors in order to access needed credit. The CFPB issued final rules on debt collection, which took effect November 30, 2021, that addressed this practice by requiring a debt collector to take certain actions intended to convey information about the debt to the

consumer before furnishing information on that debt to a consumer reporting agency.⁴⁰ Despite the protections offered by these rules, CFPB investigations indicate that some medical debt collectors may still be attempting to collect on medical debts that were not substantiated after consumers disputed the validity of the debts.⁴¹

Recent reporting changes announced by the NCRAs in 2022 and 2023 have begun to reduce the amount of medical debt reported on consumer reports and benefit some consumers. Specifically, the NCRAs announced that, starting on July 1, 2022, unpaid medical collections will not appear on a consumer's report for up to one year (an increase from 180 days), and paid medical collections will no longer be on consumer reports.⁴² In April 2023, the NCRAs also announced that medical collections with initial balances below \$500 had been removed from consumer reports.⁴³

The CFPB conducted an analysis of the impacts of the NCRAs' medical debt reporting changes through June 2023.⁴⁴ The CFPB found that after these changes, 15 million Americans still have \$49 billion in medical bills on their consumer reports. Because the

⁴⁰ See 12 CFR 1006.30(a).

⁴¹ See Consumer Fin. Prot. Bureau, *CFPB Takes Action Against Phoenix Financial Services for Illegal Medical Debt Collection and Credit Reporting Practices* (June 8, 2023), <https://www.consumerfinance.gov/about-us/newsroom/cfpb-takes-action-against-phoenix-financial-services-for-illegal-medical-debt-collection-and-credit-reporting-practices/>; Consumer Fin. Prot. Bureau, *CFPB Shuts Down Commonwealth Financial Systems for Illegal Debt Collection Practices* (Dec. 15, 2023), <https://www.consumerfinance.gov/about-us/newsroom/cfpb-shuts-down-commonwealth-financial-systems-for-illegal-debt-collection-practices/>.

⁴² Equifax, *First Changes to Reporting of Medical Collection Debt Roll Out July 1, 2022* (July 1, 2022), <https://www.equifax.com/newsroom/all-news/-/story/first-changes-to-reporting-of-medical-collection-debt-roll-out-july-1-2022>; Experian, *First Changes to Reporting of Medical Collection Debt Roll Out July 1, 2022* (July 1, 2022), <https://www.experianplc.com/newsroom/press-releases/2022/first-changes-to-reporting-of-medical-collection-debt-roll-out-july-1-2022>; TransUnion, *First Changes to Reporting of Medical Collection Debt Roll Out July 1, 2022* (July 1, 2022), <https://newsroom.transunion.com/first-changes-to-reporting-of-medical-collection-debt-roll-out-july-1-2022/>.

⁴³ PR Newswire, *Equifax, Experian and TransUnion Remove Medical Collections Debt Under \$500 From U.S. Credit Reports* (Apr. 11, 2023), <https://www.prnewswire.com/news-releases/equifax-experian-and-transunion-remove-medical-collections-debt-under-500-from-us-credit-reports-301793769.html>.

⁴⁴ Ryan Sandler & Zachary Blizard, Consumer Fin. Prot. Bureau, *Recent Changes in Medical Collections on Consumer Credit Records Data Point*, at 3–4, 17 (Mar. 2024), https://files.consumerfinance.gov/f/documents/cfpb_recent-changes-medical-collections-on-consumer-credit-reports_2024-03.pdf.

³⁰ Payments made to medical balances not yet sent to collections generally are not furnished to consumer reporting agencies.

³¹ Consumer Fin. Prot. Bureau, *Market Snapshot: An Update on Third Party Debt Collections Tradelines Reporting*, at 5 (Feb. 2023), https://files.consumerfinance.gov/f/documents/cfpb_market-snapshot-third-party-debt-collections-tradelines-reporting_2023-02.pdf.

³² *Id.*

³³ 15 U.S.C. 1681c(a)(4).

³⁴ Consumer Fin. Prot. Bureau, *Consumer credit reports: A study of medical and non-medical collections*, at 27 (Dec. 2014), https://files.consumerfinance.gov/f/201412_cfpb_reports_consumer-credit-medical-and-non-medical-collections.pdf.

³⁵ Consumer Fin. Prot. Bureau, *Market Snapshot: An Update on Third Party Debt Collections Tradelines Reporting*, at 16–17 (Feb. 2023), https://files.consumerfinance.gov/f/documents/cfpb_market-snapshot-third-party-debt-collections-tradelines-reporting_2023-02.pdf.

³⁶ See 15 U.S.C. 1681s–2(a)(9).

³⁷ 15 U.S.C. 1681c(a)(6); see 15 U.S.C. 1681s–2(a)(9) (requiring medical information furnishers to notify consumer reporting agencies of such status).

³⁸ Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

³⁹ Consumer Fin. Prot. Bureau, *Complaint Bulletin: Medical billing and collection issues described in consumer complaints* (Apr. 2022), https://files.consumerfinance.gov/f/documents/cfpb_complaint-bulletin-medical-billing_report_2022-04.pdf.

medical collections tradelines removed by the NCRAs were those with low balances, the total dollar balances of medical collections on consumer reports fell by only 38 percent nationwide.

Several States and at least one Federal agency have also enacted policies that limit the inclusion of medical debt on consumer reports.⁴⁵ For example, Colorado⁴⁶ and New York⁴⁷ each passed laws in 2023 prohibiting medical debts from appearing on consumer reports. Connecticut and Virginia followed suit earlier this year.⁴⁸ Illinois and Minnesota state legislatures have also passed similar legislation pending signature from their States' governors.⁴⁹ Maine, in 2019, passed a law requiring consumer reporting agencies to remove medical debt upon receiving reasonable evidence that the debt has been settled or paid.⁵⁰ In 2022, the U.S. Department of Veterans Affairs (VA) finalized a rule providing that the VA will report medical debt to consumer reporting agencies only if all other debt collection efforts have been exhausted, the individual is not catastrophically disabled or entitled to free medical care from the VA, and the outstanding debt is over \$25.⁵¹

E. Current Use of Medical Debt in Credit Scoring and Underwriting

Collections tradelines are considered negative information and can lower consumers' credit scores. A 2014 CFPB analysis found that the presence of medical collections tradelines on consumer reports are less predictive of future defaults or serious delinquencies than the presence of nonmedical collections tradelines, and that consumers with paid medical debts have delinquency rates well below those

of consumers with the same credit scores whose medical debts were mostly unpaid.⁵² Following the CFPB's publication of its research and in recognition of the limited predictive value of medical bills, major credit score providers FICO and VantageScore made changes so that newer versions of their credit scoring models differentiate between medical and nonmedical collections tradelines, give less weight to unpaid medical collections tradelines than to other collections tradelines, and ignore paid medical collections of any kind.⁵³ In January 2023, VantageScore implemented changes to VantageScore models 3.0 and 4.0 to ignore all medical collections tradelines.⁵⁴

Older FICO scoring models that do not differentiate between medical and nonmedical collections tradelines, however, remain common in the market. For example, while the Government-Sponsored Enterprises (GSEs), the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac), and the Federal Housing Administration generally do not consider medical debt in their credit risk assessments within their respective automated underwriting systems,⁵⁵ the GSEs require creditors to provide credit scores derived from the older Classic FICO⁵⁶ for each borrower on a loan that the GSEs purchase to assess eligibility

for certain loan products and make certain pricing decisions.⁵⁷ The GSEs and the Federal Housing Finance Agency (FHFA) announced in 2022 that they had validated and approved two of the new credit score models that lessen the weight or do not consider medical collections, but that transition is not expected to occur until the fourth quarter of 2025.⁵⁸

II. Statutory and Regulatory History

A. Fair Credit Reporting Act

The FCRA was enacted in 1970 and was one of the world's first data privacy laws. The law was enacted after growing public concern about the lack of regulation concerning the widespread dissemination of sensitive information about Americans. One of Congress' main purposes in passing the FCRA was a respect for the consumer's right to privacy.⁵⁹ The law has been amended several times in the ensuing years, including by the FACT Act.⁶⁰ The FCRA governs the collection, assembly, and use of consumer report information and provides the framework for the consumer reporting system in the United States. The FCRA regulates the practices of consumer reporting agencies that collect and compile consumer information into consumer reports for use by creditors, insurance companies, employers, landlords, and other entities in making eligibility decisions affecting consumers. The FCRA also limits the circumstances under which persons, such as creditors, may obtain and use consumer report information from consumer reporting agencies.

The FCRA was enacted to (1) prevent the misuse of sensitive consumer information by limiting recipients to those who have a legitimate need for it; (2) improve the accuracy and integrity of consumer reports; and (3) promote the efficiency of the nation's banking and consumer credit systems.⁶¹ An

⁵² Kenneth P. Brevoort & Michelle Kambara, Consumer Fin. Prot. Bureau, *Data point: Medical debt and credit scores* (May 2014), https://files.consumerfinance.gov/f/201405_cfpb_report_data-point_medical-debt-credit-scores.pdf.

⁵³ See Ethan Dornhelm, *The Impact of Medical Debt on FICO Scores*, FICO Blog (July 13, 2015), <https://www.fico.com/blogs/impact-medical-debt-fico-scores>; VantageScore, *How will changes in how medical collection accounts get reported impact credit scores?* (July 5, 2022), <https://www.vantagescore.com/how-will-changes-in-how-medical-collection-accounts-get-reported-impact-credit-scores/>.

⁵⁴ See AnnaMaria Andriotis, *Major Credit-Score Provider to Exclude Medical Debts*, Wall St. J. (Aug. 10, 2022), <https://www.wsj.com/articles/major-credit-score-provider-to-exclude-medical-debts-11660102729> (VantageScore CEO quoted as saying that having medical debt is not necessarily reflective of a consumer's ability to pay back a loan).

⁵⁵ See Fed. Nat'l Mortg. Ass'n, *Single Family Selling Guide*, B3-2-03 (2021), <https://selling-guide.fanniemae.com/#Public.20Records.2C.20Foreclosures.2C.20and.20Collection.20Accounts> (noting that "[c]ollection accounts reported as medical collections are not used in the DU risk assessment"); Fed. Home Loan Mortg. Corp., *The Single-Family Seller/Servicer Guide*, 5201.1 (2022), <https://guide.freddie-mac.com/app/guide/section/5201.1>; U.S. Dep't of Hous. & Urban Dev., *Single Family Housing Policy Handbook*, 4000.1 (2021), <https://www.hud.gov/sites/dfiles/OCHCO/documents/4000.1hsg-102021.pdf>.

⁵⁶ The Classic FICO score is comprised of the following models: Equifax Beacon® 5.0, Experian/Fair Isaac Risk Model V2SM, and TransUnion FICO® Risk Score, Classic 04.

⁵⁷ See, e.g., Fed. Nat'l Mortg. Ass'n, *Single Family Selling Guide* (Oct. 5, 2022), <https://selling-guide.fanniemae.com/sel/b3-5.1-01/general-requirements-credit-scores>.

⁵⁸ Fed. Hous. Fin. Agency, *FHFA Announces Key Updates for Implementation of Enterprise Credit Score Requirements* (Feb. 29, 2024), <https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-Announces-Key-Updates-for-Implementation-of-Enterprise-Credit-Score-Requirements.aspx>.

⁵⁹ FCRA section 602(a)(4) (15 U.S.C. 1681(a)(4)).

⁶⁰ Public Law 108-159 (Dec. 4, 2003). Congress also enacted specific protections for servicemembers and veterans, including with respect to medical debt and credit monitoring. Economic Growth, Regulatory Relief, and Consumer Protection Act, Public Law 115-174, section 302, 132 Stat. 1296, 1333 (2018).

⁶¹ *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 52 (2007); see also 15 U.S.C. 1681(a)(4) (recognizing "a need to insure that consumer reporting agencies

⁴⁵ In 2022, the CFPB issued an interpretive rule clarifying that because FCRA's express preemption provisions have a narrow and targeted scope, States retain substantial flexibility to pass laws involving consumer reporting to reflect emerging problems affecting their local economies and citizens, including problems related to medical debt. Consumer Fin. Prot. Bureau, *The Fair Credit Reporting Act's Limited Preemption of State Laws*, 87 FR 41042 (July 11, 2022).

⁴⁶ Colo. Rev. Stat. section 5-18-109.

⁴⁷ N.Y. Pub. Health Law art. 49-A.

⁴⁸ 2024 Conn. Act 24-6; 2024 Va. Acts ch. 751.

⁴⁹ See Forest Nelson, *Medical debt may no longer negatively impact your credit in Illinois*, WIFR (May 16, 2024), <https://www.wifr.com/2024/05/16/medical-debt-may-no-longer-negatively-impact-your-credit-illinois/>; Off. of Minn. Att'y Gen. Keith Ellison, *Attorney General Ellison commends Senate for final passage of the Debt Fairness Act* (May 16, 2024), https://www.ag.state.mn.us/Office/Communications/2024/05/16_DebtFairnessAct.asp.

⁵⁰ *Consumer Data Indus. Ass'n v. Frey*, 26 F.4th 1 (1st Cir. 2022), cert. denied, 143 S. Ct. 777 (2023).

⁵¹ U.S. Dep't of Veterans Affairs, *Threshold for Reporting VA Debts to Consumer Reporting Agencies*, 87 FR 5693 (Feb. 2, 2022).

important purpose of the FCRA is to enable creditors to make appropriate credit decisions based on accurate consumer reporting information that truly reflects whether a consumer will repay a loan, while simultaneously protecting the privacy of consumer data.⁶²

The FCRA protects consumer privacy in multiple ways, including by clearly prohibiting certain uses of data. The law limits the circumstances under which consumer reporting agencies may disclose consumer information. For example, FCRA section 604, entitled *Permissible purposes of consumer reports*, identifies an exclusive list of permissible purposes for which consumer reporting agencies may provide consumer reports.⁶³ The statute states that a consumer reporting agency may provide consumer reports under these circumstances “and no other.” In addition, FCRA section 607(a) requires that “[e]very consumer reporting agency shall maintain reasonable procedures designed to . . . limit the furnishing of consumer reports to the purposes listed under section 604.”⁶⁴

In addition to imposing permissible purpose limitations on consumer reporting agencies, the FCRA limits the circumstances under which third parties may obtain and use consumer report information from consumer reporting agencies. FCRA section 604(f) provides that a person shall not use or obtain a consumer report unless the consumer report is obtained for a purpose for which the consumer report is authorized to be furnished under FCRA section 604 and the purpose is certified in accordance with FCRA section 607 by a prospective user of the report.⁶⁵

The FCRA’s permissible purpose provisions are thus a key component to the statute’s protection of consumer privacy. Consumers suffer harm when consumer reporting agencies provide consumer reports to persons who are not authorized to receive the information or when recipients of

consumer reports obtain or use such reports for purposes other than permissible purposes. These harms include the invasion of consumers’ privacy, as well as reputational, emotional, physical, and economic harms.

B. Fair and Accurate Credit Transactions Act of 2003 and Implementing Regulations

Congress passed the FACT Act and it became law on December 4, 2003.⁶⁶ Congress, through the FACT Act, amended the FCRA to include additional protections for consumer privacy, such as restricting the use and transfer of sensitive medical information, enhancing the ability of consumers to combat identity theft, increasing the accuracy of consumer reports, and allowing consumers to exercise greater control regarding the type and amount of marketing solicitations they receive.⁶⁷

Congress added, in FCRA section 604(g)(2), a broad new limitation on the ability of creditors to obtain or use medical information pertaining to a consumer in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit.⁶⁸ Congress also limited the circumstances under which consumer reporting agencies could furnish consumer reports containing medical information for credit, employment, or insurance purposes,⁶⁹ and generally required consumer reporting agencies providing consumer reports not to furnish contact information for medical information furnishers—who were also required to identify themselves to consumer reporting agencies⁷⁰—without restrictions or coding “that do not identify, or provide information sufficient to infer, the specific provider or the nature of such services, products, or devices to a person other than the consumer.”⁷¹ Congress also broadly defined medical information in FCRA

section 603(i) to include “information or data . . . created or derived from a health care provider or the consumer, that relates to . . . the payment for the provision of health care to an individual.”⁷²

Congress initially granted rulemaking authority to the Agencies to make exceptions to the limitation on creditors obtaining and using medical information that are necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs (including administrative verification purposes), consistent with congressional intent to restrict the use of medical information for inappropriate purposes.⁷³ Pursuant to this authority, the Agencies promulgated final rules that, among other things, implemented the statute’s general prohibition on creditors obtaining or using medical information pertaining to a consumer in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit and created exceptions to the prohibition.⁷⁴

The Agencies’ final rules contain the financial information exception for creditors obtaining and using medical information in credit eligibility determinations.⁷⁵ The financial information exception consists of a three-part test which allows creditors to use medical information in connection with credit eligibility determinations so long as (1) the information is the type of information routinely used in making credit eligibility determinations; (2) the creditor uses the information in a manner and to an extent no less favorably than comparable nonmedical information; and (3) the creditor does not take the consumer’s physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account when making the determination. The Agencies stated that the “three-part test strikes a balance between permitting creditors to obtain and use certain medical information about consumers when necessary and appropriate to satisfy prudent underwriting criteria and to ensure that credit is extended in a safe and sound manner, while restricting the use of medical information for inappropriate purposes.”⁷⁶ Although the Agencies

exercise their grave responsibilities with fairness, impartiality, and a respect for the consumer’s right to privacy”).

⁶² S. Rep. No. 91–517, at 1 (1969); see also *Trans Union Corp. v. FTC*, 81 F.3d 228, 234 (D.C. Cir. 1996).

⁶³ 15 U.S.C. 1681b(a). Other sections of the FCRA identify additional limited circumstances under which consumer reporting agencies are permitted or required to disclose certain information to government agencies. See 15 U.S.C. 1681f, 1681u, 1681v. Further, the Debt Collection Improvement Act of 1996, Public Law 104–134, 110 Stat. 1321, section 31001(m)(1), allows the head of an executive, judicial, or legislative agency to obtain a consumer report under certain circumstances relating to debt collection. See 31 U.S.C. 3711(h).

⁶⁴ 15 U.S.C. 1681e(a).

⁶⁵ 15 U.S.C. 1681b(f).

⁶⁶ Public Law 108–159, 117 Stat. 1952 (2003).

⁶⁷ H. Rep. No. 108–396, at 1 (2003) (Conf. Rep.); S. Rep. No. 108–166, at 3 (2003) (Conf. Rep.).

⁶⁸ FACT Act sections 411(a), 412(f)(2), 117 Stat. 1999–2000, 2003 (15 U.S.C. 1681b(g)(2)). FCRA section 604(g)(2) provides: “Except as permitted pursuant to paragraph (3)(C) or regulations prescribed under paragraph (5)(A), a creditor shall not obtain or use medical information (other than medical information treated in the manner required under section 1681c(a)(6) of this title) pertaining to a consumer in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit.” 15 U.S.C. 1681b(g)(2).

⁶⁹ FACT Act section 411(a), 117 Stat. 2000 (15 U.S.C. 1681b(g)(1)).

⁷⁰ FACT Act section 412(a), 117 Stat. 2002 (15 U.S.C. 1681s–2(a)(9)).

⁷¹ FACT Act section 412(b), 117 Stat. 2002 (15 U.S.C. 1681c(a)(6)).

⁷² FACT Act section 411(c), 117 Stat. 2001 (15 U.S.C. 1681a(i)).

⁷³ FACT Act section 411(a), 117 Stat. 2001 (15 U.S.C. 1681b(g)(5)(A)).

⁷⁴ 70 FR 70664 (Nov. 22, 2005). See also interim final rules published at 70 FR 33958 (June 10, 2005).

⁷⁵ 70 FR 70664, 70667 (Nov. 22, 2005).

⁷⁶ 69 FR 23380, 23384 (Apr. 28, 2004).

explained the boundaries of their three-part test, and gave responses to commenters on various examples, they did not provide evidence or reasoning to support the main conclusion that an exception from a congressionally created legal requirement was warranted, other than a single conclusory sentence in the proposed rule stating that “[a] creditor should not be prohibited from obtaining or using information about a debt, for example, in connection with making a credit decision, just because that debt happens to be for medical products or services.”⁷⁷

The Agencies’ final rules also identified a limited number of other particular purposes for which a creditor may use medical information in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit.⁷⁸ For example, a creditor may use medical information in credit eligibility determinations to comply with applicable requirements of local, State, or Federal laws.⁷⁹ The Agencies found that this exception, and the other enumerated specific exceptions, are necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs (including administrative verification purposes), and are consistent with the congressional intent to restrict the use of medical information for inappropriate purposes.⁸⁰

Congress (through the CFPA) transferred to the CFPB primary regulatory authority for the FCRA.⁸¹ The CFPB restated the Agencies’ regulations as an interim final rule, with request for comment, on December 21, 2011.⁸² On April 28, 2016, the CFPB finalized the interim final rule without assessing or otherwise reconsidering the policy decisions and justifications that served as the basis for the regulations.⁸³

III. Prior Proceedings, Stakeholder Outreach, and Consultation

A. Small Business Advisory Review Panel

Pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA),⁸⁴ the CFPB issued its Outline of Proposals and Alternatives

under Consideration (Outline or SBREFA Outline).⁸⁵ The SBREFA Outline addressed a number of consumer reporting topics under the FCRA, including medical debt collections information proposals under consideration. The CFPB convened a SBREFA Panel on October 16, 2023, and held Panel meetings on October 18 and 19, 2023.⁸⁶ Representatives from 16 small businesses were selected as small entity representatives for this SBREFA process. These entities represented small businesses that the CFPB determined would likely be directly affected by one or more of the proposals under consideration. On December 15, 2023, the Panel completed the Final Report of the Small Business Review Panel on the CFPB’s Proposals and Alternatives Under Consideration for the Consumer Reporting Rulemaking (Panel Report or SBREFA Report).⁸⁷ In addition to the SBREFA Panel and Panel Report, the CFPB also invited feedback on the proposals under consideration from other stakeholders, including small stakeholders who were not small entity representatives.⁸⁸ The CFPB has considered the feedback related to the medical debt collection information proposals from small entity representatives and other stakeholders, as well as the findings and recommendations of the Panel in preparing this proposed rule.

B. Other Stakeholder Outreach

The CFPB has long been engaged in outreach and research related to medical debt information in the consumer reporting ecosystem. In 2013, the CFPB and FTC jointly hosted a public roundtable for industry and other stakeholders on the integrity of record keeping by debt collectors, debt buyers, and original creditors. Participants acknowledged that record keeping practices may introduce variability or

inaccuracy to the consumer reporting systems.⁸⁹ In December 2014, following the CFPB’s publication of its research report, *Data Point: Medical Debt and Credit Scores*,⁹⁰ the CFPB issued a study of medical and nonmedical collections tradelines on consumer reports that assessed the furnishing practices of debt collectors and debt buyers, the incidence and type of collections tradelines on consumer reports, and differences between medical and nonmedical debt reporting.⁹¹ The CFPB has continued to monitor the incidence of medical debt on consumer reports and released several other market analyses and research reports on medical debt collection and consumer reporting between 2019 and 2024.⁹²

Prior to issuing this proposed rule and in accordance with CFPA section 1022(b)(2)(B), the CFPB consulted with staff from various Federal agencies to discuss aspects of its proposal. Specifically, the CFPB met with staff from the Board of Governors of the Federal Reserve System, the Office of Comptroller of the Currency, the Federal Deposit Insurance Corporation, the National Credit Union Administration (NCUA), the Federal Trade Commission, the Department of Health and Human Services, Department of Housing and Urban Development, the FHFA, the Small Business Administration, the VA, and the Department of Agriculture.

IV. Legal Authority

A. CFPA Section 1022(b)

Section 1022(b)(1) of the CFPA authorizes the CFPB to prescribe rules

⁸⁹ Fed. Trade Comm’n & Consumer Fin. Prot. Bureau, *Roundtable on Data Integrity in Debt Collection: Life of a Debt* (2013), <https://www.ftc.gov/news-events/events/2013/06/life-debt-data-integrity-debt-collection>.

⁹⁰ See Kenneth P. Brevoort & Michelle Kambara, Consumer Fin. Prot. Bureau, *Data point: Medical debt and credit scores* (May 2014), https://files.consumerfinance.gov/f/201405_cfpb_report_data-point_medical-debt-credit-scores.pdf.

⁹¹ Consumer Fin. Prot. Bureau, *Consumer credit reports: A study of medical and non-medical collections* (Dec. 2014), https://files.consumerfinance.gov/f/201412_cfpb_reports_consumer-credit-medical-and-non-medical-collections.pdf.

⁹² Consumer Fin. Prot. Bureau, *Market Snapshot: Third-Party Debt Collections Tradeline Reporting* (July 2019), https://files.consumerfinance.gov/f/documents/201907_cfpb_third-party-debt-collections_report.pdf; Consumer Fin. Prot. Bureau, *Market Snapshot: An Update on Third-Party Debt Collections Tradeline Reporting* (Feb. 2023), https://files.consumerfinance.gov/f/documents/cfpb_market-snapshot-third-party-debt-collections-tradelines-reporting_2023-02.pdf; Ryan Sandler & Zachary Blizard, Consumer Fin. Prot. Bureau, *Recent Changes in Medical Collections on Consumer Credit Records Data Point*, at 3–4, 17 (Mar. 2024), https://files.consumerfinance.gov/f/documents/cfpb_recent-changes-medical-collections-on-consumer-credit-reports_2024-03.pdf.

⁸⁵ Consumer Fin. Prot. Bureau, *Small Business Advisory Review Panel for Consumer Reporting Rulemaking Outline of Proposals and Alternatives Under Consideration* (Sept. 15, 2023), https://files.consumerfinance.gov/f/documents/cfpb_consumer-reporting-rule-sbreffa_outline-of-proposals.pdf.

⁸⁶ The Panel was comprised of a representative from the CFPB, the Chief Counsel for Advocacy of the Small Business Administration (Office of Advocacy), and a representative from the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.

⁸⁷ Consumer Fin. Prot. Bureau, *Final Report of the Small Business Review Panel on the CFPB’s Proposals and Alternatives Under Consideration for the Consumer Reporting Rulemaking* (Dec. 15, 2023), https://files.consumerfinance.gov/f/documents/cfpb_sbreffa-final-report_consumer-reporting-rulemaking_2024-01.pdf. As required under SBREFA, the CFPB considers the Panel’s findings in its IRFA, as set out in part VIII.B below.

⁸⁸ See SBREFA Outline at 5.

⁷⁷ Id.

⁷⁸ 70 FR 70664, 70668 (Nov. 22, 2005).

⁷⁹ This exception is restated at § 1022.30(e)(1)(ii).

⁸⁰ 69 FR 23380, 23382 (Apr. 28, 2004).

⁸¹ Title X of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376, 1955 (2010).

⁸² 76 FR 79308 (Dec. 21, 2011).

⁸³ 81 FR 25323 (Apr. 28, 2016).

⁸⁴ Public Law 104–121, 110 Stat. 857 (1996).

“as may be necessary or appropriate to enable the [CFPB] to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.”⁹³ The term “Federal consumer financial laws” includes the “enumerated consumer laws,” which include the FCRA.⁹⁴

Section 1022(b)(2) of the CFPA prescribes certain standards for rulemaking that the CFPB must follow in exercising its authority under section 1022(b)(1).⁹⁵ For a discussion of the CFPB’s standards for rulemaking under CFPA section 1022(b)(2), see part VII below.

B. FCRA Sections 621(e) and 604(g)(5)

Effective July 21, 2011, section 1088 of the CFPA made conforming amendments to the FCRA transferring rulemaking authority under much of the FCRA, except those regulations applicable to certain motor vehicle dealers, to the CFPB. Section 621(e) of the FCRA authorizes the CFPB to issue regulations as “necessary or appropriate to administer and carry out the purposes and objectives of [the FCRA], and to prevent evasions thereof or to facilitate compliance therewith.”⁹⁶

FCRA section 604(g)(5) specifically authorizes the CFPB to prescribe regulations to create exceptions from the statutory prohibition on obtaining or using medical information in connection with determinations of credit eligibility, but only if the CFPB determines such exceptions to the general prohibition in FCRA section 604(g)(2) are necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs (including administrative verification purposes), consistent with the congressional intent to restrict the use of medical information for inappropriate purposes.⁹⁷ Because the CFPB has preliminarily determined that a regulatory exception for certain financial information is not necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs (including administrative verification purposes), the CFPB is proposing to remove the exception. This would ensure that only exceptions that are necessary and appropriate, consistent with the CFPB’s rulemaking authority under FCRA section 604(g)(5), remain in § 1022.30.

V. Discussion of the Proposed Rule

A. Removal of the Financial Information Exception to the Creditor Prohibition On Obtaining or Using Medical Information

Current § 1022.30(b) incorporates the creditor prohibition in section 604(g)(2) of the FCRA.⁹⁸ The creditor prohibition restricts creditors from obtaining or using (*i.e.*, considering) medical information pertaining to a consumer in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit. There are exceptions to this prohibition in current § 1022.30(d) and (e). The CFPB proposes to remove the exception at § 1022.30(d) (the financial information exception) to the creditor prohibition. As explained in part V.A.3, *Medical information related to income, benefits, or the purpose of the loan*, the CFPB proposes to retain certain elements of the financial information exception related to income, benefits, and purpose of the loan by moving relevant provisions to the list of specific exceptions to the creditor prohibition at § 1022.30(e). The CFPB also proposes conforming amendments to § 1022.30(c) to remove the reference to the § 1022.30(d) financial information exception.

Congress put in place strong privacy protections for consumers’ medical information in the FCRA, including by enacting the creditor prohibition through FCRA section 604(g)(2).⁹⁹ Congress also provided additional protections by stipulating that the CFPB may permit exceptions to the creditor prohibition only when the CFPB has determined the exceptions to be “necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs . . . consistent with the intent of [FCRA section 604(g)(2)] to restrict the use of medical information for inappropriate purposes.”¹⁰⁰

Consistent with the general creditor prohibition in FCRA section 604(g)(2), current § 1022.30(b)(1) provides that “[a] creditor may not obtain or use medical information pertaining to a consumer in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit, except as provided in this section.” In 2005, before the CFPA

transferred primary regulatory authority for the FCRA to the CFPB, the Agencies adopted the exceptions to this prohibition that are now codified in § 1022.30(d) (the financial information exception) and (e) (listing specific exceptions).

The financial information exception allows a creditor to consider medical information pertaining to a consumer in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit if the conditions of the following three-part test are met: (1) the information is the type routinely used in making credit eligibility determinations, such as information relating to debts, expenses, income, benefits, assets, collateral, or the purpose of the loan, including the use of proceeds; (2) the creditor uses the medical information in a manner and to an extent no less favorable than it would use comparable information that is not medical information; and (3) the creditor does not take the consumer’s physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of the credit eligibility determination.¹⁰¹

The predecessor Agencies explained their belief that the financial information exception struck a balance between permitting creditors to obtain and use certain medical information about consumers when necessary and appropriate to satisfy prudent underwriting criteria and ensuring that credit is extended in a safe and sound manner, while restricting the use of medical information for inappropriate purposes.¹⁰² However, the Agencies did not cite evidence or provide analysis in support of this statement of their conclusion.

1. Medical Information Related to Debts

The financial information exception permits a creditor to consider certain medical information related to a consumer’s debts in connection with any determination of the consumer’s eligibility, or continued eligibility, for credit.¹⁰³ Medical information related to medical debt includes, for example, “[t]he dollar amount, repayment terms, repayment history, and similar information regarding medical debts to calculate, measure, or verify the repayment ability of the consumer, the use of proceeds, or the terms for granting credit”¹⁰⁴ and “[t]he identity

⁹³ 12 U.S.C. 5512(b)(1).

⁹⁴ See 12 U.S.C. 5481(12), (14).

⁹⁵ See 12 U.S.C. 5512(b)(2).

⁹⁶ See CFPA section 1088(a)(10)(E) (15 U.S.C. 1681s(e)).

⁹⁷ 15 U.S.C. 1681b(g)(5).

⁹⁸ FCRA section 604(g)(2) (15 U.S.C. 1681b(g)(2)).

⁹⁹ As described above, Congress also limited the circumstances under which consumer reporting agencies can provide consumer reports containing medical information for credit, employment, or insurance purposes, and required consumer reporting agencies to restrict or code contact information for medical information furnishers. 15 U.S.C. 1681b(g)(1), 1681c(a)(6).

¹⁰⁰ 15 U.S.C. 1681b(g)(5).

¹⁰¹ 12 CFR 1022.30(d)(1).

¹⁰² Fair Credit Reporting Medical Information Regulations (2004 NPRM), 69 FR 23380, 23384 (Apr. 28, 2004).

¹⁰³ 12 CFR 1022.30(d)(1)(i).

¹⁰⁴ 12 CFR 1022.30(d)(2)(i)(A).

of creditors to whom outstanding medical debts are owed in connection with an application for credit, including but not limited to, a transaction involving the consolidation of medical debts”¹⁰⁵ (collectively referred to herein as financial information). By proposing to eliminate the financial information exception, the CFPB would prohibit creditors from considering, in connection with credit eligibility determinations, such financial information related to consumers’ medical debts, unless one of the specific exceptions in proposed § 1022.30(e) applies.

Owes or Owed to a Health Care Provider

The FCRA section 603(i) definition of “medical information,” incorporated in Regulation V at § 1022.3(k), informs the types of medical debt that creditors are generally prohibited from considering, but for which the financial information exception currently applies. Medical information is defined as “[i]nformation or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer” that relates to, among other things, “[t]he payment for the provision of health care to an individual.”

With regard to “[t]he payment for the provision of health care to an individual”—i.e., the subset of “medical information” concerning debt—the CFPB has preliminarily interpreted FCRA section 603(i) to mean that medical information about a consumer’s debt must relate to a debt the consumer owes, or at one time owed (for example, in the case of paid medical debt), directly to a health care provider or to the health care provider’s agent or assignee.¹⁰⁶ Specifically, the statute provides that medical information is information or data “created by or derived from a health care provider or the consumer” that relates to “the payment for the provision of health care to an individual.” The CFPB has preliminarily interpreted the statute’s use of the phrase “provision of health care,” following the requirement that the medical information must be “created by or derived from a health care provider or the consumer,” to mean that for information on a debt to be medical information under the FCRA,

the information must relate to a debt arising from a payment obligation that the consumer owes (or at one time owed) directly to a health care provider for the provision of the health care underlying the payment obligation.

The CFPB’s interpretation also includes medical debt that has been sold or resold to a debt buyer, who has become the health provider’s assignee for the debt, because the payment obligation that was sold was created by a health care provider and at one time was owed to the health care provider. It would also include medical debt that has been assigned to a third-party debt collector, who is acting as an agent on behalf of the health care provider or debt buyer, to whom the debt is owed.¹⁰⁷ Further, it would include medical information in the form of a civil judgment arising from a debt collection action as to a medical debt directly owed to a health care provider or debt buyer, whether provided on a consumer report, by the consumer on a credit application, or if the creditor learns of the civil judgment through other means; a credit score that had weighed medical debt information; and debts arising from medical care that is elective, or otherwise not medically necessary (e.g., some cosmetic surgeries).

Because medical information on a consumer’s debt must relate to a debt the consumer owes (or owed) directly to a health care provider under the CFPB’s preliminary interpretation, medical debt would not include a debt owed to a third-party lender (including a medical credit card issuer whose products are offered specifically for the payment of medical services or general purpose credit card issuer), from whom a consumer took out a loan to pay medical expenses or bills. Such loans are new debt obligations used to pay the medical debt obligation owed to a health care provider. The CFPB also preliminarily concludes that debts owed to such third-party lenders are distinguishable from debts that health care providers have sold to debt buyers because medical debts are assigned to such debt buyers, but not to third-party lenders. The CFPB seeks comment on its approach and also seeks comment on whether, in the alternative, the CFPB should consider information about debts generally incurred to pay for medical bills and expenses to be “medical information” that is “derived” from a health care provider or consumer. And, the CFPB also seeks comment on the

feasibility of furnishing such medical debt information under this latter approach to consumer reporting agencies and reporting to creditors in a way that distinguishes between loan obligations and disbursements that pay for medical expenses and those that do not.

FCRA section 603(i) specifies that medical information must relate to the payment for the provision of health care to “an individual.” The CFPB has preliminarily interpreted the FCRA definition for medical information to mean that for information about a debt to be considered medical information, the debt must arise from the provision of health care to a human being.¹⁰⁸ And, as a result, information relating to debts arising from veterinary care would not be considered medical information under the CFPB’s preliminary interpretation.

Generally, much of what Americans consider to be medical debt is owed directly to health care providers such as hospitals or doctors’ or dentists’ offices, even though, as noted previously, medical debt furnishing to consumer reporting agencies is usually done by third-party debt collectors.¹⁰⁹ The CFPB believes that such directly owed debt is likely the type of debt a consumer would clearly consider medical debt. Furnishers of information about these types of debt obligations are required to notify consumer reporting agencies of their status as medical information furnishers and thus debts are likely to be clearly marked as medical debts in consumer reports and in consumer reporting agency databases.¹¹⁰ Therefore, the CFPB anticipates that a consumer reporting agency should also be able to easily identify or determine if information concerning a specific debt is medical debt information, which will make compliance with the proposed rule less burdensome.

Definition—Medical Debt Information (§ 1022.3(j))

Accordingly, the CFPB proposes to add a definition for medical debt information at § 1022.3(j) to facilitate

¹⁰⁸ See *Mohamad v. Palestinian Auth.*, 566 U.S. 449, 454–55 (2012) (explaining that “individual” usually refers to a “natural person” when used in a statute).

¹⁰⁹ See, e.g., Michael Karpman, Urban Inst., *Most Adults with Past-Due Medical Debt Owe Money to Hospitals* (Mar. 2023), <https://www.urban.org/sites/default/files/2023-03/Most%20Adults%20with%20Past-Due%20Medical%20Debt%20Owe%20Money%20to%20Hospitals.pdf> (survey results indicate that 72.9 percent of adults with past-due medical debt owe at least some of that debt to hospitals, including 27.9 percent to hospitals only and 45.1 percent to both hospitals and other providers).

¹¹⁰ See 15 U.S.C. 1681c(a)(6), 1681s–2(a)(9).

¹⁰⁵ 12 CFR 1022.30(d)(2)(i)(D).

¹⁰⁶ The CFPB uses the word “owed” to refer to the characterization of the debt by the health care provider or its agent or assignee. As discussed in part I.C, *Unique characteristics of medical debt in the United States*, the American medical billing system is byzantine and consumers frequently find errors with their medical bills and with medical collections tradeline information on their consumer reports. Accordingly, in some instances consumers may not truly “owe” the debt in question.

¹⁰⁷ Cf. 15 U.S.C. 1681s–2(a)(9) (providing that the term “medical information furnisher” includes the “agent or assignee” of a medical provider).

compliance with various aspects of the proposed rule, including by clarifying the types of medical debts that a creditor would be prohibited from considering in connection with a credit eligibility determination if the financial information exception is removed and that a consumer reporting agency would be limited from including information about on consumer reports under proposed § 1022.38 (which uses the proposed defined term).¹¹¹ Medical debt information would be defined as medical information that pertains to a debt owed by a consumer to a person whose primary business is providing medical services, products, or devices (e.g., a medical or health care provider), or to the person's agent or assignee, for the provision of such medical services, products, or devices. The definition would also clarify that medical debt information includes, but is not limited to, medical bills that are not past due or that have been paid.

The CFPB intends for the definition of medical debt information to align with the scope of information about medical debt that creditors would be prohibited from considering if the financial information exception is removed. The proposed definition is adapted from FCRA section 623(a)(9), which defines the term "medical information furnisher" as a person whose primary business is providing medical services, products, or devices, or the person's agent or assignee, who furnishes information to a consumer reporting agency on a consumer.¹¹² The CFPB believes that aligning the definition of "medical debt information" with the FCRA definition for "medical information furnisher" will provide a familiar standard under the FCRA that will facilitate compliance with the proposed rule. For consumer reporting agencies specifically, the self-identification of medical information furnishers under FCRA section 623(a)(9) will assist consumer reporting agencies in identifying and excluding medical debt information from consumer reports provided to creditors, as would be required under proposed § 1022.38.

The proposed definition for medical debt information would also clarify that the term includes information about a debt owed to a health care provider's agent or assignee. By including agents and assignees in the medical debt information definition, the CFPB intends to include medical debt that has

been purchased by a debt buyer or that is being collected by a third-party debt collector. As explained above, the CFPB considers medical debt that has been sold to a debt buyer or otherwise assigned to a third-party debt collector to be debt arising from a payment obligation that the consumer owes (or owed, for debt that has been paid or sold) directly to the health care provider that provided the health care at issue. The CFPB seeks comment on whether this aspect of the proposed definition should be modified, such as to ensure it accommodates circumstances where the medical debt has been sold and then resold, as well as on its proposed definition for medical debt information generally.

In the course of the SBREFA process for this rulemaking, a few small entity representatives asked the CFPB to define medical debt and asked whether debts arising from certain health-related expenses would be included within the scope of the CFPB's creditor prohibition proposal.¹¹³ The CFPB seeks comment on whether the proposed definition provides the clarity needed for consumers, creditors, and consumer reporting agencies to implement the proposed rule if finalized.

Preliminary Determination That Medical Debt Information is Not Necessary and Appropriate for Credit Eligibility Determinations

Under the FCRA, the CFPB has authority to permit an exception that it determines to be necessary and appropriate, consistent with the intent of the creditor prohibition to restrict the use of medical information for inappropriate purposes.¹¹⁴ Upon further review of predecessor Agencies' rationale for the financial information exception, it appears that while the Agencies addressed specific comments on the parameters of their proposal for the financial information exception (which they substantially finalized as proposed), the Agencies did not provide evidence or analysis to support their determination.¹¹⁵

The CFPB understands that the financial information exception is the primary regulatory exception by which creditors are able to obtain and use financial information relating to a

consumer's medical debts. However, since the predecessor Agencies enacted their rule, there has been a significant body of research and marketplace changes that have shed more light on the nature of medical debt and financial information available to creditors about medical debt. These developments, which provide a more nuanced picture that raises questions about the necessity and appropriateness of creditors' use of medical debt information in credit underwriting, show that a broad exception for creditors to consider information on a consumer's medical debt is not necessary and appropriate, consistent with the intent of the creditor prohibition to protect consumers' sensitive medical information.

First, recent research has demonstrated that unlike other types of debt, medical debt often results from an event such as an accident or sudden illness.¹¹⁶ In these circumstances, consumers have no control over whether to incur a debt; they may have limited or no ability to shop around and may not be able to control the amount or timing of their costs.

Second, in the period of time since the predecessor Agencies enacted their rule, more evidence has come to light showing that information about medical debt is prone to error. Third-party surveys and complaints received by the CFPB have shown that medical bills commonly contain errors and are frequently disputed by consumers.¹¹⁷ Further, the complexity of medical billing, the third-party reimbursement process, and debt collection practices can lead to consumer confusion on payment due dates and amounts owed for medical bills, as well as questions about the accuracy of their bills.¹¹⁸

¹¹⁶ Lunna Lopes et al., Kaiser Fam. Found., *Health Care Debt in the U.S.: The Broad Consequences of Medical and Dental Bills* (June 16, 2022), <https://www.kff.org/health-costs/report/kff-health-care-debt-survey/> (results of national survey show that 7 in 10 adults with health care debt say that the bills that led to their debt were for a one-time or short-term medical expense).

¹¹⁷ See, e.g., Karen Pollitz & Kaye Pestaina, Kaiser Fam. Found., *Could Consumer Assistance Be Helpful to People Facing Medical Debt?* (July 14, 2022), <https://www.kff.org/policy-watch/could-consumer-assistance-be-helpful-to-people-facing-medical-debt/> (reporting survey results that 43 percent of all adults and 53 percent of adults with health care debt say they thought they received a medical or dental bill with an error).

¹¹⁸ See, e.g., Consumer Fin. Prot. Bureau, *Medical Debt Burden in the United States*, at 9–14 (Feb. 2022), https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf (describing issues with medical billing and collections practices); Gideon Weissman et al., Frontier Grp. & U.S. Pub. Int. Rsch. Grp. Educ. Fund, *Medical Debt Malpractice: Consumer Complaints About Medical Debt Collectors, and How the CFPB Can Help*

Continued

¹¹¹ See part V.B, *Limits on consumer reporting agency's disclosure of medical debt information*.

¹¹² 15 U.S.C. 1681s–2(a)(9) (requiring a medical information furnisher to notify a consumer reporting agency of its status as a medical information furnisher).

¹¹³ SBREFA Report at 35 (noting small entity representatives' questions about whether gym memberships, counseling or therapy sessions, veterinarian services, and dental care, or medical expenses charged to credit cards would be covered).

¹¹⁴ FCRA section 605(g)(5) (15 U.S.C. 1681b(g)(5)).

¹¹⁵ 70 FR 33958, 33966–67 (June 10, 2005). See also part II.B, *Fair and Accurate Credit Transactions Act of 2003 and implementing regulations*.

Third, the CFPB's work shows that medical debt information has relatively limited predictive value. Research by the CFPB in 2014 found that medical debt collections tradelines (also referred to as medical collections) are less predictive of future consumer credit performance than nonmedical collections.¹¹⁹ The CFPB's 2014 analysis showed that individuals with more medical than nonmedical collections and individuals with more paid than unpaid medical collections were less likely to be delinquent than other individuals with the same credit score.¹²⁰

Other recent CFPB research also supports that medical debt information, in the form of medical collections, has limited value for credit underwriting. As described in part XI, *Technical Appendix*, CFPB researchers reviewed de-identified consumer report data after the NCRAs implemented changes pursuant to a 2015 settlement with over thirty State attorneys general requiring the NCRAs to prevent the reporting and display of medical debt furnished by debt collection agencies when the date of first delinquency is less than 180 days prior to the date the debt is reported by the debt collector.¹²¹ After this reporting change, the NCRAs had data on consumers' medical debts that were less than 180 days past due, but creditors making credit eligibility determinations did not receive them in consumer reports provided by the NCRAs. The CFPB researchers compared the performance of credit accounts originated just before a medical collection was added to a consumer report to the performance of credit accounts originated just after a medical collection was added to a consumer report. Under the assumption that consumer delinquency risk is similar in both scenarios, the only difference in these originated accounts is the inclusion of the medical collection on the consumer's report

when the consumer applied for the credit account. The CFPB researchers noted that if medical collection reporting is useful in creditor underwriting to reduce delinquency risk, the CFPB would have generally expected a credit account originated for a consumer with unreported medical collections at the time the creditor was making the credit eligibility determination to have a higher delinquency risk than a credit account originated for a consumer that had medical collection information on their consumer report. However, the CFPB researchers found that, on average, new credit accounts of consumers whose medical collections were not included on their consumer reports at the time of their credit applications were no more likely to be seriously delinquent within two years of a credit account's origination than the new credit accounts of consumers whose medical collections were included on their consumer reports at the time of their credit applications. This research suggests that not only can creditors underwrite credit without information about consumers' medical debts, but also that such information may lead to a market failure because it may be an inaccurate signal of whether a consumer will pay a future debt. Under the assumption that two-year serious delinquency is a good proxy for the overall risk of a credit account, the CFPB's research described the *Technical Appendix* implies that information about consumers' medical debts distorts underwriting decisions, impairs creditors' ability to make safe and low-risk credit approvals, and thus reduces credit approval volumes within creditors' risk-tolerances.

Further confirming the limited value of medical debt information for ensuring that credit decisions are based on whether a consumer will repay a loan, in the time since the CFPB's 2014 study, two major credit score providers adjusted their newer models to reduce or eliminate the weight of medical debt collections.¹²² Nonetheless, some widely used models still weigh medical and nonmedical collections equally.¹²³

This means that consumers with medical debt may still be negatively affected if creditors use older scoring models that overweight medical debt.

Fourth, the inconsistent nature of medical collection furnishing and medical debt collection practices likely limits the value of such information for credit underwriting. Data suggests that medical debt collections are disproportionately represented on consumer reports compared to, for example, collections for credit card and other financial debt.¹²⁴ The vast majority of such medical debt reporting is done by third-party debt collectors,¹²⁵ who use consumer reporting as a way to coerce consumers to pay medical debt, even in some cases for medical debt that the consumer may not owe or that has already been paid.¹²⁶ But, not all medical debt is reported; not all medical debt collectors report medical debts to consumer reporting agencies and health care providers themselves rarely do so.¹²⁷ These issues suggest that even consumers with similar amounts amount of medical debt may face markedly different outcomes in the credit market based on whether their medical debt is furnished or not.

Fifth, many industry participants have reduced or stopped their reliance

https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf.

¹²⁴ *Id.* at 5.

¹²⁵ Consumer Fin. Prot. Bureau, *Market Snapshot: An Update on Third-Party Debt Collections Tradelines Reporting*, at 16 (Feb. 2023), https://files.consumerfinance.gov/f/documents/cfpb_market-snapshot-third-party-debt-collections-tradelines-reporting_2023-02.pdf (as of Q1 2022, 57 percent of all tradelines were medical collections and were the most common collections type); Consumer Fin. Prot. Bureau, *Market Snapshot: Third-Party Debt Collections Tradeline Reporting*, at 12–13 (July 2019), https://files.consumerfinance.gov/f/documents/201907_cfpb_third-party-debt-collections_report.pdf (finding that 58 percent of collections tradelines in credit records from 2004 to 2018 were for medical debt); Consumer Fin. Prot. Bureau, *Consumer credit reports: A study of medical and non-medical collections*, at 5 (Dec. 2014), https://files.consumerfinance.gov/f/201412_cfpb_reports_consumer-credit-medical-and-non-medical-collections.pdf (medical collections account for 52.1 percent of all collections tradelines).

¹²⁶ See Consumer Fin. Prot. Bureau, *Market Snapshot: An Update on Third-Party Debt Collections Tradelines Reporting*, at 12 n.9 (Feb. 2023), https://files.consumerfinance.gov/f/documents/cfpb_market-snapshot-third-party-debt-collections-tradelines-reporting_2023-02.pdf (describing how medical tradelines often do not persist on consumer reports, how medical collections accounts are rarely marked as paid, and noting “pay-to-delete” practices used by debt collectors and debt buyers to pressure consumers into paying or settling debt).

¹²⁷ Consumer Fin. Prot. Bureau, *Medical Debt Burden in the United States*, at 26 (Feb. 2022), https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf.

(Spring 2017), <https://publicinterestnetwork.org/wp-content/uploads/2017/04/Medical-Debt-Malpractice-vUS-1.pdf> (63 percent of medical debt collection complaints submitted to the CFPB asserted that the debt had never been owed in the first place, had already been paid or discharged in bankruptcy, or was not verified as the consumer's debt).

¹¹⁹ Kenneth P. Brevoort & Michelle Kambara, Consumer Fin. Prot. Bureau, *Data point: Medical debt and credit scores* (May 2014), https://files.consumerfinance.gov/f/201405_cfpb_report_data-point_medical-debt-credit-scores.pdf.

¹²⁰ *Id.* at 4–5, 13–16, 17–19.

¹²¹ Assurance of Voluntary Compliance/ Assurance of Voluntary Discontinuance (May 20, 2015), *In re Equifax Info. Servs.*, <https://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Consumer-Protection/2015-05-20-CRAs-AVC.aspx>.

¹²² See VantageScore, *Major Credit Score News: VantageScore Removes Medical Debt Collection Records From Latest Scoring Models [Update]* (Aug. 10, 2022), <https://www.vantagescore.com/major-credit-score-news-vantagescore-removes-medical-debt-collection-records-from-latest-scoring-models/> (VantageScore to remove medical collection data from VantageScore 3.0 and 4.0 models by January 2023); Ethan Dornhelm, *The Impact of Medical Debt Collections on FICO Scores*, FICO Blog (July 13, 2015), <https://www.fico.com/blogs/impact-medical-debt-collections-fico-scores> (describing changes to FICO Score 9 with regard to medical collections).

¹²³ Consumer Fin. Prot. Bureau, *Medical Debt Burden in the United States*, at 27–28 (Feb. 2022),

on information about medical debt, casting doubt on its value. The three NCRA's have stopped reporting medical collections that are under \$500, less than a year old, or paid.¹²⁸ And, as already noted, large credit scoring companies are moving to models that completely or partially exclude medical collections.¹²⁹ In addition, the CFPB learned from several small entity representatives during the SBREFA process that some creditors have stopped considering medical collections in their underwriting.¹³⁰

Sixth, some States and some Federal agencies have also acted to limit creditors' access to, or ability to consider, certain medical debt information. For example, several States have prohibited, or are considering prohibiting, the inclusion of consumer medical debt on consumer reports.¹³¹

¹²⁸ Business Wire, *Equifax, Experian, and TransUnion Support U.S. Consumers With Changes to Medical Collection Debt Reporting* (Mar. 18, 2022), <https://www.businesswire.com/news/home/20220318005244/en/Equifax-Experian-and-TransUnion-Support-U.S.-Consumers-With-Changes-to-Medical-Collection-Debt-Reporting>.

¹²⁹ One such credit score provider, VantageScore, has completely stopped factoring medical collections in the latest versions of its models due to lack of their predictiveness as compared with other accounts in collections. See AnnaMaria Andriotis, *Major Credit-Score Provider to Exclude Medical Debts*, Wall St. J. (Aug. 10, 2022), <https://www.wsj.com/articles/major-credit-score-provider-to-exclude-medical-debts-11660102729>.

¹³⁰ See Comment from Arlington Cmty. Fed. Credit Union, *Re: FCRA Proposals and Alternatives Under Consideration*, at 2–3 (Nov. 6, 2023), SBREFA Report app. A; Comment from First Sec. Bank & Tr., *Re: CFPB's Outline of Proposals and Alternatives Under Consideration*, Small Business Advisory Review Panel for Consumer Reporting Rulemaking, at 7 (Nov. 6, 2023), SBREFA Report app. A (a bank does not consider medical collections unless aware the consumer has made periodic payment arrangements with a collection agency or medical establishment).

¹³¹ See Colo. Rev. Stat. section 5–18–109; N.Y. Pub. Health Law art. 49–A; 2024 Conn. Act 24–6; 2024 Va. Acts ch. 751. The Illinois and Minnesota State legislatures have also passed legislation that would prevent medical debt from being on consumer reports, which will become law upon each State's respective governor's signature. See Forest Nelson, *Medical debt may no longer negatively impact your credit in Illinois*, WIFR (May 16, 2024), <https://www.wifr.com/2024/05/16/medical-debt-may-no-longer-negatively-impact-your-credit-illinois/>; Off. of Minn. Att'y Gen. Keith Ellison, *Attorney General Ellison commends Senate for final passage of the Debt Fairness Act* (May 16, 2024), https://www.ag.state.mn.us/Office/Communications/2024/05/16_DebtFairnessAct.asp. Similar legislation is under consideration in California, Maine, New Jersey, Virginia, and Rhode Island. See SB–1061 (Cal. 2024), https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=202320240SB1061; Libby Palanza, *Maine Lawmakers Consider Insulating Medical Debt from Credit Score Calculation, Interest Accumulation, and Legal Action*, Maine Wire (Mar. 20, 2024), <https://www.themainewire.com/2024/03/maine-lawmakers-consider-insulating-medical-debt-from-credit-score-calculation-interest-accumulation-and-legal-action/>; Robert Walker, *New Jersey Seeks to Ban Medical Debt Collectors from Credit Agency Reporting*, Shore News Network (Mar. 21, 2024), <https://www.shorenewsnetwork.com/2024/03/21/new-jersey-seeks-to-ban-medical-debt-collectors-from-credit-agency-reporting/>; HB 1265 (Va. 2024), <https://lis.virginia.gov/cgi-bin/legp604.exe?241+ful+HB1265+pdf>; RI H7103 (R.I. 2024), <https://webserver.rilegislature.gov/BillText24/HouseText24/H7103.pdf>.

Although such efforts are in their early stages, the CFPB is not aware of evidence that such actions have affected creditors' underwriting standards or that creditors have materially curtailed access to credit or tightened credit terms in those States. Some Federal government agencies have also been reviewing and modifying their underwriting practices to reduce or eliminate medical debt collections from consideration when evaluating whether a consumer will repay a loan.¹³² These changes by the States and by the Federal government indicate a growing awareness that medical debt information may have limited value for credit underwriting purposes. Consumer reporting agencies and creditors will already need to comply with these new laws and best practices and, given operational and business realities, may need to do so on a broad basis. Removing the financial information exception in Regulation V would create a uniform nationwide baseline consistent with these advancements.

Given these developments, the CFPB has preliminarily concluded that a creditor's consideration of sensitive financial information concerning a consumer's medical debt under the broad financial information exception in existing § 1022.30(d) is not “necessary and appropriate” to protect legitimate operational, transactional, risk, or consumer needs. Nor is it consistent with the intent of the creditor prohibition to restrict the use of medical information for inappropriate purposes, as required for an exception under FCRA section 604(g)(5). The CFPB seeks comment on this preliminary conclusion regarding medical debt information, as well as on whether any adjustments to the proposed rule would be “necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs (and which shall include permitting actions

necessary for administrative verification purposes).”¹³³

2. Medical Information Related to Expenses, Assets, and Collateral

In addition to debts, the financial information exception permits a creditor to consider medical information relating to expenses, assets, and collateral, including the value, condition, and lien status of a medical device that may be collateral to secure a loan. By proposing to eliminate the financial information exception, the CFPB would prohibit a creditor from obtaining and using sensitive medical information relating to expenses, assets, or collateral in making a determination of the consumer's credit eligibility, unless a specific exception in § 1022.30(e) applies.

Medical expenses and medical debts are closely related. Unpaid medical expenses may become medical debts that a creditor would be prohibited from considering in making a credit eligibility determination under the CFPB's proposal discussed in part V.A.1, *Medical information related to debts*. Because of the similarities between medical expenses and medical debts, the CFPB is proposing to treat these categories of medical information the same. The CFPB has preliminarily determined that the financial information exception for a creditor to consider medical information relating to a consumer's expenses is also not “necessary and appropriate” to protect legitimate operational, transactional, risk, or consumer needs and is not consistent with the intent of the creditor prohibition to restrict the use of medical information for inappropriate purposes as required under FCRA section 604(g)(5).

The CFPB has also considered the existing financial information exception for medical information relating to a consumer's assets and collateral and, upon further review, has preliminarily determined that the financial information exception for assets and collateral is not warranted. The CFPB understands that medical information related to a consumer's assets and collateral generally refers to medical equipment serving as an asset or as collateral for a loan, which a creditor may potentially seize or anticipate could be liquidated to pay off a loan. However, such medical equipment is often necessary and potentially lifesaving. Given the importance of medical assets and collateral to a consumer's well-being, the CFPB has preliminarily determined that it is not “necessary and appropriate . . . to

¹³² See The White House, *Fact Sheet: The Biden Administration Announces New Actions to Lessen the Burden of Medical Debt and Increase Consumer Protection* (Apr. 11, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/11/fact-sheet-the-biden-administration-announces-new-actions-to-lessen-the-burden-of-medical-debt-and-increase-consumer-protection/>.

¹³³ 15 U.S.C. 1681b(g)(5).

protect legitimate operational, transactional, risk, consumer, and other needs” as required under FCRA section 604(g)(5) to continue to have the financial information exception to the creditor prohibition apply to information about medical assets and collateral.

The CFPB seeks comment on its proposed approach to removing the financial information exception at existing § 1022.30(d) for expenses, assets, and collateral. In particular, the CFPB is interested in feedback from creditors and their representatives about whether they take medical devices as collateral or into consideration as assets that may be used by consumers to pay a future debt obligation, and if so, the business justification for doing so.

3. Medical Information Related to Income, Benefits, or the Purpose of the Loan

The financial information exception also permits creditors to consider medical information related to income, benefits, and the purpose of the loan, including the use of the loan proceeds. Although the CFPB is proposing to remove the financial information exception, the CFPB intends to retain elements of the exception relating to income, benefits, and the purpose of the loan by moving relevant material to the list of specific exceptions in § 1022.30(e), as outlined below.

Proposed § 1022.30(e)(1)(x) generally retains the financial information exception’s test for medical financial information. However, given the proposed narrow scope of the exception (applying only to income, benefits, or the purpose of the loan, including the use of proceeds), it is not necessary to retain § 1022.30(d)(1)(i), which requires the medical information creditors may consider under the exception to be information routinely used in making credit eligibility determinations. Instead, proposed § 1022.30(e)(1)(x)(A) would provide that the exception only applies to medical information relating to income, benefits, or the purpose of the loan, including the use of proceeds. Proposed § 1022.30(e)(1)(x)(A) also provides examples of the types of financial information related to income and benefits relied upon as a source of repayment by restating the examples of financial information in existing § 1022.30(d)(2)(i)(C). Proposed § 1022.30(e)(1)(x)(B) and (C) would also provide, as currently required, that the creditor must use the information in a manner and to an extent that is no less favorable than comparable, nonmedical information and that the creditor cannot take the consumer’s physical, mental, or

behavioral health, condition or history, type of treatment, or prognosis into account.

The CFPB believes that the elements of the exception relating to income, benefits, and the purpose of the loan are necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs, including permitting actions necessary for administrative verification purposes, consistent with FCRA’s intent to restrict the use of medical information for inappropriate purposes. For example, consumers whose primary source of income is disability benefits might not be able to obtain credit at all if creditors could not consider their income.¹³⁴ And since creditors may be unwilling to underwrite if they lack information about the purpose of a loan, consumers might not be able to obtain needed credit unless creditors have access to that information.

The CFPB proposes to move an existing example illustrating a use of medical information related to long-term disability income from § 1022.30(d)(2)(ii)(B) to proposed § 1022.30(e)(7). The CFPB does not propose incorporating certain examples from existing § 1022.30(d)(2)(iii) because they do not relate to a consumer’s income, benefits, or the purpose of a loan, including the use of proceeds. Some examples describe the creditor’s consideration of the consumer’s health condition in each instance in denying credit. In light of the CFPB’s preliminary determination that certain types of medical information are not necessary and appropriate for use in credit determinations, the CFPB believes that these examples do not need to be restated.¹³⁵

The CFPB seeks comment on its approach to the exception in proposed § 1022.30(e)(1)(x) and the accompanying example at proposed § 1022.30(e)(7). The CFPB also seeks comment on whether each of the other, existing specific exceptions are necessary and appropriate and whether the CFPB should amend any of the other existing exceptions and examples in the list of specific exceptions at § 1022.30(e).

¹³⁴ The CFPB notes that ECOA and Regulation B prohibit creditors from discriminating in any aspect of a credit transaction against an applicant because all or part of the applicant’s income derives from a public assistance program, which includes but is not limited to Social Security disability income. 15 U.S.C. 1691(a)(2); 12 CFR 1002.2(z), 1002.4(a); see also Regulation Z comment 1002.2(z)–3.

¹³⁵ See 12 CFR 1022.30(d)(iii)(B) (regarding a consumer’s conversation with a loan officer about the consumer’s potentially terminal disease), (C) (regarding a loan officer’s observation of a consumer’s apparent medical condition).

B. Limits on Consumer Reporting Agency’s Disclosure of Medical Debt Information

The CFPB is proposing to add new § 1022.38 to subpart D to address how a consumer reporting agency’s medical debt information reporting responsibilities would be impacted by the proposal to remove the financial information exception for obtaining and using medical information in connection with any determination of the consumer’s eligibility for credit. Proposed § 1022.38 would permit a consumer reporting agency to include medical debt information in a consumer report furnished to a creditor for credit eligibility purposes only if the following criteria are met: (1) the consumer reporting agency has reason to believe the creditor is not prohibited from obtaining or using the medical debt information under § 1022.30; and (2) the consumer reporting agency is not otherwise prohibited from furnishing to the creditor a consumer report containing the medical debt information, including by a State law that prohibits furnishing to the creditor a consumer report containing medical debt information.

FCRA section 604, entitled *Permissible purposes of consumer reports*, identifies an exclusive list of permissible purposes for which consumer reporting agencies may provide consumer reports.¹³⁶ The statute states that a consumer reporting agency may furnish consumer reports under these circumstances “and no other.”¹³⁷ One such circumstance, covered by FCRA section 604(a)(3)(A), permits a consumer reporting agency to furnish a consumer report to a person which it has reason to believe “intends to use the information in connection with a credit transaction involving the consumer on whom the information is to be furnished and involving the extension of credit to, or review or collection of an account of, the consumer” (credit permissible purpose).¹³⁸ But, FCRA section 604(g)(2) imposes a specific limitation on the

¹³⁶ 15 U.S.C. 1681b(a) (providing that, “[s]ubject to subsection (c), any consumer reporting agency may furnish a consumer report under the following circumstances and no other”).

¹³⁷ *Id.* Other sections of the FCRA identify additional limited circumstances under which consumer reporting agencies are permitted or required to disclose certain information to government agencies. See 15 U.S.C. 1681f, 1681u, 1681v. Further, the Debt Collection Improvement Act of 1996, Public Law 104–134, 110 Stat. 1321, tit. III, section 31001(m)(1), allows the head of an executive, judicial, or legislative agency to obtain a consumer report under certain circumstances relating to debt collection. See 31 U.S.C. 3711(h).

¹³⁸ 15 U.S.C. 1681b(a)(3)(A).

ability of creditors to obtain or use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility for credit, for which there are limited exceptions.

The CFPB preliminarily interprets the FCRA section 604(a)(3)(A) credit permissible purpose limitation and the FCRA section 604(g)(2) limitation on the ability of creditors to obtain or use medical information in connection with credit eligibility determinations together to mean that a creditor does not have a credit permissible purpose to obtain or use a consumer report containing medical information that the creditor is prohibited from obtaining or using. Under this interpretation, if the CFPB removes the financial information exception in § 1022.30(d) as proposed, a creditor would be prohibited from obtaining or using medical debt information—a subcategory of medical information—in connection with any determination of the consumer's eligibility for credit under the general prohibition in § 1022.30(b), unless a specific exception for obtaining and using medical information in § 1022.30(e) applies to the medical debt information; therefore, absent a specific exception, the creditor would not have a credit permissible purpose for a consumer report containing the medical debt information. Because a consumer reporting agency may only furnish a consumer report to a person if it has reason to believe the person has a permissible purpose for the information, it follows that a consumer reporting agency may not furnish to a creditor a consumer report containing medical debt information if it has reason to believe the creditor is prohibited from using the medical debt information. This limitation is clarified in proposed § 1022.38(b)(1).

The CFPB has also preliminarily determined that the proposed limits on a consumer reporting agency's disclosure to a creditor of a consumer's sensitive medical debt information are necessary or appropriate to administer and carry out the purposes and objectives of the FCRA, and to prevent evasions or to facilitate compliance.¹³⁹ These limitations on consumer reporting agencies would markedly facilitate compliance. If consumer reporting agencies continued to furnish to creditors, in connection with eligibility determinations, consumer reports containing medical debt information, creditors would need to screen out such information to comply with the creditor prohibition. Doing so

may be cumbersome, especially for creditors that use automated underwriting processes. On the other hand, consumer reporting agencies could more easily implement automatic processes that remove medical debt information provided by medical information furnishers from those reports that are requested for credit eligibility determinations because medical information furnishers are required to identify themselves to consumer reporting agencies.¹⁴⁰ The CFPB has also preliminarily determined that this proposed limitation is necessary and appropriate to administer and carry out the purposes and objectives of the FCRA, especially that of “need[ing] to insure that consumer reporting agencies exercise their grave responsibilities with fairness, impartiality, and a respect for the consumer's right to privacy.”¹⁴¹ Medical information is uniquely sensitive and intimate information, and it thus advances the purposes and objectives of the FCRA to protect consumers' privacy by limiting the circumstances under which consumer reporting agencies may furnish medical debt information.

Proposed § 1022.38(b)(2) would incorporate other limitations on consumer reporting agencies' furnishing of consumer reports containing medical debt information to make clear that proposed § 1022.38 does not override any other prohibition regarding the furnishing of consumer reports. For example, State legislatures and Federal agencies have enacted policies that limit the inclusion of medical debts on consumer reports. The CFPB commends the work of States to proactively protect consumers against the harms of medical debt reporting. In 2022, the CFPB issued an interpretive rule explaining that, with limited exceptions, States are permitted to enact State-level laws that provide consumer protections involving consumer reporting, including regarding the content of information contained in consumer reports, in addition to those provided by the Federal FCRA.¹⁴² The CFPB intends for the proposed intervention to operate alongside Federal and State-level efforts to increase consumer protections around medical debt consumer reporting.

The CFPB is also proposing a related amendment to remove the example in § 1022.30(c)(3)(iii), which describes a

creditor receiving medical information on a consumer report furnished by a consumer reporting agency. While there may be some instances where a consumer reporting agency may furnish to a creditor a consumer report containing medical information, the proposed amendments would limit those instances and render the example less instructive and potentially confusing. Therefore, the CFPB proposes to remove the example.

SBREFA panelists raised concerns about the consequences of prohibiting the inclusion of medical debts on consumer reports used for credit underwriting. The CFPB is not proposing to impose a blanket prohibition on the consumer reporting of medical debt information. Proposed § 1022.38 addresses how a consumer reporting agency's responsibilities, with respect to medical debt information, would be impacted by the proposal to remove the financial information exception discussed in part V.A, *Removal of the financial information exception to the creditor prohibition on obtaining or using medical information.*

The CFPB has considered alternatives to this approach. For example, as discussed in the SBREFA Outline, the CFPB considered mandating a delay in the furnishing and reporting of medical debt for a particular period of time, and not reporting or furnishing medical debt below a particular dollar amount.¹⁴³ This approach would have been similar to the voluntary changes that the NCRAs implemented in 2022 and 2023 that stopped the reporting of some, but not all, medical debt on a consumer report. SBREFA panelists questioned whether the proposals under consideration were necessary, given recent market changes regarding medical debt consumer reporting.¹⁴⁴

The CFPB acknowledges the value of these voluntary consumer reporting changes by the three NCRAs, but has preliminarily determined that these types of changes do not do enough to protect the privacy of consumers' medical data during the credit underwriting process. Although these market changes have reduced the total number of medical collections tradelines reflected on consumer reports, their voluntary nature means there is some uncertainty about whether the changes could be reversed in the future, and, as discussed in part I.D, *Medical debt and consumer reporting*, 15 million Americans still have \$49 billion in medical bills on their consumer reports even after the NCRAs'

¹⁴⁰ See 15 U.S.C. 1681s–2(a)(9).

¹⁴¹ See 15 U.S.C. 1681(a)(4).

¹⁴² Consumer Fin. Prot. Bureau, *The Fair Credit Reporting Act's Limited Preemption of State Laws* (June 2022), https://files.consumerfinance.gov/f/documents/cfpb_fcra-preemption_interpretive-rule-2022-06.pdf.

¹⁴³ SBREFA Outline at 19.

¹⁴⁴ See generally SBREFA Report.

¹³⁹ See 15 U.S.C. 1681s(e)(1).

voluntary changes. In addition, as discussed in part V.A.1, *Medical information related to debts*, the CFPB has preliminarily determined that a creditor's consideration of sensitive financial information concerning a consumer's medical debt is not warranted.

The CFPB also considered requiring consumer reporting agencies and medical information furnishers, upon receiving a dispute, to conduct an independent investigation to certify that a disputed medical debt is accurate and not subject to pending insurance disputes.¹⁴⁵ However, consumer reporting agencies are already subject to accuracy and dispute resolution requirements. Therefore, the CFPB has preliminarily determined that its rulemaking goals are best achieved through the proposed approach.

The CFPB seeks comment on all aspects of proposed § 1022.38.

C. Example To Comply With Applicable Requirements of Local, State, or Federal Laws

During the SBREFA process, several financial institutions, furnishers, small entity representatives, and debt collectors expressed concern about how the proposal under consideration to remove the financial information exception in § 1022.30(d) and prohibit consumer reporting agencies from including medical debt collections tradelines on consumer reports furnished to creditors for credit eligibility determinations would interact with repayment ability determination requirements under the Truth in Lending Act (TILA) and Regulation Z for mortgage loans and credit cards.¹⁴⁶ Stakeholders stated that these laws require creditors to consider all of a consumer's current debt obligations, such that the proposal under consideration would impede their ability to make the required determination in compliance with Federal law. A small entity representative recommended that the CFPB consider stating what creditors should tell consumers regarding whether medical debt information should be disclosed on applications for credit, and any limitations on financial institutions' use of consumer-provided information for underwriting.

For the reasons discussed above, the CFPB preliminarily finds it is generally not necessary and appropriate for creditors to obtain or use information about a consumer's medical debt in determining a consumer's credit

eligibility. However, the CFPB has preliminarily determined to not repeal other exceptions, including one for medical information is necessary to comply with applicable local, State, or Federal laws. In response to comments during the SBREFA process, the CFPB is proposing an example in new § 1022.30(e)(6) to direct creditors and card issuers that are creditors regarding how to obtain and use medical information provided by the consumer in compliance with TILA and Regulation Z, as set forth in § 1022.30(e)(1)(ii), for purposes of compliance with the ability-to-repay rule under § 1026.43(c) for closed-end mortgages, the repayment ability rule under § 1026.34(a)(4) for open-end, high-cost mortgages, and the ability-to-pay rule under § 1026.51(a) for open-end (not home-secured) credit card accounts.

Under existing § 1022.30(c)(1), a creditor does not violate the prohibition on obtaining medical information in § 1022.30(b) if the creditor receives medical information pertaining to a consumer in connection with the creditor's determination of the consumer's eligibility for credit without specifically requesting such information. For example, if a consumer applies for a mortgage loan and the creditor has not specifically requested medical information on the application, but asks for all current debts or obligations, and the consumer self-discloses by providing medical information in the form of a monthly medical payment plan, the creditor does not violate the prohibition on obtaining medical information. In this circumstance, the creditor would be permitted to use this limited category of information by considering the existence and the amount of the medical payment plan as required in considering certain factors under § 1026.43(c)(2), such as the current debt obligations, consumer's monthly debt-to-income ratio, and residual income, in making the repayment ability determination required under § 1026.43(c)(1). Proposed § 1022.30(e)(6) also provides that, in accordance with § 1026.43(c)(3)(iii), the creditor would not be required to independently verify the existence and amount of the consumer's monthly medical payment plan if the consumer's application states a current debt, even if that debt is not shown in the consumer report. This is also consistent with Regulation Z comment 43(c)(3)–6 describing a situation where a consumer, through the application, provides a creditor with information on a debt obligation that is

not listed on a consumer report.

Therefore, the creditor would not violate the prohibition on obtaining or using medical information in § 1022.30(b) if the creditor obtains and uses this limited category of medical information disclosed by the consumer on their application as an ongoing payment obligation.

Proposed § 1022.30(e)(6) explains that a creditor (for mortgage loans) or card issuer (for credit cards) relying on the specific exception for compliance with applicable laws at § 1022.30(e)(1)(ii) is not permitted to obtain or use medical information from a consumer report. The CFPB has preliminarily determined that the creditor or card issuer can comply with the applicable laws using the information provided by the consumer on the application, including any unsolicited medical information; therefore, it would not be necessary or appropriate for a creditor or card issuer to use medical information contained in a consumer report or request a consumer report in an attempt to obtain medical information in order to comply with the applicable laws. As explained in part V.B, *Limits on consumer reporting agency's disclosure of medical debt information*, the CFPB also believes it would be administratively difficult for consumer reporting agencies to determine which information in a consumer's credit file is necessary for a particular creditor's compliance with the requirement to make a repayment ability determination and which information is not. In the context of creditors' obligations to make repayment ability determinations under Regulation Z, the limited amount of medical debt information that would be relevant to ability-to-repay or ability-to-pay rules, as well as the administrative burdens of segmenting this information out, is impractical for a consumer reporting agency to undertake. For the reasons discussed above, the CFPB preliminarily finds that preventing creditors from purposefully obtaining—and under new § 1022.38, consumer reporting agencies from furnishing—medical information on consumer reports for credit eligibility purposes will both ease burdens on consumer reporting agencies and prevent attempts by creditors to evade the rule by requesting consumer reports in the hopes of learning indirectly the same sensitive medical information the rule prohibits creditors from soliciting directly under the guise of compliance with the ability-to-repay and ability-to-pay rules, and is necessary and appropriate and will prevent evasions

¹⁴⁵ SBREFA Outline at 19.

¹⁴⁶ SBREFA Report at 36.

and facilitate compliance with the FCRA.

The CFPB does not believe that creditors would need to begin obtaining medical information from consumers under the proposed rule if they do not already do so. For example, the CFPB does not intend this proposal to change any existing law or guidance regarding the extent to which creditors may rely on consumer reports to assess consumers' current obligations in complying with repayment ability determination requirements.¹⁴⁷

The CFPB requests feedback on this aspect of the proposed rule and whether the proposal under consideration would assist a creditor or card issuer in making its repayment ability determination under TILA/Regulation Z. The CFPB also seeks comment on whether amendments should be made to § 1022.30(e)(1)(ii) to reflect the language in proposed § 1022.30(e)(6)—providing that a creditor or card issuer may not obtain or use medical information from a consumer reporting agency to comply with the ability-to-repay rule under 12 CFR 1026.43(c) for closed-end mortgages, the repayment ability rule under 12 CFR 1026.34(a)(4) for open-end, high-cost mortgages, or the ability-to-pay rule under 12 CFR 1026.51(a) for open-end (not home-secured) credit card accounts—or if the language in proposed § 1022.30(e)(6) is sufficient to explain how creditors can comply with the repayment ability determination requirements under TILA/Regulation Z.

VI. Proposed Effective Date

The Administrative Procedure Act generally requires that rules be published not less than 30 days before their effective dates.¹⁴⁸ The CFPB proposes that, once issued, the final rule for this proposed rule would be effective 60 days after it is published in the **Federal Register**. The CFPB preliminarily concludes that 60 days should be enough time for implementation. Creditors will likely need to do very little to comply with the rule to the extent that creditors currently only utilize medical debt information provided through consumer reports, which the CFPB understands is creditors' main source of medical debt information. In such cases, so long as

the consumer reporting agency providing the consumer report has complied with the rule, no medical debt information would be conveyed to the creditor, unless the consumer reporting agency has reason to believe the creditor intends to use the medical debt information in a manner not prohibited by the creditor prohibition. Creditors who currently obtain and use medical debt information (and other prohibited medical information) from other sources will need to establish controls to ensure that they do not obtain or use the medical debt information in a manner prohibited by the rule. Consumer reporting agencies will need to make coding changes to exclude data identified as medical information from consumer reports sent to creditors. However, the CFPB expects this to be a relatively simple coding change, particularly for the NCRAs and the consumer reporting agencies that obtain consumer reports from NCRAs for resale because the NCRAs already limit their reporting of medical collections. In addition, consumer reporting agencies may have already scoped out this kind of coding change to comply with reforms in several States. The CFPB requests comment on this proposed effective date.

VII. CFPB Section 1022(b) Analysis

The CFPB is considering the potential benefits, costs, and impacts of the proposed rule. The CFPB requests comment on the analysis presented below, as well as submissions of additional data that could inform its consideration of the impacts of the proposed rule. This section contains an analysis of the benefits and costs of the proposed rule for consumers, consumer reporting agencies, creditors, and other entities, such as health care providers and debt collectors.

A. Statement of Need

The FCRA supports the fairness, accuracy, and privacy of personal information in consumer reporting. Among the protections in the FCRA for consumers' medical information, FCRA section 604(g)(2) generally restricts creditors from obtaining or using medical information in connection with credit eligibility determinations, absent a regulatory exception. FCRA section 604(g)(5) requires that the CFPB determine that any such exception be necessary and appropriate and consistent with the intent of FCRA section 604(g)(2) to restrict the use of medical information for inappropriate purposes. The CFPB is also authorized under section 621(e) of the FCRA to issue regulations as may be necessary or

appropriate to administer and carry out the purposes and objectives of the FCRA, and to prevent evasions thereof or to facilitate compliance therewith. The CFPB anticipates that the proposed rule would enhance consumer privacy by removing the financial information exception at § 1022.30(d) that currently permits creditors to consider medical debt information and medical information about expenses, assets, and collateral, among other types of medical information, in underwriting decisions under certain circumstances.

Medical debt is prevalent in the United States, with 20 percent of households reporting that they had medical debt in 2022.¹⁴⁹ Reflecting this prevalence, medical collections have recently comprised the majority of credit collection tradelines found on consumer reports.¹⁵⁰ Like other information on consumer reports, medical collections information may be used by creditors to assess a consumer's ability to handle credit obligations.

Medical collections may result from unplanned expenditures, making medical collections information on consumer reports a potentially noisy or inaccurate signal of a consumer's ability to meet credit obligations. In the United States, high health care prices, uneven insurance coverage, complex health insurance networks, and cost-sharing features of health insurance may cause unexpected or chronic illnesses to result in large medical bills for individual consumers. Due to opaque medical pricing and billing practices, consumers often do not know the cost of medical services at the time those services are incurred, and may receive medical bills that they are uncertain they actually owe.¹⁵¹ Some consumers are unable to pay these bills on time, and some of these past-due medical bills eventually become medical collections.

Another factor that potentially makes medical collections an imprecise signal is that they are unevenly reported. Some health care providers allow debt collectors to furnish to consumer reporting agencies, while others do not.

¹⁴⁹ Consumer Fin. Prot. Bureau, *CFPB Estimates \$88 Billion in Medical Bills on Credit Reports* (Mar. 1, 2022), <https://www.consumerfinance.gov/about-us/newsroom/cfpb-estimates-88-billion-in-medical-bills-on-credit-reports/>.

¹⁵⁰ Consumer Fin. Prot. Bureau, *Medical debt burden in the United States*, at 5 (Mar. 1, 2022), <https://www.consumerfinance.gov/data-research/research-reports/medical-debt-burden-in-the-united-states/>.

¹⁵¹ See Consumer Fin. Prot. Bureau, *Complaint Bulletin: Medical billing and collection issues described in consumer complaints*, at 7–8 (Apr. 20, 2022), <https://www.consumerfinance.gov/data-research/research-reports/complaint-bulletin-medical-billing-and-collection-issues-described-in-consumer-complaints/>.

¹⁴⁷ See, e.g., Regulation Z comment 51(a)(1)(i)–7 (“A card issuer may consider the consumer’s current obligations based on information provided by the consumer or in a consumer report.”); see also § 1026.43(c)(3)(iii) (“[I]f a creditor relies on a consumer’s credit report to verify a consumer’s current debt obligations and a consumer’s application states a current debt obligation not shown in the consumer’s credit report, the creditor need not independently verify such an obligation.”)

¹⁴⁸ 5 U.S.C. 553(d).

Because of this, it is possible for consumers' medical debt in collections to be included unevenly on consumer reports, potentially leading to different financial outcomes. While a consumer could theoretically be able to factor this into their decision when selecting a health care provider, it is more likely that a consumer is not aware of which health care providers furnish and usually does not choose a health care provider based solely on a health care provider's collection policies, if they consider them at all.¹⁵²

When creditors base underwriting decisions on information that is unevenly reported and potentially erroneous, an economic tradeoff arises. Creditors balance the probabilities of making two types of error when deciding whether to lend to consumers. The first type of error occurs when creditors lend to consumers who are unable to repay the loan. The second type of error occurs when creditors choose not to lend to consumers who are able and willing to repay. Creditors lose potential revenues when they decline credit for consumers with reported medical collections. Similarly, consumers, who would have benefitted from access to credit, also lose from being denied credit because of reported medical collections.

The likelihood of making each of these types of error is affected by the informativeness of the signal medical collections provide to creditors. When medical collections are reported for debts that do not exist (for instance, because medical bills have been paid by insurance) and are prevalent, using this information will tend to increase the likelihood of the second type of error, without reducing the likelihood of the first type of error. In that situation, creditors who use medical collection information would benefit from not considering this information in their credit decisions. When medical collections are reported on the basis of debts that may in fact impair consumers' future repayment and are prevalent, creditors would experience a reduction in revenue if they do not consider medical collections in their credit decisions, due to an increase in likelihood of the first type of error. As a result, whether creditors would benefit from not being able to consider medical collections in their credit decisions is an empirical question. As discussed in part XI, *Technical*

Appendix, empirical analysis suggests that on balance, preventing creditors from using medical collection information in credit decisions would result in creditors extending credit to more consumers without diminishing the average performance of newly opened credit accounts.

If creditors could in fact benefit from disregarding medical debt information when making credit decisions, one would expect that creditors would have abandoned the practice out of their own profit motive. While, as discussed above, the industry has trended in this direction in recent years, the transition has not occurred fully, or quickly. The CFPB hypothesizes that the nexus of current contracts, expectations, and institutional structures that govern creditors' behavior prevents markets from moving to a potentially better equilibrium outcome. For instance, the market for mortgages is heavily driven by the secondary market for those loans. Similar factors likely drive creditor behavior in other consumer loan markets. Mortgage originators must follow underwriting practices that are expected by buyers in the secondary market, or they will not be able to securitize their loans. Since consideration of medical debt information has been expected by the market (if only implicitly through the use of commercially available credit scores), it is difficult for any one firm to move away from using that information, even if doing so would not increase risks for investors.¹⁵³

The proposed rule would generally prohibit creditors from considering medical debt information from consumer reports (among other sources) in underwriting decisions. Consequently, the incentive for medical debt holders and collectors to furnish to consumer reporting agencies would decrease. As a result, the proposed rule would enhance consumers' privacy with respect to their medical information, while also reducing the likelihood that the uneven reporting of medical collections would affect credit outcomes. While the proposed rule would reduce the amount, though not necessarily the quality, of information on which creditors can base underwriting decisions, the CFPB expects that, over time, those credit scoring models that currently use medical collections would be adjusted to reweight the remaining information on consumer reports. In the long run,

the expected adjustments to credit scoring models may help markets move toward a more efficient allocation of credit.

Adjustments to credit scoring models may result in credit being extended to more consumers who are able and willing to repay their credit obligations. This may allow consumers to benefit from increased access to credit and creditors to increase overall revenues. Moreover, since medical collections tradelines on consumer reports are prone to error, removing medical debt from consumer reports would reduce the need for dispute resolution, potentially saving both consumers and consumer reporting agencies time and resources.

B. Data and Evidence

The CFPB's analysis of costs, benefits, and impact is informed by data from a range of sources. As discussed in part III.A, when the interventions discussed in this proposed rule were part of the broader Consumer Reporting Rulemaking, the CFPB convened a Small Business Review Advisory Panel in October 2023 to gather input from small businesses. The discussions at the panel meetings and the comment letters submitted by small entity representatives during this process were presented in a Panel Report completed in December 2023. The CFPB also invited and received feedback on the proposals under consideration from other stakeholders, including stakeholders who were not small entity representatives. The impact analysis is further informed by academic research, reports on research by industry and trade groups, practitioner studies, and comment letters received by the CFPB. Where used, these specific sources are cited in this analysis.

The CFPB also used its own Consumer Credit Information Panel (CCIP) to estimate the potential impacts of the proposed rule on consumers and creditors. The CCIP is a 1-in-50, nationally representative sample of deidentified consumer reports from one of the three nationwide consumer reporting agencies (NCRAs). The data allowed the CFPB to conduct analyses of the predictive value of medical collections information in the context of whether a consumer's application for credit was successful (determined by whether a creditor's inquiry following such an application led to the origination of a credit account or, in other words, inquiry success) and future credit account delinquencies. Such analyses are useful for quantifying the proposed rule's potential impacts to consumers and creditors. While the

¹⁵² Noam M. Levey, *Hundreds of Hospitals Sue Patients or Threaten Their Credit*, a KHN Investigation Finds. Does Yours?, KFF Health News (Dec. 21, 2022), <https://kffhealthnews.org/news/article/medical-debt-hospitals-sue-patients-threaten-credit-khn-investigation/>.

¹⁵³ Loretta J. Mester, *Fed. Rsvr. Bank of Phila., What's the Point of Credit Scoring?*, *Bus. Rev.*, at 6 (Sept./Oct. 1997), <https://www.philadelphiafed.org/-/media/frbp/assets/economy/articles/business-review/1997/september-october/brso971m.pdf>.

CCIP is nationally representative, it only contains information for consumers who have consumer reports. In addition, because the CCIP data are drawn from consumer reports from a single NCRA and because medical collections are unevenly reported, the data might not contain all medical collections that exist in the United States. The CFPB requests additional data that can be used to expand the impact analysis.

To quantify health care providers' exposure to unpaid medical bills, the CFPB used data from the Hospital Cost Reporting Information System (HCRIS), which is administered by the Centers for Medicare and Medicaid Services. The HCRIS data contain annual cost reports filed by Medicare-certified hospitals in the United States. The data comprise information on hospitals, their revenues, operating costs, and bad debt expenses not reimbursable by Medicare. While almost all hospitals file these cost reports, the data do not include unpaid medical debts owed to health care providers that are not hospitals.¹⁵⁴ The CFPB requests additional data from health care providers and debt collectors that can be used to quantify potential impacts on entities other than hospitals.

Due to these data limitations, the analysis presented in this part generally provides a qualitative discussion of the proposed rule's costs and benefits and includes quantitative estimates whenever possible. The CFPB requests data that can be used to quantify the analysis of impacts, or submission of studies that contain relevant estimates that can be used in the analysis of impacts.

C. Coverage of the Proposed Rule

Part VIII.B.3 provides a discussion of the estimated number and types of entities potentially affected by the proposed rule.

D. Baseline for Consideration of Costs and Benefits

The impact analysis compares the proposed rule's potential benefits and costs against a baseline in which the CFPB takes no regulatory action. This baseline includes existing Federal and State law and current furnishing practices. Under the baseline, creditors are generally allowed to consider medical collections information on consumer reports in underwriting

decisions due to the financial information exception at § 1022.30(d).

Over the last few years, the three NCRA's implemented several voluntary changes in the consumer reporting of medical debt. In September 2017, the NCRA's implemented a 180-day waiting period before including furnished medical collections on consumer reports.¹⁵⁵ In July 2022, the NCRA's extended the waiting period from 180 days to one year and removed all paid medical collections from consumer reports. Finally, in April 2023, the NCRA's removed both paid and unpaid medical collections under \$500 from consumer reports.¹⁵⁶

It is the CFPB's understanding that health care providers and debt collectors they contract with currently use three types of collection practices to collect medical debt: contacting consumers by mail, phone, or other means; debt collection litigation; and furnishing medical collections information to consumer reporting agencies. The impact analysis considers how health care providers and debt collectors may respond to the proposed rule by switching to the first two collection practices if furnishing becomes a less effective means of inducing payment.

The evolving landscape of State laws and consumer reporting practices may change medical collections reporting in the absence of the proposed rule, affecting the baseline. The voluntary changes recently implemented by the NCRA's could be reversed at any time, and such reversals would tend to amplify the impacts of the proposed rule.

In the current state of the world, creditors are generally allowed to consider medical debt information in underwriting decisions, including medical collections information found on consumer reports. Some recently passed State laws establish when medical collections information originating from these States can be furnished to consumer reporting agencies or included on consumer reports.¹⁵⁷ The only medical collections

that the NCRA's include in their consumer reports are those that: (1) are more than one year past due, (2) are for collection amounts greater than \$500, (3) are unpaid, and (4) would not violate State laws that restrict or prohibit consumer reporting of medical collections. By August 2023, after the voluntary NCRA changes were fully implemented but before most of the State-level changes took effect, an estimated 5 percent of consumers had medical collections on their consumer reports.¹⁵⁸ The proposed rule would remove these remaining medical collections from, and generally prohibit future medical collections from being included in, consumer reports provided to creditors.

E. Potential Benefits and Costs to Consumers and Covered Persons

1. Costs to Consumer Reporting Agencies

The proposed rule would generally prohibit consumer reporting agencies from including medical collections information on consumer reports provided to creditors. Consumer reporting agencies may lose revenue if, due to the proposed rule, debt collectors perceive consumer reports as less informative for guiding collection activities. This prohibition may also decrease the incentive for health care providers and debt collectors to furnish medical collections to consumer reporting agencies, although consumer reporting agencies would still be able to include medical collections information on the reports that they provide for non-credit eligibility determination purposes such as with regard to employment or insurance, or to consumers seeking a copy of their own consumer reports. This means that health care providers and debt collectors may still see some value in reporting medical collections to consumer reporting agencies, including to the three NCRA's. However, it is possible that in response to the proposed rule, consumer reporting agencies would remove medical collections from consumer reports under all circumstances. Consumer reporting agencies may also incur fixed operational and compliance costs to conform to the proposed rule.

¹⁵⁵ Nat'l Pub. Radio, *Credit Agencies To Ease Up On Medical Debt Reporting* (July 11, 2017), <https://www.npr.org/sections/health-shots/2017/07/11/536501809/credit-agencies-to-ease-up-on-medical-debt-reporting>.

¹⁵⁶ Fredric Blavin et al., *Urban Wire*, Urban Inst., *Medical Debt Was Erased from Credit Records for Most Consumers, Potentially Improving Many Americans' Lives* (Nov. 2, 2023), <https://www.urban.org/urban-wire/medical-debt-was-erased-credit-records-most-consumers-potentially-improving-many>.

¹⁵⁷ See, e.g., Colo. Rev. Stat. section 5–18–109; N.Y. Pub. Health Law art. 49–A; 2024 Conn. Act 24–6; 2024 Va. Acts ch. 751.

¹⁵⁴ Nat'l Pub. Radio, *Nursing homes are suing friends and family to collect on patients' bills* (July 28, 2022), <https://www.npr.org/sections/health-shots/2022/07/28/1113134049/nursing-homes-are-suing-friends-and-family-to-collect-on-patients-bills>.

¹⁵⁸ Ryan Sandler & Zachary Blizard, Consumer Fin. Prot. Bureau, *Recent Changes in Medical Collections on Consumer Credit Records Data Point*, at 3–4 (Mar. 2024), https://files.consumerfinance.gov/f/documents/cfpb_recent-changes-medical-collections-on-consumer-credit-reports_2024-03.pdf.

Creditors May Be Less Willing To Pay for Consumer Reports

Creditors use information from consumer reports, usually obtained from the NCRAs, to reduce the risk of lending to consumers who may be unable to repay. Removing medical collections information from consumer reports provided to creditors for credit decisions would reduce the information they contain relative to the case today or, in other words, the baseline. In theory, if creditors expect medical collections information to be on consumer reports, or if they view medical collections information as critical to their assessment of the riskiness of lending to consumers, their willingness to pay consumer reporting agencies for consumer reports that do not contain medical collections information may decrease. While this is not a view shared by the CFPB, one NCRA commenter who submitted views to the CFPB during the SBREFA process stated that it considers medical collections as predictive of a consumer's willingness and repayment ability and believes that the complete removal of medical collections from consumer reporting would "degrade the accuracy of consumer reporting." However, creditors would likely find the remaining information on consumer reports to still be valuable, mitigating the reduction in demand for consumer reports that may result from the proposed rule. The CFPB requests comment on this issue, as well as data that can be used to quantify creditors' demand for consumer reports.

CFPB research finds that the use of medical collections information from consumer reports provided by the NCRAs to creditors seems to vary by creditor type. Medical collections information appears to be most used by credit card providers, with a credit card inquiry being less successful when it is made after (rather than before) a medical collection appears on a consumer report of a consumer that previously had no nonmedical collections tradelines. To a lesser extent, mortgage providers also appear to use medical collections information.¹⁵⁹ However, the CFPB has no information on the extent to which consumer reporting agencies' revenues from consumer reports generally are driven by sales to these creditor types. The CFPB requests further information to quantify its analysis of the potential revenue losses due to different creditors' decreased demand for consumer reports.

Debt Collectors May Be Less Willing To Pay for Consumer Reports

At baseline, debt collectors may use information from consumer reports to determine a consumer's ability to pay the collection amount and to guide what collection practices will be most cost-effective. Debt collector small entity representatives, in their submitted comments, stated that they found medical debt information on consumer reports to be relevant to estimating whether a consumer will repay a debt that is in collections.¹⁶⁰ Should medical debt holders and their assignees (e.g., debt collectors or debt buyers) cease furnishing medical collections information to consumer reporting agencies as a result of this proposed rule, debt collectors would no longer have access to medical collections information previously included in consumer reports to assess whether a consumer will repay a specific medical debt in collections. While the remaining information on consumer reports may still be useful to guide their decisions, the loss of medical collections information may reduce debt collectors' willingness to pay for consumer reports from consumer reporting agencies. The CFPB requests data from debt collectors to assess the usefulness of medical collections information for debt collectors' collection practices, as well as data from the NCRAs and other consumer reporting agencies, to quantify the potential revenue losses from reduced sales of consumer reports to debt collectors.

One-Time Operational and Compliance Costs

Consumer reporting agencies may incur one-time costs to comply with the proposed rule. Consumer reporting agencies may need to modify their reporting systems and databases and revise the guidance documents they provide to furnishers. Consumer reporting agencies may also need to reorganize their computer systems and databases such that no medical debt information is contained in consumer reports provided to creditors for credit eligibility determinations. However, some operational and compliance costs that may have otherwise been caused by the proposed rule may have already been incurred to some degree to comply with certain States' laws. The CFPB does not have information on the reporting systems and databases used by most consumer reporting agencies at baseline and requests data that can be used to quantify costs that may be

incurred or have already been incurred by consumer reporting agencies.

Compliance costs may be different for the three NCRAs (Equifax, Experian, and TransUnion) and Innovis compared to other consumer reporting agencies. The NCRAs and Innovis are known to provide a standardized data format to furnishers, called Metro 2, and have organized their databases to process and screen data furnished in this format.¹⁶¹ At baseline, the three NCRAs do not include medical collections under \$500, medical collections that are less than one year past due, or paid medical collections on any consumer report provided to third parties. The use of the Metro 2 format constitutes an ongoing compliance cost for the NCRAs. It is likely that they already have systems in place to screen out any furnished medical collections that may violate these conditions. It is possible that the NCRAs' and Innovis's screening process may have to be expanded such that they do not accidentally include medical collections submitted by furnishers on consumer reports provided to creditors. However, the Metro 2 format that the NCRAs and Innovis currently provide to furnishers may help facilitate compliance, because tradeline information submitted by furnishers is already required to include codes that specify when a debt is a medical debt.¹⁶² In addition, complying with the proposed rule may only require an extension of the changes the NCRAs and Innovis have made or plan to make to account for laws passed in several states, including New York, Colorado, Connecticut, and Virginia.¹⁶³ A SBREFA commenter, not representing the NCRAs, posited that making the necessary changes would be a significant undertaking in terms of time and cost and that the NCRAs would have to reconfigure, test, and validate their current compliance programs. Consumer reporting agencies that have different screening processes and databases that do not rely on the Metro 2 format may incur different compliance costs associated with their own systems, though, as noted above, some

¹⁶¹ The CFPB does not have information on whether other consumer reporting agencies also rely on the Metro 2 format. For an overview of how NCRAs and Innovis, another CRA, receive and screen furnished data, see Consumer Fin. Prot. Bureau, *Key Dimensions and Processes in the U.S. Credit Reporting System: A review of how the nation's largest credit bureaus manage consumer data*, at 19 (Dec. 2012), https://files.consumerfinance.gov/f/201212_cfpb_credit-reporting-white-paper.pdf.

¹⁶² *Id.* at 16–19.

¹⁶³ See, e.g., Colo. Rev. Stat. section 5–18–109; N.Y. Pub. Health Law art. 49–A; 2024 Conn. Act 24–6; 2024 Va. Acts ch. 751.

¹⁵⁹ See part XI, *Technical Appendix*, to this proposed rule.

¹⁶⁰ SBREFA Report at 36.

compliance costs may already have been incurred to comply with State laws. The compliance costs for consumer reporting agencies could be greater if medical information furnishers do not comply with their FCRA section 623(a)(9) obligation to notify consumer reporting agencies of their status,¹⁶⁴ though the CFPB does not have any indication that medical information furnishers are not complying with that notification requirement. Consumer reporting agencies may incur costs to screen medical information provided by such furnishers, or for which there is no medical information furnisher within the meaning of FCRA section 623(a)(9), from consumer reports provided to creditors for credit eligibility determinations. The CFPB requests comment and information on this potential compliance cost. The CFPB also requests data to quantify general operational and compliance costs that may be incurred by consumer reporting agencies, as well as information on other possible one-time costs.

2. Benefits to Consumer Reporting Agencies

The removal of medical collections information from consumer reports provided to creditors may also reduce consumer reporting agencies' costs by potentially reducing the number of accounts that consumer reporting agencies must screen or conduct accuracy checks for, and the number of consumer disputes that they may need to resolve. Consumer reporting agencies regularly process significant amounts of data. For example, the NCRAs receive information on over 1 billion tradelines each month and must accurately compile this information for each consumer.¹⁶⁵ Under the FCRA, consumers have the right to dispute inaccuracies on their consumer report, and consumer reporting agencies are obligated to investigate and resolve them if necessary.¹⁶⁶ This dispute resolution process imposes costs on consumer reporting agencies. A CFPB analysis shows that 5.7 percent of medical collections tradelines had a dispute flag at one point, much higher than the rate of dispute flags for credit cards and student loans.¹⁶⁷ One NCRA commenter reported that their data shows that while consumers dispute

medical collections tradelines more often than other tradelines, they do so at a similar rate to consumers disputing delinquent tradelines. To the extent that medical collections tradelines contribute to the number of disputes that consumer reporting agencies resolve, removing medical collections information from consumer reports may reduce consumer reporting agencies' costs associated with dispute resolution. However, the CFPB does not have data to estimate the cost reduction in dispute management that consumer reporting agencies may experience if medical debt information is prohibited from appearing on most consumer reports provided to creditors. The CFPB requests data to quantify these potential cost-reducing benefits.

3. Costs to Health Care Providers

As discussed above, the CFPB understands that some health care providers and their debt collectors currently use furnishing of medical debt information as a means of inducing payment on post-service billed amounts owed by the patient, although this is not one of the purposes of credit reporting as stated in the FCRA.¹⁶⁸ Because medical debt information generally would no longer be included on consumer reports provided for credit eligibility determinations, the proposed rule may reduce the effectiveness of this means of inducing payment on post-service billed amounts owed by the patient. However, post-service billed amounts paid out of pocket by patients is a small fraction of overall health care revenue and thus the overall impact on revenue is likely to be limited. In addition, the effect on health care providers that incur additional costs from pursuing debt collection lawsuits to mitigate non-payment would be marginal given that, at baseline, recovery rates associated with furnished medical collections are already low and health care providers already use litigation to pursue some debts.¹⁶⁹ As discussed in *Costs to Medical Debt Collectors*, debt buyers that also engage in debt collection may be less willing to pay for medical debt if furnishing becomes a less effective way of inducing payment from consumers. This may

further reduce the revenues of health care providers that sell medical debt to debt buyers. The CFPB requests comment on these issues, as well as data that can be used to quantify potential impacts to health care revenues and costs from potential non-payment of post-service bills, increases in debt collection litigation, and reduction in sales of medical debt to debt buyers who also engage in debt collection. These impacts are discussed in detail below.

Potential Reduction in Revenues From Post-Service Bills Sent to Patients

The vast majority of health care providers' revenues comes from insurance (e.g., Medicare, Medicaid, private insurance) and other third-party payers. Out-of-pocket spending by consumers only accounts for about 11 percent of national health expenditures.¹⁷⁰ Of that 11 percent, a significant proportion is paid at point of service at a pharmacy or doctor's office.¹⁷¹ The CFPB's analysis of hospital-level cost reports from the Healthcare Provider Cost Reporting Information System (HCRIS) provided by the Centers for Medicare and Medicaid Services (CMS) indicates that 72 percent of hospitals had non-Medicare bad debt expenses in 2021.¹⁷² These bad debt expenses on average represent about 6 percent of total costs in 2021 for hospitals that had non-Medicare bad debt. At baseline, industry expectations of bad debt recovery are low, with a 25 percent recovery rate used as a benchmark.¹⁷³ Assuming that

¹⁷⁰ Ctrs. for Medicare & Medicaid Servs., *NHE Fact Sheet*, <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet> (last modified Dec. 12, 2023). Several SBREFA commenters claimed that the voluntary reporting changes implemented by the NCRAs would result in an 11 percent decrease in their revenues, which likely is an outlier or perhaps a misstatement given the overall share of out-of-pocket spending.

¹⁷¹ In addition, 55 percent of patients with health insurance paid their out-of-pocket bill in 2021. See Crowe, *Hospital collection rates for self-pay patient accounts*, at 8 (Aug. 2022), <https://www.crowe.com/insights/asset/h/hospital-collection-rates-for-self-pay-patient-accounts-report>.

¹⁷² 2021 is the latest year for which the cost report data are available. Hospitals classify medical bills as bad debt expenses when they determine that consumers are unlikely to repay. Non-Medicare bad debt consists of past-due medical bills from patients who are not Medicare beneficiaries. See Am. Hosp. Ass'n, *Uncompensated Hospital Care Cost Fact Sheet* (Feb. 2022), <https://www.aha.org/fact-sheets/2020-01-06-fact-sheet-uncompensated-hospital-care-cost> and Ctrs. for Medicare & Medicaid Servs., *Hospital Provider Cost Report Data Dictionary* (Dec. 13, 2023), <https://data.cms.gov/resources/hospital-provider-cost-report-data-dictionary>.

¹⁷³ See, e.g., MD Clarity, *RCM Metrics Bad Debt Recovery Rate*, <https://www.mdclarity.com/rcm-metrics/bad-debt-recovery-rate> (last visited May 22, 2024).

¹⁶⁴ 15 U.S.C. 1681s–2(a)(9).

¹⁶⁵ *Id.* at 23.

¹⁶⁶ 15 U.S.C. 1681i(a)(1)(A).

¹⁶⁷ Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

¹⁶⁸ See 15 U.S.C. 1681(a).

¹⁶⁹ It is possible for debt collectors to furnish to consumer reporting agencies and pursue debt litigation for the same account. As discussed in *Costs to Medical Debt Collectors*, only 2.5 percent of medical collections on consumer reports are ever reported as paid. See Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

health care providers achieve a 25 percent recovery rate at baseline, the CFPB estimates that bad debt expenses may rise to at most 7.5 percent of total costs on average. However, this rise assumes that bad debt recovery rates decrease to zero. This may be unlikely given health care providers' use of other collection practices, such as patient outreach and debt collection litigation.¹⁷⁴ The CFPB requests comment on this issue, as well as data that may be used to quantify potential increases in non-Medicare bad debt.

Given the state of health care industry billing practices and business models at baseline, it is unlikely that the proposed rule would change industry practices with respect to billing. In theory, to mitigate potential revenue losses, health care providers could implement operational changes including adding upfront payment options for patients and refusing non-emergency services if patients have an overdue account. However, the CFPB notes that it is illegal to refuse to provide some health care services in certain emergency contexts and that emergency services represent a significant share of health care spending.¹⁷⁵ At baseline, there is already a substantial economic incentive to require upfront payment or deny service to patients with overdue accounts given that recovery rates on billed expenses to patients are already low.¹⁷⁶ The proposed rule may only marginally increase the incentive to require prepayment or upfront payment. Upfront payment is already a uniform practice in pharmacies, and prepayment or point-of-service payment for out-of-pocket expenses is commonplace for

providers of health care services as well.¹⁷⁷ The CFPB expects that it is unlikely that a decrease in the recovery rates of furnished medical collections would cause health care providers to substantially change their operational and billing procedures in light of already existing incentives. The CFPB requests comment on these issues and requests information on health care providers' billing practices and provision of health care services that can be used to quantify the magnitude of potential revenue losses and consequences.

The CFPB understands that many health care providers sell medical debt to debt buyers. These debt buyers often also engage in debt collection and furnish medical collections information to consumer reporting agencies. Debt buyers purchase these bundles of medical debt from health care providers at a price that is a fraction of the nominal value of the medical bills.¹⁷⁸ Because the proposed rule may reduce the effectiveness of furnishing medical collections as a collection practice, the CFPB expects debt buyers' demand for medical debt bundles sold by health care providers to potentially decrease. If so, the resulting decrease in the price of medical debt bundles would further reduce the revenues of the affected health care providers. Depending on the magnitude of the decrease in price, health care providers may consider collecting the debt themselves or writing the debt off. However, the revenues of health care providers that at baseline do not allow debt collectors to furnish medical collections information would not be affected in this way. The CFPB does not have data with which to quantify the magnitude of this expected decrease in the price of medical debt bundles on the secondary market, nor does it have information on the current prevalence of health care providers allowing debt collectors to furnish medical collections information to consumer reporting agencies. The CFPB requests data from health care providers to help quantify their potential reduction in revenues from the sale of medical debt bundles to debt buyers.

¹⁷⁷ According to an HFMA survey, 96 percent of health care industry respondents reported having pre-payment or point-of-service collection policies and procedures. Healthcare Fin. Mgmt. Ass'n, *Analyzing pre-payment and point-of-service collections efforts* (Aug. 15, 2021), <https://www.hfma.org/technology/analyzing-pre-payment-and-point-of-service-collections-efforts/>.

¹⁷⁸ Fed. Trade Comm'n, *The Structure and Practices of the Debt Buying Industry*, at 22–23 (Jan. 2013), <https://www.ftc.gov/reports/structure-practices-debt-buying-industry>.

Potential Increased Use of Litigation To Collect Medical Debt

The potential for revenue losses described above may affect the rate at which health care providers or the debt collectors they work with choose to file debt collection lawsuits against consumers.¹⁷⁹ Should this happen, it may impose additional costs on health care providers, since pursuing litigation entails some fixed and variable costs. However, repayment rates for medical debt in collections have been historically quite low, and pursuing additional lawsuits as a result of the proposed rule is not likely to result in an increase in marginal recovery rates.¹⁸⁰ At baseline, health care providers can already pursue debt collection litigation in conjunction with other collection practices. Accordingly, the CFPB expects that any increase in overall litigation frequency would be limited. The CFPB requests comment on this issue and requests data that may help quantify this potential increase.

Medical debt collection lawsuits tend to be filed in small claims courts and to involve amounts of less than \$10,000, with most lawsuits ending in default judgment in favor of plaintiffs.¹⁸¹ Health care providers may contract with debt collectors to file debt collection lawsuits on their behalf.¹⁸² Depending on whether health care providers sell or assign medical debt to debt collectors, it can be difficult to assess who decides to bring and incur the costs associated with debt collection lawsuits. Health care providers may sell medical debt to debt buyers who also engage in debt collection, thereby transferring ownership for the debt.¹⁸³ In such cases, the decision of whether to pursue

¹⁷⁹ Judith Garber, Lown Inst., *Which hospitals are suing patients? Investigation reveals hospital billing practices*, (Feb. 17, 2023), <https://lowninstitute.org/which-hospitals-are-suing-patients-investigation-reveals-hospital-billing-practices/>.

¹⁸⁰ CFPB research suggests that only around 2.5 percent of medical collection accounts furnished to the NCRAs are ever reported as paid. See Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

¹⁸¹ The Pew Charitable Trusts, *How Debt Collectors Are Transforming the Business of State Courts* (May 6, 2020), <https://www.pewtrusts.org/en/research-and-analysis/reports/2020/05/how-debt-collectors-are-transforming-the-business-of-state-courts>.

¹⁸² John Ingold & Chris Vanderveen, *UCHealth sues thousands of patients every year. But you won't find its name on the lawsuits*, *Colorado Sun* (Feb. 19, 2024), <https://coloradosun.com/2024/02/19/uchhealth-debt-collectors/>.

¹⁸³ Fed. Trade Comm'n, *The Structure and Practices of the Debt Buying Industry* (Jan. 2013), <https://www.ftc.gov/reports/structure-practices-debt-buying-industry>.

¹⁷⁴ In practice, the bad debt recovery rate may be even lower than the industry benchmark, further limiting the potential rise in non-Medicare bad debt that may result from the proposed rule. Using a 2018 survey, the recovery rate for collection accounts generally was estimated to be 11 percent. See ACA Int'l, *Kaulkin Ginsberg 2020 State of the Industry Report* (Sept. 21, 2020), <https://policymakers.acainternational.org/whitepapers/2020/09/21/2018-state-of-the-industry-report/>.

¹⁷⁵ See, e.g., Scott KW et al., *Healthcare spending in US emergency departments by health condition, 2006–2016*, *PLoS One* (Oct. 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8550368/>.

¹⁷⁶ According to a Healthcare Financial Management Association (HFMA) report, the industry expectation is health care providers will recover only 30 percent of amounts billed after discharge. Healthcare Fin. Mgmt. Ass'n, *Address Patient Financial Risk in Pre-Service to Boost Revenue and Earn Loyalty* (July 12, 2018), <https://www.hfma.org/revenue-cycle/financial-counseling/61208/>. In addition, collecting post-service bills is time consuming, with 75 percent of health care providers needing more than one statement to collect a patient balance. See J.P. Morgan Healthcare Payments, *Trends in Healthcare Payments* (Mar. 26, 2024), <https://www.jpmorgan.com/insights/payments/payment-trends/healthcare-payment-trends>.

litigation is made by the debt buyer, and they become the main plaintiff in a debt collection lawsuit. However, some health care providers only assign medical debt to debt collectors, while retaining ownership of the medical debt, and ultimately deciding themselves whether to pursue debt collection litigation. When debt collection litigation happens this way, the debt collectors may be listed as plaintiffs even though it may be the health care providers that pay the bulk of the litigation costs. For example, debt collectors working with UC Health, the largest hospital system in Colorado, were recently reported to have filed 15,710 lawsuits from 2019 through 2023.¹⁸⁴ In this case, the medical debts were “assigned” to debt collectors, but UC Health retained ownership of the medical debts and shared a portion of the recovered payments with the debt collectors.

Health care providers themselves can also file debt collection lawsuits on their own behalf.¹⁸⁵ Health care providers may incur a mix of fixed costs and variable litigation costs. Fixed costs of litigation may include the costs of retaining and maintaining relationships with legal providers, as well as hiring additional staff. Health care providers that already take legal action against their patients might not need to incur these fixed costs. Using a random 10 percent sample of hospitals in the United States, a recent investigation found that over two-thirds of hospitals already take legal action to collect unpaid medical bills, implying that many health care providers currently have some capacity to file debt collection lawsuits at baseline.¹⁸⁶

Separate from fixed costs are variable costs that increase with the number and complexity of the debt collection lawsuits that hospitals choose to pursue. These are primarily court filing fees and attorney fees. Court filing fees vary depending on the jurisdiction and the collection amounts, making it difficult to estimate costs that hospitals may

face.¹⁸⁷ Attorneys can be paid on an hourly basis or on a contingency fee basis. However, if health care providers already employ in-house attorneys, this may reduce the need to pay additional attorney fees to pursue debt collection litigation. In addition, some jurisdictions allow health care providers to add filing fees, attorney fees, and other litigation costs to the judgment amount, partially shifting some of the cost of pursuing debt collection lawsuits to consumers if health care providers secure a favorable judgment.¹⁸⁸ The CFPB does not have data to quantify these costs of debt collection litigation that health care providers may incur and requests information from health care providers who currently pursue debt collection lawsuits.

Because health care providers already have the option to pursue debt collection lawsuits under the baseline, the total costs of increased debt collection litigation would depend on how many additional medical debt collection lawsuits arise because of the proposed rule. The proposed rule would affect the consumer reporting of medical collections above \$500, because medical debts under \$500 are already removed from consumer reports from the NCRAs at baseline. Since debt collection lawsuits are filed and recorded in State or lower-level courts, the CFPB does not have data to quantify the additional debt collection lawsuits that health care providers may pursue after the proposed rule is implemented.¹⁸⁹ The CFPB requests information from health care providers on the amounts involved in current debt collection litigation.

4. Costs to Medical Debt Collectors and Debt Buyers

Debt collectors (including debt buyers who also engage in debt collection) generally use three types of collection practices. Debt collectors may use means of communication such as mail and phone calls to locate consumers,

inform them of the stated collection amount, and negotiate payment. They may also furnish medical collections information to consumer reporting agencies (generally, one or more of the NCRAs) to induce payment from consumers. Finally, debt collectors can file debt collection lawsuits against consumers.

Debt collectors may switch to the other two types of collection practices if consumer reporting agencies stop including medical collections information on consumer reports provided for credit eligibility determinations. To the extent that debt collectors rely primarily on furnishing to induce payment at baseline, the proposed rule may reduce their profits if the other collection practices that are not restricted under the proposed rule are costlier or less effective. Comments received from debt collector small entity representatives during the SBREFA process indicate that furnishing medical collections information to NCRAs costs approximately \$10 per account, while debt collection litigation costs approximately \$500 per account.¹⁹⁰ At baseline, it is possible for debt collectors to furnish to the NCRAs and pursue debt litigation for the same account. Due to the cost difference, debt collectors likely incur furnishing costs on a much larger percentage of accounts than they incur litigation costs, and so this may represent either a net saving or net cost for debt collectors, depending on the specific firm’s furnishing practices and increase in litigation activity. The CFPB requests comment on this issue and data to quantify changes in litigation costs. Debt collectors may have to incur both fixed and variable costs to increase their use of collection practices other than medical collections furnishing if the proposed rule is finalized. If collecting medical debt becomes more difficult, debt buyers, including those that also engage in debt collection, may also attempt to negotiate a lower price when they purchase medical debt from health care providers. This lower price might reduce health care providers’ willingness to sell medical debt to debt buyers.

Given the reporting changes implemented by the NCRAs in recent years, it is possible that some debt collectors have at least partially incurred the fixed and variable costs of switching to collection practices that do not involve furnishing of medical debt. However, the CFPB does not have data to assess the relative prevalence, costs, and effectiveness of the various collection practices that debt collectors

¹⁸⁴ John Ingold & Chris Vanderveen, *Colorado’s largest hospital system is quietly suing thousands of patients every year over unpaid bills*, The Denver Post (Feb. 21, 2024), <https://www.denverpost.com/2024/02/21/uchealth-medical-debt-lawsuits-colorado/>.

¹⁸⁵ Joseph Giuseppe R. Paturzo et al., *Trends in Hospital Lawsuits Filed Against Patients for Unpaid Bills Following Published Research About This Activity*, JAMA Network Open (Aug. 23, 2021), <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2783297>.

¹⁸⁶ Noam M. Levey, *Hundreds of Hospitals Sue Patients or Threaten Their Credit, a KHN Investigation Finds. Does Yours?*, KFF Health News (Dec. 21, 2022), <https://kffhealthnews.org/news/article/medical-debt-hospitals-sue-patients-threaten-credit-khn-investigation/>.

¹⁸⁷ See, e.g., the fee schedule for Small Claims Court in Maryland, <https://www.mdcourts.gov/legalhelp/smallclaims>, the corresponding fee schedule for regular civil cases, <https://www.mdcourts.gov/courts/feeschedules>, a comparison between small claims and regular civil cases in California, <https://selfhelp.courts.ca.gov/small-claims-or-limited-civil> (all last visited May 12, 2024).

¹⁸⁸ Casey Tolan & Ed Lavandera, *Arkansas hospital sued thousands of patients over medical bills during the pandemic, including hundreds of its own employees*, CNN (Sept. 8, 2023), <https://www.cnn.com/2023/09/08/us/arkansas-hospital-debt-collections-lawsuits-pandemic/index.html>.

¹⁸⁹ Blake N. Shultz et al., *Hospital Debt Collection Practices Require Urgent Reform*, Health Affairs (May 2, 2022), <https://www.healthaffairs.org/content/forefront/hospital-debt-collection-practices-require-urgent-reform>.

¹⁹⁰ SBREFA Report at 38.

use at baseline. The CFPB requests data to quantify the impacts on debt collectors.

Increased Use of Traditional Methods of Debt Collection

Because many debt collectors rely on furnishing medical collections information at baseline, they may have to incur costs from having to increase their use of the collection practices that would not be restricted under the proposed rule. Relative to furnishing medical collections information, contacting consumers through traditional methods of debt collection that include mail, phone, or other means may be more time-intensive and expensive. Some debt collector small entity representatives expect to have to increase staffing by 10 percent as a result. This potential staffing increase may create new jobs. Increased staffing may also impose additional labor costs on debt collectors. These small entity representatives also expect to incur fixed costs associated with “rewriting policies and procedures, training employees, updating systems, and renegotiating contracts” with health care providers.¹⁹¹ The CFPB requests additional information on the costs that debt collectors incur when using traditional methods of communication with consumers, and the effectiveness of these methods for recovering the collection amounts.

Increased Use of Debt Collection Litigation

Debt collectors may also respond to the proposed rule by increasing their use of debt collection lawsuits. In choosing whether to pursue debt collection litigation, debt collectors likely compare the cost of litigation with the expected recovery amount in the event of a favorable judgment. Under the baseline, debt collectors also likely compare the expected effectiveness of litigation against furnishing, although they can choose to furnish and pursue litigation for the same debt. The CFPB does not have data to directly compare the relative efficacy of furnishing and litigation for inducing payment.

Debt collectors may incur a mix of fixed costs and variable costs when they increase their use of debt collection lawsuits. Fixed costs of litigation include the costs of hiring and maintaining relationships with attorneys. Debt collectors that already pursue debt collection lawsuits may not need to incur these fixed costs. However, the CFPB does not have information on the current prevalence of

debt collection lawsuits relative to other collection practices used by debt collectors.

Debt collectors may also incur variable costs that increase with the number and complexity of debt collection lawsuits. Court filing fees vary depending on the jurisdiction and the collection amounts, making it difficult to estimate the increase in costs that debt collectors may incur.¹⁹² Attorneys can be paid on an hourly basis or on a contingency fee basis. However, if debt collectors already employ attorneys in house or under a flat fee arrangement, this may reduce the need to pay additional attorney fees should they increasingly pursue debt collection lawsuits. The CFPB does not have data to quantify these costs of debt collection litigation, and requests further information on the debt collection litigation activities of debt collectors.

The CFPB expects that the increase in total costs associated with debt collection litigation would depend on the number of additional debt collection lawsuits that debt collectors pursue if the proposed rule is finalized. At baseline, medical collections information is included in the consumer reports from the NCRAs if the medical collections are for amounts above \$500. Debt collectors appear to use debt collection litigation for both small and large collection amounts, but some research indicates that most debt collection lawsuits are pursued for collection amounts larger than \$500.¹⁹³ Without comprehensive data on the distribution of stated medical collection amounts, the CFPB cannot provide an estimate of the number of additional debt collection lawsuits that debt collectors may pursue.

Potentially Decreased Recovery Rates

Based on available information, the CFPB expects that approximately 2.5 percent of medical collection accounts are recovered by debt collectors who furnish medical collections information to the NCRAs, as estimated using the share of medical collections marked as paid on consumer reports.¹⁹⁴ The CFPB

requests comment or data submissions that may better approximate the share of medical collections that are recovered by debt collectors. If consumers are no longer concerned that unpaid medical bills will appear on their consumer report when they are seeking credit, they may have less incentive to pay the collection amount even if debt collectors seek to induce payment by using mail, text messages, or phone calls. Thus, despite the changes that debt collectors make to their collection practices, the proposed rule may lead to a further decrease in recovery rates. Decreased recovery rates would reduce debt collectors’ revenues, potentially worsening the impact of the increased costs associated with other types of collection practices.

Because recovery of collection amounts is how debt buyers that also engage in debt collection (referred to here as debt collectors) profit from buying medical debt from health care providers, reduced recovery rates would reduce debt collectors’ demand for medical debt. If debt collection becomes more difficult or costly, debt collectors’ willingness to pay for medical debt would decrease. Depending on the relative bargaining position of debt collectors and health care providers, debt collectors may be able to pass on some of the decrease in expected revenues to health care providers by negotiating a lower price when they purchase medical debt.

The CFPB does not have data that would allow estimation of the potential reduction in recovery rates, or on transactions between debt collectors and health care providers that would allow estimation of expected reduction in the price paid by debt collectors to health care providers, and requests data that can be used to quantify these impacts.

5. Costs and Benefits to Creditors

Under the proposed rule, creditors generally would not be permitted to use consumer report information related to medical debt in their determinations of consumers’ eligibility for credit by utilizing the financial information exception at § 1022.30(d), which the CFPB understands is currently how creditors’ primarily use medical debt information. This may affect the performance of creditors’ loan portfolios if the absence of this medical debt information reduces the accuracy of

before paid medical collections were removed from consumer reports in June 2022. Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

¹⁹² See, e.g., the fee schedule for Small Claims Court in Maryland, <https://www.mdcourts.gov/legalhelp/smallclaims>, the corresponding fee schedule for regular civil cases, <https://www.mdcourts.gov/courts/feeschedules>, a comparison between small claims and regular civil cases in California, <https://selfhelp.courts.ca.gov/small-claims-or-limited-civil> (all last visited May 12, 2024).

¹⁹³ Keith Ericson & Tal Gross, *Limits on Medical Debt Lawsuits*, The Abell Found. (Feb. 9, 2021), <https://abell.org/wp-content/uploads/2022/02/Final20Medical20Debt20Report.pdf>.

¹⁹⁴ Approximately 2.5 percent of medical collections were marked as paid in the five years

¹⁹¹ *Id.*

creditors' assessments of delinquency risk. Indeed, the removal of information from the set of variables that can be used in underwriting models should not improve performance if models optimally assess risk at baseline.

However, the CFPB's research in the Technical Appendix instead suggests that creditors would benefit from the removal of medical collections from consumer reports. The CFPB finds that creditors are much less likely to grant credit to consumers with reported medical collections tradelines information, despite also finding that credit accounts originated when creditors were able to observe applicants' medical collections on their consumer reports perform no better in terms of likelihood of serious delinquency, on average, than when creditors were unable to observe that information. This implies that the use of medical collections in underwriting may prevent creditors from making what would be profitable loans.

The Technical Appendix is described in detail below in part XI. Before discussing the CFPB's empirical findings and conclusions, the CFPB discusses more general economic analysis for how creditors may be affected by the proposed rule.

The CFPB understands that creditors for many types of credit products do not generally ask explicitly for medical debt information on applications for credit, and instead rely on the medical collection information provided in consumer reports. Some forms of credit, like mortgages, more commonly require that an applicant report all debts on the credit application.¹⁹⁵ The CFPB does not have access to credit applications and the analysis that follows assumes that creditors currently only use medical debt information that is included on consumer reports, except where stated otherwise. While the proposed rule would allow creditors to use medical debt information that consumers provide in credit applications to satisfy ability to repay requirements, the proposed rule would not change any existing law or guidance regarding the information that creditors must request from applicants, and thus would not impose additional costs in that regard. The CFPB requests evidence for how the continued ability to observe medical debt on credit applications may impact creditors and consumers.

Because most consumers with medical debt do not have medical

collections on their consumer report, creditors currently provide credit accounts to many consumers who have medical debt without any knowledge of that debt. Nationally representative surveys indicate that between 15 and 41 percent of adults had some form of outstanding medical debt between 2021 and 2022, depending on the definition of "medical debt" used.¹⁹⁶ However, only 14 percent of consumers had a medical collection on their consumer report in 2022.¹⁹⁷ By June 2023, after the NCRAs' voluntary removal of all medical collections under \$500 in April 2023, only 5 percent of people with a consumer report had a medical collection included on their consumer report.¹⁹⁸

The medical collections included on consumer reports comprise only a subset of consumers' medical debt for several reasons. First, not all medical debt, including past-due medical debt, is in collections at any given time. Further, not all medical debts that are in collections are included on consumer reports, for a variety of reasons. The NCRAs entered into a settlement, called the National Consumer Assistance Plan (NCAP), with over thirty States' attorneys general in 2015 that required them to remove from consumer reports all medical collections that were paid by insurance, as well as ensure that medical collections were not included on consumer reports until they were at least 180 days past due from the date of first delinquency.¹⁹⁹ Since that agreement, the NCRAs have voluntarily removed many types of medical collections from consumer reports, including medical collections that were

paid by any source, medical collections under \$500, and medical collections that have not been outstanding for at least one year.²⁰⁰ In addition, the medical collections that currently appear on consumer reports are rarely reported for the full seven years that the FCRA permits. Previous CFPB research found that fewer than half of medical collections over \$500 were reported for longer than one year, and just over 10 percent were reported for at least four years.²⁰¹ Since the NCRAs' voluntary medical debt reporting changes were fully implemented in April 2023, the persistence of medical collection reporting has been substantially lower. The CFPB analyzed CCIP data and found that fewer than half of the medical collections reported in May 2023 were reported in November 2023, and just 26 percent were reported in February 2024. The CFPB understands that medical collections are not primarily reported to the NCRAs to assist creditors in assessing delinquency risk, but rather to induce repayment. Creditors may also not observe a medical collection on a consumer report if the debt collector did not report to all three NCRAs.²⁰² Finally, several States, including Colorado, New York, Virginia, and Connecticut, have enacted laws that significantly restrict or prohibit consumer reporting of medical debt information.²⁰³ Creditors that serve consumers for whom consumer reports will have medical collections removed pursuant to these State laws provide or will soon be providing credit without knowledge from consumer reports of their applicants' outstanding medical debt.

The discussion above presupposes that extending credit to consumers with medical debt is less profitable than extending credit to consumers without, conditional on the other information available to the creditor. It further assumes that being aware of consumers' medical debts would increase creditors' expected revenue, and removing medical debt information would lower revenue. In other words, the discussion

¹⁹⁶ U.S. Census Bureau, *Wealth, Asset Ownership, & Debt of Households Detailed Tables: 2021* (2021), <https://www.census.gov/data/tables/2021/demo/wealth/wealth-asset-ownership.html>; Lunna Lopes et al., Kaiser Fam. Found., *Health Care Debt In The U.S.: The Broad Consequences Of Medical And Dental Bills* (June 16, 2022), <https://www.kff.org/report-section/kff-health-care-debt-survey-main-findings/>.

¹⁹⁷ Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

¹⁹⁸ Ryan Sandler & Zachary Blizard, Consumer Fin. Prot. Bureau, *Recent Changes in Medical Collections on Consumer Credit Records Data Point* (Mar. 2024), https://files.consumerfinance.gov/f/documents/cfpb_recent-changes-medical-collections-on-consumer-credit-reports_2024-03.pdf.

¹⁹⁹ Assurance of Voluntary Compliance/ Assurance of Voluntary Discontinuance (May 20, 2015), *In re Equifax Info. Servs.*, <https://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Consumer-Protection/2015-05-20-CRAs-AVC.aspx>. <https://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Consumer-Protection/2015-05-20-CRAs-AVC.aspx>.

²⁰⁰ PR Newswire, *Equifax, Experian and TransUnion Remove Medical Collections Debt Under \$500 From U.S. Credit Reports* (Apr. 11, 2023), <https://www.prnewswire.com/news-releases/equifax-experian-and-transunion-remove-medical-collections-debt-under-500-from-us-credit-reports-301793769.html>.

²⁰¹ Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

²⁰² *Id.*

²⁰³ See Colo. Rev. Stat. section 5–18–109; N.Y. Pub. Health Law art. 49–A; 2024 Conn. Act 24–6; 2024 Va. Acts ch. 751.

¹⁹⁵ See, e.g., Fannie Mae, *Uniform Residential Loan Application (Form 1003)*, <https://singlefamily.fanniemae.com/delivering/uniform-mortgage-data-program/uniform-residential-loan-application> (last visited May 9, 2024).

presupposes that medical collections tradelines are predictive of creditor revenue, and in particular, predictive of serious delinquency.²⁰⁴ But in fact, previous CFPB research showed that medical collections tradelines are less predictive of serious delinquency than nonmedical collections. This research also showed that holding credit scores constant, a consumer who has more medical collections than nonmedical collections may be less likely to become seriously delinquent within two years than a consumer with more nonmedical than medical collections.²⁰⁵ The CFPB understands that medical collections may still have some predictive value in the sense that, on average and without considering other consumer characteristics, consumers with medical collections are more likely to become seriously delinquent than consumers without medical collections. However, as explained below, the CFPB expects that medical collections can be removed from underwriting models without significantly reducing their ability to predict serious delinquency if underwriting models continue to include other variables that are sufficiently predictive of delinquency risk.

The evidence available to the CFPB indicates that the predictive performance of underwriting models would not be impaired by the removal of all medical collections information. Many creditors have voluntarily minimized or eliminated the use of medical collections from their underwriting standards, and indeed, credit scoring companies have either removed or differentiated medical collections in their models and found minimal or no negative effects on performance.²⁰⁶ Furthermore, an

industry analysis of the NCRAs' June 2022 voluntary medical debt reporting changes found that because

the vast majority of the impacted consumers would likely have other derogatory information and FICO® Scores that remain low, the ability of FICO® Scores to rank order risk on the total population prior to these medical debt collections being excluded is almost identical to what lenders would experience with these medical debt collections excluded.²⁰⁷

The NCRAs' June 2022 medical debt reporting changes removed paid medical collections from consumer reports and required medical collections to be at least one year past the date of first delinquency before being included on consumer reports. Though these changes were more limited in scope than those in the proposed rule, the CFPB expects that an ex-post analysis of the proposed rule would draw a similar conclusion as the industry analysis above. Consumers with medical collections on their consumer reports in June 2023, after the NCRA voluntary reporting changes were fully implemented, had an average credit score of 582, near the deep subprime cutoff;²⁰⁸ additionally, more than 40 percent had at least one nonmedical collection and nearly 19 percent had no other tradelines.²⁰⁹ Thin credit files²¹⁰ and information about nonmedical collections would remain available to creditors under the proposed rule, to the

extent that creditors use these markers to assess delinquency risk.

The CFPB does not interpret its previous research findings as clear evidence that, holding all else equal, consumers with medical collections are seriously delinquent at the same rate as consumers with no medical debt. However, the finding that medical collections are less predictive of serious delinquency than nonmedical collections, and the remaining presence of other information such as nonmedical tradelines on the consumer reports of people with medical collections, suggest that the difference between these two serious delinquency rates is small, holding all else equal.

An important remaining question is whether consumers with medical debt and medical collections on their consumer reports are meaningfully more likely to become seriously delinquent than consumers with medical debt but no medical collections on their consumer reports, again holding all else equal. At the baseline, many creditors approve applications for credit without full knowledge of consumer medical debts because most medical debts are not included on consumer reports, as discussed above. Comparing the performance of credit accounts that creditors made without medical collections information to the performance of accounts made with this information would provide the most direct evidence on how the proposed rule may impact account performance, and therefore, creditors' profits. Ideally, this analysis would be performed with data from consumer reports linked with the timing and presence of consumers' outstanding and unreported medical debts. However, the CFPB does not have access to such linked data and is not aware of such data being available to any researcher or entity.

The research described in the Technical Appendix provides the closest feasible analysis of the potential effect of the rulemaking against the baseline by considering if the visibility of medical collections that remain on consumer reports enables creditors to provide fewer credit accounts that result in serious delinquency. The CFPB uses de-identified consumer report data from the CFPB's CCIP and leverages the 180-day waiting period for reporting medical collections implemented under NCAP.²¹¹ The CFPB's research considers inquiries made by creditors to one of the NCRAs in response to an application for credit in the 180 days before a medical collection was added to a consumer report, using data after

²⁰⁴ For purposes of this discussion, the term "serious delinquency" means an account that is at least 90 days past due. Commercial credit scoring models typically try to predict the probability that a new account made to a given consumer will become at least 90-days past due within two years of origination.

²⁰⁵ Kenneth P. Brevoort & Michelle Kambara, Consumer Fin. Prot. Bureau, *Data point: Medical debt and credit scores* (May 2014), https://files.consumerfinance.gov/f/201405_cfpb_report_data-point_medical-debt-credit-scores.pdf.

²⁰⁶ See, e.g., Fed. Nat'l Mortg. Ass'n, *Single Family Selling Guide*, B3-2-03 (2021), <https://selling-guide.fanniemae.com/#Public.20> Records.2C.20Foreclosures.2C.20and.20Collection.20Accounts (noting that "[c]ollection accounts reported as medical collections are not used in the DU [Desk Underwriter] risk assessment"); Fed. Home Loan Mortg. Corp., *The Single-Family Seller/ Servicer Guide*, 5201.1 (2022), <https://guide.freddie.com/app/guide/section/5201.1>. See also The White House, *Fact Sheet: The Biden Administration Announces New Actions to Lessen the Burden of Medical Debt and Increase Consumer Protection* (Apr. 11, 2022), <https://www.whitehouse.gov/briefing-room/statements->

[releases/2022/04/11/fact-sheet-the-biden-administration-announces-new-actions-to-lessen-the-burden-of-medical-debt-and-increase-consumer-protection/](https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/11/fact-sheet-the-biden-administration-announces-new-actions-to-lessen-the-burden-of-medical-debt-and-increase-consumer-protection/) (announcing changes to certain federal government underwriting standards); Ethan Dornhelm, *The Impact of Medical Debt Collections on FICO Scores*, FICO Blog (July 13, 2015), <https://www.fico.com/blogs/impact-medical-debt-collections-fico-scores>; VantageScore, *What was the rationale for removing Medical Debt from VantageScore 4.0?*, <https://www.vantagescore.com/fq/what-was-the-rationale-for-removing-medical-debt-from-vantagescore-4-0/> (last visited May 9, 2024).

²⁰⁷ Tommy Lee, Senior Director, Analytics & Scores, *Medical Collection Removals Have Little Impact on FICO Scores*, FICO Blog (June 30, 2022), <https://www.fico.com/blogs/medical-collection-removals-have-little-impact-fico-scores>.

²⁰⁸ Consumer Fin. Prot. Bureau, *Borrower risk profiles*, <https://www.consumerfinance.gov/data-research/consumer-credit-trends/student-loans/borrower-risk-profiles/> (last visited May 9, 2024).

²⁰⁹ Ryan Sandler & Zachary Blizard, Consumer Fin. Prot. Bureau, *Recent Changes in Medical Collections on Consumer Credit Records Data Point* (Mar. 2024), https://files.consumerfinance.gov/f/documents/cfpb_recent-changes-medical-collections-on-consumer-credit-reports_2024-03.pdf.

²¹⁰ A thin credit file is a consumer report that contains fewer than five credit accounts. Jennifer White, Experian, *What is a Thin Credit File?* (May 25, 2022), <https://www.experian.com/blogs/ask-experian/what-is-a-thin-credit-file-and-how-will-it-impact-your-life/>.

²¹¹ See part XI, *Technical Appendix*.

the NCAP 180-day waiting period was implemented in September 2017.²¹² Credit applications made during this 180-day period were made by consumers who had outstanding, but unreported, medical collections. The CFPB's research finds that the characteristics of inquiries made before and after a medical collection's addition to a consumer report are similar; therefore, any difference in the likelihood that a credit application led to an opened line of credit, or in the performance of those opened lines of credit, is likely caused by whether or

not the creditor observed the consumer's medical collection.

The CFPB uses a regression discontinuity design in the Technical Appendix to analyze how the presence of a medical collection on a consumer report when an inquiry is made affects the likelihood that the consumer opened a new account in connection with that inquiry. The CFPB's data cannot identify the cause of an unsuccessful inquiry, which may include a credit denial, unfavorable terms, or a change in the consumer's credit demand.²¹³ For all credit account categories, the CFPB's research finds lower inquiry success

rates for inquiries made immediately after a medical collection is added to a consumer report, compared to inquiries made immediately before a medical collection is added. This implies that creditors use medical collections information to deny or worsen the terms of credit provided to applicants. Table 1 uses coefficients estimated in the Technical Appendix (provided in Column 1 of Table 7) to estimate the annual number of additional credit accounts that would be originated if medical collections were removed from all consumer reports, all else equal.

TABLE 1—ESTIMATED CHANGES IN THE NUMBER OF ORIGINATED LOANS UNDER THE PROPOSED RULE BY CREDIT ACCOUNT TYPE²¹⁴

(1) Account type	(2) Estimated coefficient	(3) Baseline inquiry success rate (%)	(4) Expected percent change in originated accounts	(5) Annual number of originated accounts	(6) Expected change in annual originated accounts
Credit card	*** −0.047	26.0	18.1	2,014,427	364,611
Mortgage	* −0.026	17.2	15.1	144,915	21,882
Other loans	* −0.014	23.9	5.9	1,083,879	63,949

Estimates marked with *** are statistically significantly different from zero at the one percent confidence level. Estimates marked with * are statistically different from zero at the 10 percent confidence level.

For all credit account categories, the CFPB expects that more loans would be originated if all medical collections were removed from consumer reports provided to creditors under the proposed rule. The estimates in Columns 5 and 6 are underestimates because not all originated loans can be connected to an inquiry in the CFPB's CCIP, as the data only include inquiries made to one NCRA, and many non-mortgage creditors pull consumer reports from only one or two NCRAs.

Additionally, these estimates assume that credit demand would not change under the proposed rule. The CFPB's research in the Technical Appendix finds that consumers are more likely to apply for credit in the weeks before a medical collection is added to their consumer report than in the weeks after. However, the characteristics of credit applications made before and after a medical collection is added (and their associated consumers) do not appear to have any statistically distinguishable

differences between them. This finding suggests that any increase in credit demand under the proposed rule would not lead to declines in credit application quality.

To provide further evidence for how credit demand may respond to the proposed rule, the CFPB used data from the CCIP to estimate if the NCRAs' voluntary removal of medical collections under \$500 in April 2023 was associated with

²¹² The April 2023 NCRA reporting changes were too recent to be the focus of the analysis in the Technical Appendix, but the appendix provides heterogeneity results for whether all medical collections were at least \$500 to provide the closest analog to the current lending environment. The CFPB relies on these results to estimate the impact of the proposed rule.

²¹³ The data used and empirical strategy of the CFPB's analysis are described in Technical Appendix. This section describes their estimation of the effect of medical collection reporting on "inquiry success," or the likelihood that a hard pull of a consumer report (an inquiry) made by a creditor in response to a consumer's credit application led to an originated loan. Under the assumption that inquiries made just before and just after a medical collection is added to a consumer report have similar underlying delinquency risk and reflect similar consumer preferences for terms and other loan qualities, differences in inquiry success can be attributed to creditors' use of

medical collections information in their underwriting processes. These assumptions are justified in the Technical Appendix.

²¹⁴ All credit accounts in the CFPB's CCIP (excluding collections and non-loan information, such as child support tradelines) are included in one of the three categories of Column 1. Estimated coefficients in Column 2 are taken from Table 7 in the Technical Appendix. Column 3 includes the baseline inquiry success rate for inquiries made when medical collections are reported in the sample of the Technical Appendix. These baselines differ from those in the Technical Appendix because the CFPB reports baseline inquiry success rates for inquiries made when medical collections are unreported in the Technical Appendix, as it is standard to provide the average of the dependent variable to the left of the threshold in regression discontinuity analyses. Column 4 calculates the estimated percent change in the number of loans that would be originated under the proposed rule by first dividing the estimated coefficient in

Column 2 by the baseline average inquiry success rate in Column 3. Column 4 is then multiplied by negative one because the coefficients in Column 2 were estimated for medical collections moving from being unreported to reported in the Technical Appendix, but the change here is estimated for medical collections moving from being reported to unreported. Column 5 includes the number of inquiries made by creditors for consumer reports with reported medical collections between May 2023 and October 2023 in the CFPB's CCIP, multiplied by 50 to create a national estimate from the CCIP's two percent sample, annualized by multiplying by 2, and then multiplied by the baseline inquiry success rate for people with reported medical collections in Column 3 to estimate the annual number of credit accounts originated. Column 6 multiplies Column 4 by Column 5 to calculate the expected change in the number of originated credit accounts under the proposed rule.

increased credit demand.²¹⁵ The CFPB found that consumers in the treated group were just 0.07 percent less likely to have an associated inquiry in the six months after medical collections under \$500 were removed from their consumer reports. This suggests that credit demand is not responsive to the removal of medical collections from consumer reports, at least in the short run.

The CFPB assumes that creditors only make loans at baseline to people with reported medical collections if they are profitable on average. If the marginal loans that would be made under the proposed rule have similar revenue potential, the increase in the number of loans made to people with medical collections would increase creditor profits. To estimate the revenue potential of originated accounts, the CFPB estimates the likelihood of serious

delinquency within two years of a credit account's origination date for accounts that are opened in connection with an inquiry made in the 180 days before or after a medical collection is included on a consumer report. If creditors effectively use medical collections information in their underwriting decisions to reduce the delinquency risk of newly opened accounts, one would expect that credit provided to consumers with outstanding, but unreported, medical collections will have higher delinquency propensity than credit provided to consumers with outstanding and reported medical collections.

The CFPB's research in the Technical Appendix finds no statistically significant evidence to support this hypothesis. Instead, the CFPB's research finds that credit accounts provided to

people whose medical debts were not included on their consumer reports (as medical collections tradelines) were no more likely to be seriously delinquent within two years than credit accounts made to people whose medical collections were included on their consumer reports, on average. To estimate the effects of the proposed rule, the CFPB estimates the number of delinquent loans that would be issued if medical collections were not included on consumer reports, as if the proposed rule is finalized. These ranges also incorporate the evidence from the Technical Appendix on how the number of newly originated loans would change, discussed above. The estimated coefficients from Column 1 of Table 8 in the Technical Appendix are listed in Table 2 in Column 2.

TABLE 2—ESTIMATED CHANGES IN THE NUMBER OF SERIOUSLY DELINQUENT LOANS UNDER THE PROPOSED RULE BY CREDIT ACCOUNT TYPE ²¹⁶

(1) Account type	(2) Estimated coefficient	(3) Baseline D90+ rate (%)	(4) Expected change in annual originated accounts	(5) Expected number of D90+ accounts within two years of origination at baseline D90+ rate	(6) Expected number of annual D90+ accounts within two years of origination at estimated delinquency rate for unreported medical collections
Credit card	0.000	20.7	364,611	75,474	75,474
Mortgage	0.011	3.1	21,882	678	438
Other	0.012	17.1	63,949	10,935	10,168

None of the estimated coefficients are statistically significantly different from zero.

The CFPB expects that, at baseline, creditors only provide credit to people with reported medical collections if they expect a positive profit. As described above and reproduced in Column 4 of Table 2, the CFPB expects that more accounts are originated under the proposed rule. If these accounts are delinquent at the same rates as accounts provided to consumers with reported medical collections, these accounts would increase creditor profits, all else equal. Instead, the CFPB's research finds

that, for mortgages and other (not credit card and not mortgage) account types, accounts originated by consumers with reported medical collections have slightly higher delinquency propensity than accounts originated by consumers with unreported medical collections. These coefficients are not statistically distinguishable from zero, so the CFPB cannot conclude that the expansion of credit under the proposed rule would yield a serious delinquency rate that is lower than the serious delinquency rate

currently faced by creditors for accounts they provide to consumers with reported medical collections. However, the CFPB interprets its findings as evidence against any significant increase in the serious delinquency rate as compared to the serious delinquency rate for accounts provided to consumers with reported medical collections at baseline. The CFPB notes that this claim holds if consumer demand for credit and the supply of credit do not change in response to the proposed rule.

²¹⁵ The CFPB compared the credit demand of "treated" consumers, who had medical collections under \$500 included on their consumer reports in the first quarter of 2023, to the credit demand of "control" consumers, who had medical collections under \$500 included on their consumer reports in the last quarter of 2022, but not in 2023. Neither group had any medical collections over \$500 on their consumer reports in 2023. The treated group was directly affected by the April 2023 removal of medical collections under \$500, but the control group was not, though both groups likely have similar underlying delinquency risk and credit demand. The CFPB estimated a linear regression of a binary monthly indicator describing if consumers had an inquiry on their consumer report in each of the six months between May and October 2023 on a binary indicator describing whether the consumer

was in the treated or control group. The regression further included month fixed effects.

²¹⁶ All credit accounts in the CFPB's CCIP (excluding collections and non-loan information, such as child support tradelines) are included in one of the three categories of Column 1. Estimated coefficients in Column 2 are taken from Table 8 in the Technical Appendix. Column 3 includes the baseline two-year serious delinquency propensity for loans opened when medical collections were reported in the sample of the Technical Appendix, though the CFPB provides baseline inquiry success rates for inquiries made when medical collections are unreported in the Technical Appendix, as is standard in reporting regression discontinuity results. Column 4 is copied from Column 6 of Table 1. Column 5 multiplies Column 3 by Column 4, describing the expected number of additional

accounts that would be originated under the proposed rule and would be D90+ within two years at the baseline D90+ rate. Column 6 multiplies Column 4 by the difference between Column 3 and Column 2 (where Column 3 is reflected as a decimal instead of as a percent, e.g., 20.7 percent is equal to 0.207), describing the expected number of additional accounts that would be originated under the proposed rule and would be D90+ within two years at the D90+ rate for accounts originated when consumers have unreported medical collections. Columns 2 and 3 are differenced instead of added because the coefficients in Column 2 were estimated for medical collections moving from being unreported to being reported in the Technical Appendix, but the expected impact of the proposed rule is for medical collections moving from being reported to being unreported.

If consumer demand for credit is affected by the proposed rule, the credit applications that creditors receive may have different underlying delinquency risk. Some consumers may avoid applying for credit when a medical collection appears on their consumer report if they understand that this information lowers the likelihood that their credit application will be approved or provided with favorable terms. Removing medical collections from consumer reports may lead these consumers to submit credit applications, which could lead to an increase or decrease in the delinquency risk of applicant pools, depending on how affected consumers' delinquency propensity compares to that of the average applicant. The CFPB does not have information available to estimate the direction or magnitude of potential changes.

This may change the propensity for a credit application to lead to an opened credit account, as well as the performance of opened credit accounts. The CFPB finds that consumers are less likely to apply for credit after a medical collection is added to their consumer report; however, the underlying delinquency risk of the remaining credit applications is not statistically distinguishable from the delinquency risk of credit applications made before the medical collection is reported. In equilibrium, the CFPB expects that consumer demand for credit may increase without the use of medical collections information in underwriting, but the CFPB is unaware of any evidence that either those consumers' underlying delinquency risk, or creditors' ability to predict those consumers' delinquency risk, would change under the proposed rule.

Creditors may change their underwriting processes in response to the proposed rule. The CFPB's research in the Technical Appendix analyzed inquiries that were made when some medical debt information was available to creditors. If creditors instead knew that they could not generally use any medical debt information in their underwriting processes, they may change their underwriting models to put more weight on other variables. However, under the assumption that creditors only change their underwriting models if those changes improve model performance, creditors' model updates should only mitigate any potential for reduced account performance under the proposed rule. That is, any changes that creditors implement will improve their ability to identify accounts likely to become seriously delinquent, compared to the models used to evaluate the

inquiries observed in the Technical Appendix.

Although the CFPB does not estimate that there would be a significant number of additional seriously delinquent accounts if the proposed rule were finalized, the CFPB does not have data available that would enable it to calculate the monetary cost to creditors of such additional delinquencies as may occur. The CFPB requests information on the dollar cost to creditors of an account that becomes seriously delinquent within two years of its origination. Furthermore, the profitability of a loan is not solely defined by its delinquency. For example, credit card borrowers who carry a balance month-to-month (often termed revolvers), are more profitable for credit card companies than other types of consumers.²¹⁷

Under the proposed rule, the CFPB expects that creditors would provide more credit to consumers without significantly increasing average delinquency rates. The CFPB does not have data available to quantify the monetary benefit to creditors from these additional accounts. The CFPB requests comment on this issue.

Aside from the impact on delinquency risk from the change in information, creditors may incur compliance costs from the proposed rule. Creditors will need to ensure that they are not unintentionally using medical information in making lending determinations in circumstances that fall outside the exceptions to the creditor prohibition. These costs should be minor to the extent that creditors currently only utilize medical debt information provided through consumer reports. In such cases, so long as the consumer reporting agency providing the consumer report has complied with the proposed rule, no medical debt information would be conveyed to the creditor, unless the consumer reporting agency has reason to believe the creditor intends to use the medical debt information in a manner not prohibited by the creditor prohibition. Creditors who use consumer reports may have additional costs if they utilize consumer reports from which the consumer reporting agency has not excluded medical debt information in compliance with proposed § 1022.38. In such cases creditors would need to employ systems and staff time to identify and exclude that information. The CFPB requests comment on the compliance costs for

creditors that use consumer reports with this type of information.

In addition, creditors that rely on information outside of consumer reports will face compliance costs related to identifying medical information from other sources and excluding it from their underwriting (except as permitted by an exception to the creditor prohibition). The CFPB does not have data available to quantify the extent or dollar amount of any of these compliance costs, and requests comment on this issue.

6. Costs and Benefits to Consumers

The proposed rule provides that information about a consumer's medical debt cannot be obtained or used by a creditor in connection with any determination of the consumer's eligibility, or continued eligibility, for credit, unless one of the narrow, specific exceptions listed in the regulation apply. This may affect consumers' access to credit in various ways.

The CFPB expects that the proposed rule would lead to significant benefits for consumers who have medical debt in collections. The CFPB additionally anticipates significant benefits for consumers whose medical debt is not in collections and requests information to estimate these effects. The use of medical debt information in lending determinations compounds the financial consequences of medical debt, even though medical debt is often incurred without a consumer having full knowledge of its costs, given the complex nature of medical billing and insurance coverage. Under the proposed rule, consumers would continue to be liable for their medical debts. Instead, the proposed rule reduces consumers' incentives to pay incorrect or erroneous medical debts and relieves the harm that outstanding medical debt causes to consumers' credit access.

As discussed in part VII.E.3, *Costs to health care providers*, some health care providers and debt buyers use furnishing of unpaid medical debt, through third-party debt collection agencies acting as their agents, as a means of inducing payment from consumers. To the extent that this practice is effective, the proposed rule would reduce those payments induced through furnishing of unpaid medical debt to consumer reporting agencies. However, consumers with medical debt would still owe the debt, and health care providers and debt collectors would still be permitted to collect on that debt. As discussed in parts VII.E.4, *Costs to debt collectors and debt buyers* and VII.E.3, *Costs to health care providers*, some health care providers

²¹⁷ Robert Adams et al., Bd. of Governors of the Fed. Rsr. Sys., *Credit Card Profitability* (Sept. 9, 2022), <https://www.federalreserve.gov/econres/notes/feds-notes/credit-card-profitability-20220909.html>.

and debt collectors may use litigation to induce payment more frequently or instead. The CFPB does not view any of these scenarios as likely.

The allocation of credit may change across consumers with and without medical debt relative to the current baseline allocation if creditors change their underwriting practices. Some consumers may be more likely to be approved for credit, or receive more favorable terms for credit, if creditors cannot use medical debt information in the manner they do now. The Technical Appendix estimates meaningful expansions of credit for consumers with reported medical collections, as described in part VII.E.5, *Costs and benefits to creditors*, and again below. Finally, a small number of consumers may become credit invisible or lose their credit score if medical collections are removed from their consumer reports, though the CFPB expects that this does not lead to substantial reductions in credit access for affected consumers, as described below.

The CFPB received feedback from several health care providers during the SBREFA process stating that the proposed rule would lead them to deny non-emergency care to consumers who cannot pay upfront or have not paid their previous balances in full. However, these views are not shared by the CFPB. The CFPB views these outcomes as unlikely given that many health care providers already require payment before treatment.²¹⁸

The CFPB expects that the proposed rule would have a small or negligible impact on consumers' ability to access emergency medical care, as all hospital emergency rooms that receive Medicare funds are required to provide emergency medical care, irrespective of an individual's ability to pay.²¹⁹

The CFPB estimates that the impact will be minimal but does not have data or information available to estimate the exact extent to which the proposed rule would impact the availability of health

care. The CFPB requests comment on this issue, in particular quantitative estimates of the expected size of these impacts and any disparate regional impact. The CFPB further requests information from health care providers describing changes in their pricing and willingness to provide care in response to the voluntary NCRA changes that have greatly reduced the share of medical debts that are included on consumer reports,²²⁰ or in response to the removal of medical collections from consumer reports subject to restrictions under the laws of states such as New York or Colorado, or in Connecticut or Virginia after the their laws go into effect in July 2024.²²¹

Some health care providers who submitted comments to the SBREFA Outline stated that the removal of medical debt from consumer reports would "eliminate" a consumer's incentive to pay for a health insurance plan, especially for consumers that are young and in good health. The providers stated that, as a result, the cost of health insurance will increase for those that do want or need to be insured. The CFPB does not share this view and expects that the proposed rule would cause very few consumers to become uninsured. The CFPB understands that the predominant factor in whether a consumer is likely to have health insurance is whether they have access to affordable health care coverage, as opposed to other factors. Uninsured consumers cite "coverage not affordable" and "not eligible for coverage" as the most common reasons for lacking health insurance.²²²

In summary, the evidence available to the CFPB finds that people are uninsured largely because they cannot access health insurance or find it unaffordable, and the CFPB expects that the proposed rule would be unlikely to affect either of these margins.

The CFPB does not have data to estimate if the proposed rule would reduce on-time payments for medical services. Even if some consumers were less likely to make on-time payments, it is not necessarily the case that the proposed rule would significantly reduce health care providers' revenues, and thus lead health care providers to take actions. Consumers would remain

liable for their unpaid medical debts under the proposed rule. For patients with ongoing relationships with providers, health care providers would continue to require payment for past-due bills at subsequent appointments. Health care providers and debt collectors could continue to use methods other than furnishing to induce payments, including calls, text messages, letters, and litigation. Debt collectors who were small entity representatives in the SBREFA process reported that the average cost of furnishing is \$10 per account, compared to \$500 for litigation.²²³ The CFPB expects that litigation costs may be lower for larger debt collectors, or for larger health care providers if they sue patients directly, given the potential for economies of scale. Though the cost of litigation is much higher, so too is the expected recovery. The CFPB understands that, while consumer reporting sometimes results in the payment of overdue debt, existing research suggests that consumer debt litigation more often leads to a default judgment in favor of the plaintiff.²²⁴ These judgments can lead to asset seizures or wage garnishment.²²⁵ The CFPB expects that these remaining alternative mechanisms of inducing payment would ensure that consumers continue to maintain health insurance coverage, apply for financial assistance, and pay their medical debt under the proposed rule, as the consequences of litigation may be more severe than the consequences of creditors' use of medical debt information on consumer reports in underwriting.

The CFPB expects that the threat of litigation faced by consumers would mitigate potential costs to health care providers arising from consumers' failure to pay for medical services and prevent those costs from being passed on to consumers in the form of reduced care or higher prices. However, litigation is more costly than furnishing medical debt information to consumer reporting agencies for consumers, health care providers, and debt collectors. Because medical debt litigation can impose large costs on consumers, the CFPB has considered if such litigation would become more common under the proposed rule. In the current baseline, medical collections are removed from the NCRA's consumer reports when

²¹⁸ Melanie Evans, *Hospitals are Refusing to Do Surgeries Unless You Pay in Full First*, Wall St. J. (May 9, 2024), https://www.wsj.com/health/healthcare/hospitals-pay-before-treatment-patients-c477e2d6?mod=hp_lead_pos10. According to an HFMA survey, 96 percent of health care industry respondents reported having pre-payment or point-of-service collection policies and procedures. Healthcare Fin. Mgmt. Ass'n, *Analyzing pre-payment and point-of-service collections efforts* (Aug. 15, 2021), <https://www.hfma.org/technology/analyzing-pre-payment-and-point-of-service-collections-efforts/>.

²¹⁹ Ctrs. for Medicare & Medicaid Servs., *Emergency Room Rights*, <https://www.cms.gov/priorities/your-patient-rights/emergency-room-rights> (last visited May 9, 2024) (noting Emergency Medical Treatment and Active Labor Act, 42 U.S.C. 1395dd, protections).

²²⁰ See part I.D, *Medical debt and consumer reporting* (describing the NCRA's reporting changes).

²²¹ See Colo. Rev. Stat. section 5–18–109; N.Y. Pub. Health Law art. 49–A; 2024 Conn. Act 24–6; 2024 Va. Acts ch. 751.

²²² Jennifer Tolbert et al., Kaiser Fam. Found., *Key Facts about the Uninsured Population* (Dec. 18, 2023), <https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/>.

²²³ SBREFA Report at 38.

²²⁴ The Pew Charitable Trusts, *How Debt Collectors Are Transforming the Business of State Courts* (May 6, 2020), <https://www.pewtrusts.org/en/research-and-analysis/reports/2020/05/how-debt-collectors-are-transforming-the-business-of-state-courts>.

²²⁵ *Id.*

paid.²²⁶ Consumers seeking credit may pay medical collections included on their consumer reports to ensure these collections are removed and unobservable to creditors and improve their credit scores. These consumers may be more sensitive to the threat of medical debts being furnished or the availability of medical debt information to creditors than they are to the threat of litigation. The CFPB understands that, at baseline, some consumers may be pressured to pay debts they do not actually owe if they have an immediate credit demand, and the removal of furnishing may reduce the likelihood that these consumers pay spurious debts.²²⁷ For the subset of consumers who legally owe the debt, the proposed rule may lead to increased debt resolution costs if the consumers are required to pay for the plaintiff's court filing fees or legal fees, which may occur for the majority of cases that end in a default judgement against the consumers, as discussed in part VII.E.4 *Costs to debt collectors and debt buyers*. At least one debt collector suggested that the proposed rule may also lead to increased costs for consumers, if debt collectors are currently more likely to settle medical debts for less than the dollar amount owed when consumers respond to medical debt collections added to their consumer reports, but may not be willing to settle or will settle only for relatively high amounts during the course of litigation.²²⁸

The CFPB does not have data or information available to estimate the exact extent to which the proposed rule may affect the use of litigation, relative to the baseline, by debt collectors who seek to induce payment of medical debts. Because recovery rates on medical debts are already quite low, as noted above, it is unlikely that any increase in litigation would be substantial. The CFPB requests comment on this issue, particularly data or quantitative estimates of the expected

changes in litigation were the rule to go into effect. The CFPB is particularly interested in data regarding any changes in litigation propensity that have occurred in response to the voluntary NCRA changes, or the removal of medical collections from consumer reports subject to restrictions under New York or Colorado law, or in Connecticut or Virginia after their laws are implemented in July 2024.²²⁹

During the SBREFA process, debt collectors expressed concern that creditors would be concerned about the possibility of providing credit to consumers who cannot pay their medical debt under the proposed rule. Commenters expected that this may lead creditors to raise interest rates and fees to account for anticipated increased delinquency rates. However, as described above in part VII.E.5, *Costs and benefits to creditors*, the CFPB does not expect that creditors would experience any significant decline in applicant quality or account performance under the proposed rule. Instead, the evidence available to the CFPB and described in the Technical Appendix suggests that creditors would experience an increase in profitable loan volume under the proposed rule, as market frictions have prevented creditors from fully reaching this more profitable equilibrium at baseline as described above in part VII.A, *Statement of Need*. Therefore, the CFPB expects that the proposed rule would enable creditors to make more loans that have similar delinquency risk to loans in their existing lending portfolio, and would not lead to higher credit costs for consumers.

Because commonly used commercial credit scoring models require a minimal number of credit tradelines to generate a score, some consumers may lose their credit scores if medical collections are removed from their consumer reports. For instance, FICO will only provide a credit score if the consumer has at least one credit account that is at least six months old and there has been activity on the credit account in the previous six months.²³⁰ Similarly, VantageScore requires at least one tradeline with any activity before providing a score.²³¹ For consumers with few tradelines, the removal of medical collections could lead them to lose their credit score. To

provide some evidence for the scale of this effect, the CFPB analyzed CCIP data from the months immediately before and after the NCRAs' voluntary removal of medical collections under \$500 in April 2023. This internal analysis estimated that these reporting changes caused approximately 5,500 consumers to lose their credit score, representing 0.03 percent of consumers who had all their medical collections removed because of the April 2023 reporting changes. The median credit score for these consumers before their medical collections were removed was 581. The CFPB estimates using consumer reports from January 2024 in CFPB's CCIP as the current baseline, that fewer than 1,000 consumers may lose their credit scores if all medical collections were to be removed from consumer reports. The median credit score for these consumers in January 2024 was 573. Though not having a credit score can reduce access to credit, so too does having a subprime credit score, and the generally low baseline credit scores of affected consumers indicate that any increase in the population without credit scores under the proposed rule may not lead to an overall reduction in consumers' access to credit. Indeed, as stated by one NCRA, generally "no credit is better than bad credit" for the purposes of accessing credit.²³² The CFPB expects that any reduction in access to credit because of an increase in the population without credit scores would be very small but requests additional information.

Despite these potential negative effects, the CFPB expects that consumers with medical collections included on their consumer reports would experience increased access to credit under the proposed rule, in part caused by increases in their credit scores. Consumers with medical collections on their consumer reports in August 2022 had credit scores that were 30 points higher in August 2023 than in August 2022, after the implementation of the voluntary removal of medical collections under \$500 in April 2023; consumers without medical collections on their consumer reports in August 2022 experienced a one-point decline in their average credit scores by August 2023.²³³ Evidence from CFPB research

²²⁶ Business Wire, *Equifax, Experian, and TransUnion Support U.S. Consumers with Changes to Medical Collection Debt Reporting* (Mar. 18, 2022), <https://www.businesswire.com/news/home/20220318005244/en/Equifax-Experian-and-TransUnion-Support-U.S.-Consumers-With-Changes-to-Medical-Collection-Debt-Reporting>.

²²⁷ See, e.g., Consumer Fin. Prot. Bureau, *Fair Debt Collection Practices Act: CFPB Annual Report 2023*, at 2–5 (Nov. 2023), https://files.consumerfinance.gov/f/documents/cfpb_fdcpa-annual-report_2023-11.pdf (describing consumer medical collection complaints received by the CFPB).

²²⁸ Comment from Jennifer Whipple, Collection Bureau Servs., Inc., RE: Small Entity Representative Jennifer Whipple's Comment to CFPB regarding the Small Business Review Panel regarding the Fair Credit Reporting Act Proposal, SBREFA Report app. A.

²²⁹ See Colo. Rev. Stat. section 5–18–109; N.Y. Pub. Health Law art. 49–A; 2024 Conn. Act 24–6; 2024 Va. Acts ch. 751.

²³⁰ Louis DeNicola, Experian, *Improve Credit: How to Establish Credit if You're Unscoreable* (Feb. 12, 2024), <https://www.experian.com/blogs/ask-experian/how-to-establish-credit-if-youre-unscoreable/>.

²³¹ Id.

²³² Jim Akin, Experian, *Credit Reports & Scores: Is No Credit Better than Bad Credit* (Oct. 3, 2022), <https://www.experian.com/blogs/ask-experian/is-no-credit-better-than-bad-credit/>.

²³³ Fredric Blavin et al., Urban Wire, Urban Inst., *Medical Debt Was Erased from Credit Records for Most Consumers, Potentially Improving Many Americans' Lives* (Nov. 2, 2023), <https://www.urban.org/urban-wire/medical-debt-was-erased-from-credit-records-for-most-consumers-potentially-improving-many-americans-lives>.

suggests that consumers experience a 25-point increase in their credit score, on average, after their last medical collection is removed from their consumer report.²³⁴ However, the causes of the studied medical collection removals were unknown, and there may be unobservable factors that caused both the medical collection removal and increases in consumer credit scores, so these results cannot be interpreted causally. Other CFPB research has leveraged the recent voluntary removal of medical collections tradelines below \$500, finding that consumers for whom all medical collections were below \$500 prior to the changes saw their credit scores increase 20 points more than consumers who had some medical collections tradelines above \$500.²³⁵ For a sample of fewer than 3,000 consumers who had their medical debts removed from their consumer reports after their debt was relieved by a nonprofit organization, Kluender et al. (2024) found that credit scores increased by an average of just three points; however, this sample was not representative of all consumers with medical debts, as the reported collections were much older on average than most medical collections on consumer reports.²³⁶ VantageScore removed all medical collections from its credit scoring model in 2022 and reported that “millions of consumers may see an increase of up to 20 points in their VantageScore credit scores.”²³⁷ The CFPB expects that consumers may experience similar increases in their credit scores from other credit scoring companies if medical debt information is removed from consumer reports under the proposed rule. Higher credit scores can lead to higher loan approval rates and more favorable terms.²³⁸ The

CFPB requests information on the dollar value to consumers of higher credit scores.

As described above in the discussion of costs and benefits to creditors, creditors currently appear to use medical collections information to either deny consumers’ applications for credit or provide worse terms. Without any changes in the underlying quality of consumer credit applications or in creditor underwriting practices, consumer credit applications would be more likely to lead to originated loans if the proposed rule were in effect and creditors could not observe medical debt information. The CFPB does not have data available to estimate the dollar value of this increased access to credit, and requests information on the dollar benefit to consumers of additional lending.

Increases in access to credit through either of these channels may be short-term if credit scoring companies change their models or creditors change their underwriting practices in response to the proposed rule. Other consumer report information could receive more or less weight to compensate for the loss of medical collection information, which could attenuate these increases or even reduce access to credit for some consumers. However, the CFPB understands that credit scoring companies and creditors would only implement these changes if the benefit from doing so outweighed the likely substantial costs of changing these models and procedures. The results shown in the Technical Appendix suggest that medical collections reporting does not enable creditors to make fewer delinquent loans, implying that creditors would not experience any decline in revenue from the absence of this information. The expected small (or zero) benefit of recalibrating credit scoring models and underwriting practices may lead to longer-term increases in access to credit for consumers with medical debt.

Furthermore, consumers facing debt collection attempts may pay or settle debts to remove the tradelines from their consumer report. Previous research from the CFPB found evidence indicating that consumers may act to remove medical collections from their consumer reports when they plan to apply for a mortgage.²³⁹ Additionally, a debt collector commenter in the SBREFA process stated that there would

be a “significant decrease in the number of individuals with overdue medical debt who take proactive steps to resolve their accounts.” This suggests that furnishing is an effective tool for inducing payment of debts, though other collection mechanisms, such as litigation, would remain available under the proposed rule. Consumers with a current need for credit would benefit under the proposed rule from reduced pressure to pay medical debts before applying for credit. The CFPB does not have data available to estimate the size of this benefit.

The CFPB understands that many medical collections included on consumer reports reflect incorrect billing, debts that were already paid by either the consumer or by insurance companies, or debts that are not owed by the consumer. Nearly half of consumers who made formal complaints to the CFPB about medical debt collection in 2021 reported that they did not owe the debt, and many consumers did not know that they had outstanding medical debt until they discovered a collections tradeline on their consumer report.²⁴⁰ Consumers whose reported medical debts contain inaccurate information may dispute the information with NCRAs and debt collectors at baseline, as discussed above. Consumers would benefit from not needing to dispute these debts under the proposed rule. The CFPB does not have information available to estimate how many medical debts are paid despite containing inaccurate information, but expects that fewer of these erroneous debts would be paid without debt collectors’ use of furnishing. The CFPB requests comment and submissions of data, or any other relevant information, that may be helpful in estimating this reduction in erroneous debts paid.

F. Specific Impacts on Consumers in Rural Areas

The potential costs and benefits to consumers of the proposed rule would likely be the same, on average, for consumers regardless of where they reside. However, consumers who have outstanding medical debt may be more likely to be affected by the rule. Research by the CFPB and others shows that medical collections on consumer reports are more common for consumers who reside in rural areas, compared to

erased-credit-records-most-consumers-potentially-improving-many.

²³⁴ Alyssa Brown & Eric Wilson, Consumer Fin. Prot. Bureau, *Consumer Credit and the Removal of Medical Collections from Credit Reports* (Apr. 2023), https://files.consumerfinance.gov/f/documents/cfpb_consumer-credit-removal-medical-collections-from-credit-reports_2023-04.pdf.

²³⁵ Consumer Fin. Prot. Bureau, *Data Spotlight: Early Impacts of Removing Low-balance medical collections* (May 16, 2023), <https://www.consumerfinance.gov/data-research/research-reports/data-spotlight-early-impacts-of-removing-low-balance-medical-collections/>.

²³⁶ Raymond Kluender et al., *The effects of medical debt relief: evidence from two randomized experiments*, Nat’l Bureau of Econ. Rsch. Working Paper No. 32315 (Apr. 2024), https://www.nber.org/system/files/working_papers/w32315/w32315.pdf.

²³⁷ VantageScore, *VantageScore Excluding Medical Debt from Credit Scores* (Aug. 12, 2022), https://www.vantagescore.com/press_releases/vantagescore-excluding-medical-debt-from-credit-scores/.

²³⁸ Consumer Fin. Prot. Bureau, *What is a credit score?* (Aug. 28, 2023), <https://www.consumerfinance.gov/ask-cfpb/what-is-a-credit-score-en-315/>.

²³⁹ Alyssa Brown & Eric Wilson, Consumer Fin. Prot. Bureau, *Consumer Credit and the Removal of Medical Collections from Credit Reports* (Apr. 2023), https://files.consumerfinance.gov/f/documents/cfpb_consumer-credit-removal-medical-collections-from-credit-reports_2023-04.pdf.

²⁴⁰ Consumer Fin. Prot. Bureau, *Complaint Bulletin: Medical billing and collection issues described in consumer complaints* (Apr. 2022), https://files.consumerfinance.gov/f/documents/cfpb_complaint-bulletin-medical-billing_report_2022-04.pdf.

those who reside in non-rural areas.²⁴¹ Therefore, in the aggregate, the proposed rule may have a disproportionate impact on consumers in rural areas. Additionally, to the extent that the proposed rule would lead to consumers being denied services by a health care provider, that cost could be greater for consumers in rural areas, where there are often fewer options for medical care. The CFPB requests comment as to whether the proposed rule would have distinct impacts on rural consumers.

G. Specific Impacts on Depository Institutions With \$10 Billion or Less in Assets

The CFPB does not expect that the proposed rule would have significantly different impacts on depository institutions with \$10 billion or less in assets, compared to larger institutions. The CFPB preliminarily concludes that the costs to creditors, described above, would apply equally to these smaller institutions. The CFPB requests comment as to whether this conclusion is accurate, and whether there are other costs, not described above, that would apply specifically to such smaller institutions.

H. Specific Impacts on Access to Credit

The CFPB discusses impacts on access to credit in detail above in part VII.F in reference to potential costs and benefits to consumers. In brief, the CFPB expects that some consumers would lose their credit score if the proposed rule is finalized, although it is unclear whether this would decrease these consumers' access to credit relative to only having medical collections tradelines. Other consumers would likely see increased access to credit due in part to increased credit scores.

VIII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) requires the CFPB to conduct an initial regulatory flexibility analysis (IRFA) and convene a panel to consult with small entity representatives before proposing a rule subject to notice-and-comment requirements,²⁴² unless it certifies that the rule will not have a significant economic impact on a substantial number of small entities.²⁴³

The CFPB Director hereby certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. Thus, neither an IRFA nor a Small Business Advisory Review Panel (SBREFA Panel) is required. Nonetheless, the CFPB decided for prudential reasons to include this proposed rule in the SBREFA Panel convened to address a number of topics under the FCRA on October 18 and 19, 2023, and to provide an analysis consistent with the requirements of an IRFA. The CFPB requests comments or any relevant data that may further inform its determination regarding whether the proposed rule would have a significant economic impact on a substantial number of small entities.

The Small Business Review Panel for this proposed rule is discussed in part III.A. Among other things, the IRFA contains estimates of the number of small entities that may be subject to the proposed rule and describes the impact on those entities. The IRFA for this proposed rule is set forth in this part.

A. Small Business Review Panel

Under section 609(b) of the RFA, as amended by SBREFA and the CFPA, the CFPB must seek, prior to publishing the IRFA, information from representatives of small entities that may potentially be affected by its proposed rules to assess the potential impacts of that rule on such small entities. While this requirement does not apply where, as here, the agency certifies that the proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, the CFPB complied with this requirement when it included the proposed rule in the Small Business Review Panel convened on October 18 and 19, 2023. Details on the SBREFA Panel and SBREFA Panel Report for this proposed rule are described in part III.A.

B. Initial Regulatory Flexibility Analysis

1. Description of the Reasons Why Agency Action Is Being Considered

The creditor prohibition in section 604(g)(2) of the FCRA reflects Congress' intention to protect the privacy of sensitive medical information.²⁴⁴ The creditor prohibition generally prevents creditors from considering medical information pertaining to a consumer in determining the consumer's eligibility, or continued eligibility, for credit. As described in more detail in part IV.B, Congress allowed certain Agencies, and

later the CFPB, to make exceptions to this prohibition, consistent with the congressional intent "to restrict the use of medical information for inappropriate purposes."²⁴⁵ In 2005, the Federal financial agencies and the National Credit Union Administration promulgated the financial information exception, restated in the CFPB's regulations at § 1022.30(d), which allows a creditor to consider certain medical information, including medical debt information and information relating to expenses, assets, and collateral, pertaining to a consumer in crediting decisions, provided the conditions of a three-part test are met.²⁴⁶ The CFPB has preliminarily determined that an exception for creditors to consider this type of medical information for credit eligibility determinations is not "necessary and appropriate" to protect legitimate operational, transactional, risk, consumer, or other needs, nor is an exception consistent with the intent of the creditor prohibition to restrict the use of medical information for inappropriate purposes as required for an exception under FCRA section 604(g)(5). The CFPB has also preliminarily determined that an exception for creditors to consider medical information relating to a consumer's expenses, assets, and collateral would not meet the requirements for an exception under FCRA section 604(g)(5). As a result, the CFPB is proposing to remove the financial information exception and limit the circumstances under which consumer reporting agencies can include medical collections information in consumer reports provided to creditors. Further details may be found in parts I.B and V.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The primary objectives of this proposed rule are to enhance consumer privacy with respect to sensitive medical information and enable creditors to make appropriate credit decisions based on accurate information, in line with the purposes of the FCRA. The CFPB is authorized under section 604(g)(5) of the FCRA to promulgate exceptions to the creditor prohibition "that are determined to be necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs . . . consistent with the intent of [the

²⁴¹ See, e.g., Matthew Liu et al., Consumer Fin. Prot. Bureau, *Consumer Finances in Rural Appalachia* (Sept. 2022), <https://www.consumerfinance.gov/data-research/research-reports/consumer-finances-in-rural-appalachia/>.

²⁴² 5 U.S.C. 603, 609(b), (d)(2).

²⁴³ 5 U.S.C. 605(b).

²⁴⁴ FCRA section 604(g)(2) (15 U.S.C. 1681b(g)(2)).

²⁴⁵ FCRA section 604(g)(5) (15 U.S.C. 1681b(g)(5)).

²⁴⁶ This background and the three-part test are discussed in part V.A.

prohibition] to restrict the use of medical information for inappropriate purposes.” The CFPB also has authority under section 621(e) of the FCRA to issue regulations to carry out the purposes and objectives of, and to prevent evasions of or to facilitate compliance with, the FCRA. A discussion of the background leading to the proposed rule may be found in part I, and a discussion of the legal authority relevant to this proposed rule may be found in part IV.

3. Description and, Where Feasible, Provision of an Estimate of the Number of Small Entities To Which the Proposed Rule Will Apply

The proposed rule would affect small entities that participate as creditors as that term is defined in section 702 of the ECOA, except for small entities excluded from coverage by section 1029 of the CFPA, because it would prohibit them from considering certain medical information in their underwriting decisions. This information has been available to creditors under the financial information exception. In limiting the circumstances under which medical debt information can be included on consumer reports, the proposed rule would also affect some small consumer reporting agencies. Specifically, consumer reporting agencies that currently provide medical debt information to creditors for credit eligibility determinations would generally no longer be able to do so.

For the purposes of assessing the impacts of the proposed rule on small entities, “small entities” are defined in the RFA to include small businesses, small nonprofit organizations, and small government jurisdictions.²⁴⁷ A “small

business” is determined by application of Small Business Administration (SBA) regulations in reference to the North American Industry Classification System (NAICS) classification and size standards.²⁴⁸

There are several NAICS categories of small entities that may be subject to this proposed rule. Consumer reporting agencies receive and assemble various types of consumer information and provide consumer reports to third parties for various purposes. Consumer reporting agencies are mostly contained within the NAICS category “credit bureaus” (561450). However, not all entities within this NAICS code are consumer reporting agencies, and some consumer reporting agencies that may fall within this NAICS code may not identify themselves as such.²⁴⁹ Some consumer reporting agencies specialize in providing consumer reports to facilitate other operations, such as employment screening, check and bank account screening, and insurance.²⁵⁰ Many small consumer reporting agencies would not be affected by the proposed rule, either because they do not currently furnish consumer reports containing medical debt information or because, under the proposed rule, consumer reports containing medical debt information may continue to be provided for purposes other than credit eligibility, such as employment screening or insurance.

Creditors potentially affected by the proposals under consideration are contained in multiple NAICS categories. These include depository institutions, such as commercial banks and credit unions, and non-depository institutions, such as mortgage and non-mortgage loan brokers, as well as firms that are

primarily engaged in sales lending, consumer lending, or real estate credit. Creditors that currently use medical information related to debts, expenses, assets, and collateral in connection with a determination of a consumer’s eligibility, or continued eligibility, for credit would be directly affected by the proposed rule.

The SBA size standards use asset thresholds for depository institutions and revenue thresholds for non-depository institutions. Depository institutions are small if they have less than \$850 million in assets. Consumer reporting agencies are small if they receive less than \$47 million in annual revenues. Non-depository institutions in many industries are small if they receive less than \$47 million in annual revenues, but the threshold is lower for some NAICS categories of non-depository institutions.

Table 3 shows the number of small businesses within NAICS categories that may be subject to the proposed rule according to the December 2023 NCUA and FFIEC Call Report data and the 2017 Economic Census data from the U.S. Census Bureau, which are the most recent sources of data available to the CFPB. Entity counts are provided for the specific asset amount that the SBA uses to define small depository institutions. However, entity counts are not provided for the specific revenue amounts that the SBA uses to define small entities. For these entities, Table 3 includes the closest upper and lower estimates for each revenue limit (e.g., a NAICS category with a maximum size of \$47 million in receipts has both the count of entities with less than \$50 million in revenue and the count of entities with less than \$40 million in revenue).

TABLE 3—NUMBER OF ENTITIES WITHIN NAICS INDUSTRY CODES THAT MAY BE SUBJECT TO THE PROPOSED RULE

	Number of entities	Percent of entities
A. Consumer Reporting Agencies:		
Credit bureaus (561450)	307	
<\$35M (Revenues)	279	90.9
<\$75M (Revenues)	283	92.2
B. Creditors:		
Depository Firms:		
Commercial Banking (522110)	4248	
<\$850M (Assets)	1078	25.4
Credit Unions (522130)	4702	
<\$850M (Assets)	500	10.6
Savings Institutions and Other Depository Credit Intermediation (522180)	322	
<\$850M (Assets)	83	25.8
Credit Card Issuing (522210)	6	

²⁴⁷ 5 U.S.C. 601(6).

²⁴⁸ See U.S. Small Bus. Admin., *Table of size standards*, <https://www.sba.gov/document/support-table-size-standards> (last visited May 13, 2024).

²⁴⁹ NAICS 561450 also includes mercantile credit reporting bureaus. There may also be a small

number of consumer reporting agencies classified under Investigation and Personal Background Check Services (NAICS 561611).

²⁵⁰ An overview of the types of consumer reporting agencies may be found at: Consumer Fin. Prot. Bureau, *List of consumer reporting companies*,

<https://www.consumerfinance.gov/consumer-tools/credit-reports-and-scores/consumer-reporting-companies/> (last visited Apr. 15, 2024). This list is not intended to be all-inclusive and does not cover every company in the industry.

TABLE 3—NUMBER OF ENTITIES WITHIN NAICS INDUSTRY CODES THAT MAY BE SUBJECT TO THE PROPOSED RULE—
Continued

	Number of entities	Percent of entities
<\$850M (Assets)	1	16.7
Non-Depository Firms:		
Sales Financing (522220):	2367	
<\$40M (Revenues)	2112	89.2
<\$50M (Revenues)	2124	89.7
Consumer Lending (522291)	3037	
<40M (Revenues)	2905	95.7
<50M (Revenues)	2915	96.0
Real Estate Credit (522292)	3289	
<\$40M (Revenues)	2872	87.3
<\$50M (Revenues)	2904	88.3
Mortgage and Nonmortgage Loan Brokers (522310)	6809	
<\$15M (Revenues)	6670	98.0
Financial Transactions Processing, Reserve, and Clearinghouse Activities (522320)	3068	
<\$40M (Revenues)	2916	95.0
<\$50M (Revenues)	2928	95.4
Other Activities Related to Credit Intermediation (522390)	3772	
<\$25M (Revenues)	3610	95.7
<\$30M (Revenues)	3621	96.0

Table 4 provides the estimated number of small entities within the categories of credit bureaus, depository institutions, and non-depository institutions, as well as the NAICS codes these entities may fall within. Under the proposed rule, small consumer reporting agencies would no longer be able to provide to creditors consumer reports that contain medical debt information under the financial information exception. The CFPB is not able to precisely estimate the number of small consumer reporting agencies whose activities would be affected by the proposed rule. As discussed above, many consumer reporting agencies currently specialize in providing consumer reports for purposes that would not be affected by the proposed rule. Additionally, consumer credit markets currently rely heavily on consumer reports from consumer

reporting agencies which are not small entities.²⁵¹ For these reasons, the CFPB estimates that only a small fraction of the small consumer reporting agencies identified in Table 4 would be affected by the proposed rule. The CFPB requests data to more precisely quantify the number of small consumer reporting agencies that would be affected by the proposed rule.

Small creditors that would be affected by the proposed rule are included in several NAICS categories that can be broadly divided into depository and non-depository institutions. Small creditors would be generally prohibited from considering medical information from consumer reports (and other sources) in credit eligibility determinations under the proposed rule, unless a specific exception applies. However, some small creditors currently do not consider medical information that would be prohibited under the

proposed rule, and others only consider medical debt information if consumers disclose that they have made monthly payment arrangements with medical debt holders.²⁵²

While all small creditors would be subject to the proposed rule, the CFPB lacks the data to precisely quantify how many small creditors currently make credit decisions in ways that would be affected by the proposed rule. Small creditors who are currently in compliance, whether in whole or in part, with the proposed rule might not be impacted as much as small creditors who currently consider medical debt information (and certain other categories of medical information) from consumer reports or other sources. The CFPB requests data to precisely quantify the number of small creditors that may be directly affected by the proposed rule.

TABLE 4—ESTIMATED NUMBER OF SMALL ENTITIES BY CATEGORY ²⁵³

NAICS	Small entity threshold	Est. number of small entities
Consumer Reporting Agencies:		
561450	\$41M in revenue (NAICS 561450)	281
Depository Institutions:		
522110, 522130, 522180, 522210	\$850M in assets	1662
Non-depository Institutions:		

²⁵¹ Impacts to consumer reporting agencies are also described within part VII.E.

²⁵² Two small entity representatives provided this context in their comment letters. Written Submission of Evelyn Schroeder, Vice President, First Security Bank and Trust, to the CFPB, "Re: CFPB's Outline of Proposals and Alternatives Under Consideration, Small Business Advisory Review

Panel for Consumer Reporting Rulemaking" at 7 (Nov. 6, 2023). Written Submission of Jeff Jacobson, Vice President, New Market Bank, to the CFPB, "RE: SER response to SBREFA Outline for Consumer Reporting Rulemaking" at 5 (Nov. 6, 2023).

²⁵³ The estimated number of small entities is calculated by taking the sum of the number of

entities whose assets held or annual revenues fall below the relevant SBA thresholds for each NAICS code under the three categories, using the data presented in Table 3. When entity counts for a NAICS category in Table 3 are reported for two revenue limits (an upper and a lower bound), the average of the two entity counts is taken to estimate the number of small entities in that NAICS category.

TABLE 4—ESTIMATED NUMBER OF SMALL ENTITIES BY CATEGORY ²⁵³—Continued

NAICS	Small entity threshold	Est. number of small entities
522220, 522291, 522292, 522310, 522320, 522390	\$15M in revenue (NAICS 522310); \$28.5M in revenue (NAICS 522390) \$47M in revenue (NAICS 522220, 522291, 522292, 522320).	14454

4. Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for the Preparation of the Report

The proposed rule may impose reporting, recordkeeping, and other compliance requirements on small entities subject to the proposal. These requirements generally differ for entities in two classes: credit bureaus that function as consumer reporting agencies, and depository or non-depository institutions that function as creditors. Based on Table 4, these requirements would be imposed on, at most, an estimated 281 small consumer reporting agencies and 16,116 small creditors.

Requirements for Consumer Reporting Agencies

Under the proposed rule, consumer reporting agencies would only be able to provide to creditors (in connection with credit eligibility determinations) consumer reports that contain medical debt information if they have reason to believe that the creditor intends to use the medical debt information in a manner that is not prohibited. Thus, if consumer reporting agencies continue to receive and record medical debt information from furnishers, consumer reporting agencies may need to devise policies and procedures to ensure that they appropriately restrict the provision of medical debt information to creditors. However, these compliance costs may only apply to consumer reporting agencies who, at baseline, provide consumer reports containing medical debt information to creditors based on the existing financial information exception. Compliance for affected small consumer reporting agencies would generally require professional skills related to software development, legal expertise, compliance, and customer support. The CFPB does not have the data to estimate the costs of reporting, recordkeeping, and other compliance requirements for small consumer reporting agencies, and requests data to quantify these costs.

Requirements for Creditors

The proposed rule would generally prohibit creditors from using information related to medical debt (among other categories of medical information) in credit eligibility decisions. Creditors may have to change their underwriting procedures to ensure that they are in compliance with the proposed rule. Currently, many creditors use medical debt information from consumer reporting agencies that would no longer be available under the proposed rule. The proposed rule would not change any existing law or guidance regarding the information that creditors must request from applicants. Creditors may use (or continue to use) certain information, including information relating to medical debt, that consumers provide in credit applications to satisfy ability to repay requirements. The proposed rule may cause creditors to modify their underwriting procedures to rely more heavily on consumer information that they obtain from credit applications. These changes would generally require professional skills related to compliance, underwriting, and legal expertise. The CFPB requests data and evidence to estimate these costs.

5. Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

In its SBREFA Report, which addressed proposals under consideration for other aspects of a FCRA rulemaking as well as for the instant rulemaking regarding medical debt, the Panel identified certain Federal statutes and regulations that address consumer credit eligibility, debt collection, and privacy issues related to medical or financial information, as having provisions that may duplicate, overlap, or conflict with certain aspects of the proposals under consideration.²⁵⁴ Each of the statutes and regulations identified in the SBREFA Report, as well as additional statutes and regulations that may be relevant, is discussed below.

²⁵⁴ SBREFA Report at 36.

TILA ²⁵⁵ and the CFPB's implementing regulation, Regulation Z, 12 CFR part 1026, impose disclosure and other requirements on creditors. For example, TILA and Regulation Z generally prohibit creditors from making mortgage loans unless they make a reasonable and good faith determination that the consumer will have the ability to repay the loan. TILA and Regulation Z also contain ability-to-pay requirements for credit cards.

ECOA ²⁵⁶ and the CFPB's implementing regulation, Regulation B, 12 CFR part 1002, prohibit creditors from discriminating in any aspect of a credit transaction, including a business-purpose transaction, on the basis of race, color, religion, national origin, sex, marital status, age (if the applicant is old enough to enter into a contract), receipt of income from any public assistance program, or the exercise in good faith of a right under the Consumer Credit Protection Act.

The Fair Debt Collection Practices Act (FDCPA) ²⁵⁷ and the CFPB's implementing regulation, Regulation F, 12 CFR part 1006, govern certain activities of debt collectors, as that term is defined in the FDCPA. Among other things, the FDCPA and Regulation F prohibit debt collectors from engaging in unfair, deceptive, or abusive conduct when collecting or attempting to collect debts and require debt collectors to make certain disclosures to consumers in debt collection.

The Gramm-Leach-Bliley Act (GLBA) ²⁵⁸ and the CFPB's implementing regulation, Regulation P, 12 CFR part 1016, require financial institutions subject to the CFPB's jurisdiction to provide their customers with notices concerning their privacy policies and practices, among other things. They also place certain limitations on the disclosure of nonpublic personal information to nonaffiliated third parties, and on the redisclosure and reuse of such information. Other parts of the GLBA, as implemented by regulations and guidelines of certain other Federal

²⁵⁵ 15 U.S.C. 1601 *et seq.*

²⁵⁶ 15 U.S.C. 1691 *et seq.*

²⁵⁷ 15 U.S.C. 1692 *et seq.*

²⁵⁸ 15 U.S.C. 6801 *et seq.*

agencies (e.g., the Federal Trade Commission's Safeguards Rule and the prudential regulators' Safeguards Guidelines), set forth standards for administrative, technical, and physical safeguards with respect to financial institutions' customer information.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)²⁵⁹ and the Department of Health and Human Services' implementing regulations,²⁶⁰ also limit or regulate the use, collection, and sharing of certain health information. Among other things, HIPAA, as implemented by HHS regulations, sets national standards for the protection of individually identifiable health information by health plans, health care clearinghouses, and health care providers, as well as the security of electronic protected health information.

The Americans with Disabilities Act²⁶¹ and its implementing regulations, 28 CFR parts 35 and 36, prohibit discrimination against people with disabilities in many aspects of public life. Similarly, the Fair Housing Act prohibits unlawful discrimination in all aspects of residential real estate-related transactions.²⁶²

Small entity representatives also provided suggestions of other potentially related Federal statutes and regulations, such as the Patient Protection and Affordable Care Act,²⁶³ the No Surprises Act,²⁶⁴ and Medicare cost reporting rules.²⁶⁵

The CFPB requests comment to identify any additional such Federal statutes or regulations that may impose duplicative, overlapping, or conflicting requirements on financial institutions and potential changes to the proposed rules in light of such duplicative, overlapping, or conflicting requirements, if any. The CFPB further requests comment on methods to minimize such conflicts to the extent they might exist.

6. Description of Any Significant Alternatives to the Proposed Rule Which Accomplish the Stated Objectives of Applicable Statutes and Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

The CFPB considered several alternatives to the proposed rule that would possibly result in lower costs for small entities. These alternatives include: (1) alternative compliance timelines, (2) allowing creditors to consider specific types of medical information, (3) codifying and broadening the voluntary changes in medical collections reporting implemented by the NCRAs in 2022 and 2023, (4) requiring consumer reporting agencies to independently investigate the accuracy of furnished medical debt collections, and (5) defining when a furnisher must investigate the accuracy of furnished medical collections information. The CFPB also considered exemptions for small entities. However, the CFPB has preliminarily determined that such exemptions would not achieve the objective of FCRA section 604(g)(2) and the proposed rule to protect consumer privacy with respect to sensitive medical information.

The CFPB considered making the proposed rule effective more than 60 days after the issuance of a final rule. During the SBREFA process, several small creditors stated that they would need time to comply with the proposals discussed at the panel. One small creditor stated that their compliance department is already working at full capacity to comply with recently issued rules, and that they and others in the financial industry will need additional time to comply with further rules. The CFPB has preliminarily determined that compliance with the proposed rule would not impose a significant economic impact on a substantial number of small entities. Further, allowing additional time for compliance would extend the period during which sensitive medical information may continue to be used for credit eligibility determinations.

As described in the SBREFA Outline, the CFPB considered removing the financial information exception only with respect to medical information relating to debts, while continuing to allow creditors to consider medical information relating to expenses, assets, collateral, income, benefits, and the purpose of the loan. The CFPB has preliminarily determined that a creditor's consideration of medical information relating to expenses, assets, and collateral is not warranted, and has

therefore proposed to remove the financial information exception with respect to these additional categories of medical information.

The final three alternatives considered may not achieve some of the objectives of the proposed rule. These alternatives were included in the discussions with small entity representatives and the SBREFA Panel. As discussed in part VII.D, the NCRAs voluntarily implemented changes in the credit reporting of medical debt. Because their changes were voluntary, codifying and broadening the changes may protect consumers from the possibility that NCRAs might choose to reverse their policies in the future. The last two alternatives would serve to increase the accuracy of medical collections information on credit reports. The CFPB has preliminarily determined that these three alternatives would not achieve the objective of protecting consumer privacy with respect to sensitive medical information.

7. Discussion of Impact on Cost of Credit for Small Entities

Because the proposed rule would only affect how small creditors and small consumer reporting agencies obtain or use consumers' medical information, the CFPB does not expect that the proposed rule would affect the business lending market. The CFPB preliminarily concludes that the costs of credit for small creditors and small consumer reporting agencies would not be impacted by the proposed rule. The CFPB requests comment as to whether this conclusion is accurate, and any information that may inform this analysis.

IX. Severability

The CFPB preliminarily intends that, if the consumer reporting agency prohibition on furnishing medical debt information proposed in § 1022.38 (or any provision or application of that section) is stayed or determined to be invalid, the proposed amendments to § 1022.30 are severable and shall continue in effect. But because proposed § 1022.38 relies on the proposed amendments to § 1022.30, if the proposed amendments to § 1022.30 (or any provisions or applications of those amendments) were stayed or determined to be invalid, the CFPB preliminarily intends that § 1022.38 would not take (or continue in) effect. Furthermore, if the result of a stay or judicial determination is that creditors are generally able to obtain or use medical information in connection with determinations of consumers' eligibility,

²⁵⁹ Public Law 104–191, 110 Stat. 1936 (1996).

²⁶⁰ See 45 CFR parts 160 and 164.

²⁶¹ 42 U.S.C. 12101 *et seq.*

²⁶² 42 U.S.C. 3605 (prohibiting discrimination because of race, color, religion, national origin, sex, handicap, or familial status in residential real estate-related transactions); see also 24 CFR part 100.

²⁶³ Public Law 111–148, 124 Stat. 119 (2010).

²⁶⁴ 42 U.S.C. 300gg–111 *et seq.*

²⁶⁵ See 42 CFR ch. IV.

or continued eligibility, for credit, the CFPB intends the current version of § 1022.30(d) to continue in effect.

X. Paperwork Reduction Act

The CFPB has determined that the proposed rule would have de minimis burden and therefore, would not impose any new information collections or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act.²⁶⁶

XI. Technical Appendix

This appendix describes the technical details of the CFPB's analysis that aims to estimate how medical collection consumer reporting affects consumer access to credit, considering an "equilibrium" in which all medical collections are removed from consumer reports, as under the proposed rule. The analysis also compares the performance of new credit accounts that can be traced to creditors' inquiries for consumers that have medical collections. The analysis exploits a change in consumer reporting practices that occurred in 2017 that has prevented medical collections that are less than 180 days past their date of first delinquency from appearing on consumer reports obtained from the nationwide consumer reporting agencies (NCRAs).²⁶⁷ As a result of this change, when consumers applied for credit in the 180 days before a medical collection was added to their consumer report, they had an outstanding medical debt that was in collections, but creditors would not have seen evidence of those medical collections on consumer reports when making determinations about whether to extend credit to the consumers.²⁶⁸

1. Data Used

The data for this analysis are derived from the CFPB's Consumer Credit

Information Panel (CCIP), a 1-in-50 de-identified nationally representative sample of credit records from one of the three NCRAs. The data include information on consumers' credit accounts, collections, public records, credit scores, and inquiries, which are creditor requests for consumer reports. Each credit account is described by a "tradeline," which includes the account's product type, balance amount, initial credit limit or loan principal, date of origination, anonymized firm identifier, and delinquency status.²⁶⁹ Collections are also described by tradelines, which include the collection's balance amount, the original creditor's industry classification, and the date that the collection was added to the consumer report. Each inquiry includes the product type for which the consumer applied and the date that the inquiry was made. The sample used in the analysis includes all inquiries made by creditors within 180 days of a medical collection's addition to a consumer report. In other words, the sample includes inquiries made within 180 days of the time each medical collection became visible to creditors.

The CFPB created two datasets to estimate the effect of medical collection reporting on access to credit and credit account performance. The first dataset includes all inquiries made in the 180 days before and after each medical collection's addition to a consumer report (inquiry dataset). The second dataset includes the two-year performance of all credit account tradelines that can be traced back to an inquiry in the inquiry dataset (performance dataset).²⁷⁰ Both datasets only include inquiries made and credit account tradelines opened in response to credit applications from consumers with medical collections.

The analysis is limited to inquiries associated with medical collections first reported at least six months after the final implementation of the NCAP in September 2017, which ensured that all medical collections were identifiable as such and that all consumers with reported medical collections had a past-due medical bill for at least 180 days prior to the medical collection's

appearance on their consumer report.²⁷¹ Given these constraints, the dataset includes inquiries associated with medical collections that were furnished to the NCRA that provides the CFPB's CCIP between March 2018 and July 2023.²⁷²

Each dataset includes a subsample of inquiries and tradelines that were associated with medical collections having initial balances over \$500 and that were made when any other medical collections on the consumer report had initial balances over \$500. This specification is referred to as the "over-\$500" sample and mimics the current reporting environment in which medical collections under \$500 are not included on consumer reports.²⁷³ This is the primary sample considered in the analysis, but results for the full sample (which includes inquiries associated with medical collections under \$500 and inquiries made when medical

²⁷¹ Prior to NCAP, the field in credit record data indicating the original creditor type of a collections tradeline was optional and was left blank by the furnisher for around a quarter of all collections tradelines in the CCIP. Some of these tradelines with unreported original creditor type were likely medical collections tradelines. One component of the NCAP was to make the original creditor type a mandatory field, such that all medical collections reported after September 2017 can be identified as such.

²⁷² The sample is limited to inquiries associated with medical collections added to consumer reports between March 2018 and July 2023 because the dataset needs to include all inquiries made within a 361-day window of each medical collection. A medical collection reported before March 2018 may have an associated inquiry that was made before the September 2017 reporting change, while a medical collection reported after July 2023 may have an associated inquiry that was made after the final date of the CFPB's CCIP at the time of the research analysis, January 2024. The sample includes inquiries made in the 180 days before a medical collection is reported because all consumers have an outstanding medical collection during that period, and includes inquiries made in the 180 days after a medical collection is reported in order to have a balanced window. Additionally, note that the sample may omit some inquiries associated with medical collections. Some collections may not have been reported to all three NCRAs, so the CFPB may not observe all consumers' medical collections. Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

²⁷³ The NCRAs removed medical collections with balances below \$500 from consumer reports in April 2023. The datasets include inquiries made through January 2024, and so a small portion of the inquiries in the datasets were subject to this removal. All of these inquiries are included in the "over-\$500" sample of the results. See PR Newswire, *Equifax, Experian and TransUnion Remove Medical Collections Debt Under \$500 From U.S. Credit Reports* (Apr. 11, 2023), <https://www.prnewswire.com/news-releases/equifax-experian-and-transunion-remove-medical-collections-debt-under-500-from-us-credit-reports-301793769.html>.

²⁶⁶ 44 U.S.C. 3501.

²⁶⁷ Assurance of Voluntary Compliance/Assurance of Voluntary Discontinuance (May 20, 2015), *In re Equifax Info. Servs.*, <https://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Consumer-Protection/2015-05-20-CRAs-AVC.aspx>. <https://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Consumer-Protection/2015-05-20-CRAs-AVC.aspx>.

²⁶⁸ This practice continued through June 2022, when the 180-day period was extended to one year. PR Newswire, *Equifax, Experian and TransUnion Remove Medical Collections Debt Under \$500 From U.S. Credit Reports* (Apr. 11, 2023), <https://www.prnewswire.com/news-releases/equifax-experian-and-transunion-remove-medical-collections-debt-under-500-from-us-credit-reports-301793769.html>.

²⁶⁹ Credit record data are described in detail by Christa Gibbs et al., Consumer Fin. Prot. Bureau, *Consumer Credit Reporting Data* (Dec. 6, 2023), <https://bguttmankenney.github.io/Public/CreditData/EL.pdf>.

²⁷⁰ The CFPB considered two-year delinquency as an outcome because it is the standard used in credit scoring models. VantageScore, *Credit Score Basics, Part 1: What's Behind Credit Scores?* (Nov. 2011), https://www.transunion.com/docs/rev/business/financialservices/VantageScore_CreditScoreBasics-Part1.pdf.

collections under \$500 appeared on the consumer report) are also provided.

The inquiry and performance datasets are structured at the inquiry or credit account tradeline level, and not at the consumer or medical collection level. This means the analysis can be interpreted as modeling credit decisions and outcomes from creditors' perspective, rather than modeling the decisions of consumers or debt collectors.

When a consumer has multiple medical collections, the data contain duplicates of the inquiries and credit account tradelines if they occur within 180 days of different medical collections. For example, suppose a consumer has two medical collections that are first reported on May 1 and on September 1. Suppose a creditor makes an inquiry on August 1. This inquiry will appear in the inquiry dataset twice: once for the May 1 collection, and once for the September 1 collection. Inquiries and credit account tradelines are also duplicated when consumers have multiple medical collections reported on the same day.

Three reporting changes occurred during the sample period that removed certain types of medical collections from consumer reports.²⁷⁴ However, because the analysis exploits the date that a medical collection was added to a consumer report instead of the date it was removed from a consumer report, these changes do not undermine the general methodology of the analysis. The reporting changes do affect the types of medical collections that were on consumer reports when inquiries were made.²⁷⁵ The CFPB first describes each of these three changes and their impact, before addressing the consequences for the analysis. First, all paid medical collections were removed from consumer reports in June 2022. Fewer than 2.5 percent of medical collections reported between January 2017 and March 2022 were ever marked

as paid.²⁷⁶ Second, medical collections that were between 180 days and 365 days past due were removed from consumer reports in June 2022, and the delay before medical collections could be added to consumer reports was permanently extended to one year. The CFPB does not have an estimate of how many medical collections were affected by this change, as the number of days that the medical debt is past due is not provided in the CCIP. Finally, all medical collections under \$500 were removed from the NCRAs' consumer reports in April 2023. Combined, these reporting changes contributed to a large decline in the number of consumers with medical collections on their consumer report, from 14 percent of consumers in March 2022 to 5 percent of consumers in June 2023.²⁷⁷

Because of these reporting changes for some inquiries that were made after a medical collection tradeline was first reported, the medical collection may not have been present on the consumer report by the date of the inquiry. For example, if a consumer had a medical collection with an initial balance less than \$500 first reported in February 2023, and an inquiry in May 2023, the inquiry would be classified as occurring about three months after the collection but would not in fact have that collection included on the consumer report at the time of the inquiry. The CFPB expects this to attenuate the results, as inquiries made "with medical collection reporting" would have outcomes more similar to inquiries with the medical collection not yet reported. Medical collections reported before January 2022 would not have associated inquiries affected by any of these reporting changes.

The analysis of the performance dataset is not affected by the recent reporting changes. Because the focus is on two-year performance, the performance analysis only included tradelines opened before January 2022, as they require sufficient time to measure two-year performance. Therefore, the performance regressions are not impacted by these medical collection removals.

2. Construction of the Inquiry Dataset

Because inquiries in the dataset are made in the 180 days before and after a medical collection is reported, the inquiries in the dataset occurred between September 2017 and January 2024. The dataset includes the number and type of medical and nonmedical collections that were included on the consumer report at the time each inquiry was made.

Identifying unique medical collections over time in the CCIP may be imprecise; the CFPB assumes that unique medical collections are characterized by their dollar amounts, dates of medical collection account opening (usually the date the medical collection was assigned to the debt collector or other furnisher), and dates of the account's addition to the consumer report. Medical collections are rarely consistently reported for the full seven-year period for reporting adverse information permitted by the Fair Credit Reporting Act.²⁷⁸ This poses challenges in tracking the same medical debt over time, as debts can disappear and reappear. Medical debts in collections are often transferred between debt collectors (e.g., reassigned to a different collector by the health care provider or sold to a debt buyer), and when this happens the dates and dollar amounts associated with the medical collection tradelines may change, making it difficult to link these records. While these may be experienced as unique collections by the consumer as a new debt collector attempts to make contact, they may not be representative of the number of unique medical debts that each consumer has, as many of the debts are reflected by multiple subsequent collections.²⁷⁹

The inquiry dataset is used to estimate the impact of medical collection reporting on consumers' access to credit, as measured by inquiry success. The CFPB classifies an inquiry as "successful" if the inquiry leads to an open tradeline. This definition of "success" does not necessarily mean that the specific credit application that

²⁷⁴ PR Newswire, *Equifax, Experian and TransUnion Remove Medical Collections Debt Under \$500 From U.S. Credit Reports* (Apr. 11, 2023), <https://www.prnewswire.com/news-releases/equifax-experian-and-transunion-remove-medical-collections-debt-under-500-from-us-credit-reports-301793769.html>.

²⁷⁵ Furthermore, the reporting changes may impact how creditors used medical collections in their credit eligibility determinations. For example, suppose creditors weighted medical collections more heavily in their determinations after the April 2023 reporting change. Then inquiries made with reported medical collections after April 2023 may have a lower success rate than inquiries made prior to the change. The estimated coefficient provides an average impact of medical collection reporting on inquiry success and cannot identify these potential changes in creditor behavior.

²⁷⁶ Lucas Nathe & Ryan Sandler, Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

²⁷⁷ Ryan Sandler & Zachary Blizard, Consumer Fin. Prot. Bureau, *Recent Changes in Medical Collections on Consumer Credit Records Data Point*, at 3–4, 17 (Mar. 2024), https://files.consumerfinance.gov/f/documents/cfpb_recent-changes-medical-collections-on-consumer-credit-reports_2024-03.pdf.

²⁷⁸ Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

²⁷⁹ A challenge in studying the impact of medical collections tradelines is that a shock to consumers' health, such as an injury or illness that results in hospitalization, may affect credit outcomes independently. Given this challenge, one benefit of these collection debt transfers is that it means that the medical expense that resulted in the medical collections tradeline is relatively more likely to have occurred long before the medical collection appeared.

generated the inquiry was being approved. The CFPB cannot directly observe whether the specific credit application that generated the inquiry in question was approved, and it is challenging to infer approval for a specific inquiry for several reasons. First, the CCIP does not include inquiries made to other NCRAs, and creditors do not always make inquiries to all three NCRAs. The CCIP therefore includes credit account tradelines that cannot be matched to an inquiry. These tradelines cannot be included in the CFPB's analysis because the empirical strategy requires that one know the date of each tradeline's associated inquiry. Second, the CCIP does not include creditor names, but instead has an anonymized company identifier; however, a particular creditor often has a different identifier for inquiries and for opened credit account tradelines. Thus, even if the consumer opened a tradeline with the same creditor that pulled their consumer report, it may not be identifiable as such in the data. Therefore, the CFPB cannot be certain that the observed inquiry is associated with a specific opened tradeline. The CFPB instead follows approaches used in academic research and the CFPB's Consumer Credit Trends credit tightness series and assumes that a credit account is associated with an inquiry if it is opened within a certain number of days after the observed inquiry and is of the same credit account type.²⁸⁰ The number of days varies for different account types because of differences in the typical length of time between an account application and origination.²⁸¹

²⁸⁰ See Charles Romeo & Ryan Sandler, Off. of Rsch., Consumer Fin. Prot. Bureau, *The effect of debt collection laws on access to credit*, 195 J. Econ. (2021), <https://ssrn.com/abstract=3124954>; Consumer Fin. Prot. Bureau, *Credit Trends: Market dashboards* (Dec. 10, 2019), <https://www.consumerfinance.gov/data-research/consumer-credit-trends/>.

²⁸¹ The inquiries are considered to be within a shopping window if they are within 14 days for credit cards and auto loans, 120 days for mortgages, and 30 days for all other loan types, following approaches used in academic research and the CFPB's Consumer Credit Trends credit tightness

Finally, when consumers shop for credit, multiple inquiries may be made in a narrow window of time, even though the consumer only intends to open one account. The CFPB assumes that multiple inquiries for one consumer within a certain shopping window indicate the consumer's shopping behavior, and therefore only the last of these inquiries is included in the datasets, where each credit account type's window length is equivalent to its maximum time-to-origination.²⁸² For example, if a consumer had inquiries from mortgage lenders on April 1 and May 1, these would be treated as one observation, dated May 1, and it would be counted as a successful inquiry if a mortgage account was opened by August 29.

3. Construction of the Performance Dataset

The performance dataset includes all originated credit account tradelines that are associated with successful inquiries in the inquiry dataset. The match between credit account tradelines and inquiries is one-to-one: each tradeline is matched to one inquiry, and each inquiry is matched to, at most, one tradeline.²⁸³ The CFPB calculated the two-year performance for each originated credit account tradeline, with

series, both of which use data similar to the CCIP. See Charles Romeo & Ryan Sandler, Off. of Rsch., Consumer Fin. Prot. Bureau, *The effect of debt collection laws on access to credit*, 195 J. Econ. (2021), <https://ssrn.com/abstract=3124954>; Consumer Fin. Prot. Bureau, *Credit Trends: Market dashboards* (Dec. 10, 2019), <https://www.consumerfinance.gov/data-research/consumer-credit-trends/>.

²⁸² This follows approaches used in academic research and the CFPB's Consumer Credit Trends credit tightness series, both of which use data similar to the CCIP. See Charles Romeo & Ryan Sandler, Off. of Rsch., Consumer Fin. Prot. Bureau, *The effect of debt collection laws on access to credit*, 195 J. Econ. (2021), <https://ssrn.com/abstract=3124954>; Consumer Fin. Prot. Bureau, *Credit Trends: Market dashboards* (Dec. 10, 2019), <https://www.consumerfinance.gov/data-research/consumer-credit-trends/>.

²⁸³ When multiple credit account tradelines within a time 14, 30, or 120 days of an inquiry (as appropriate for the type of credit) are observed, the tradeline with the earliest origination date is kept.

performance success measured by whether the tradeline was ever 90 or more days delinquent (seriously delinquent) within the first two years of its origination date.²⁸⁴ Because the CFPB focuses on two-year performance, credit account tradelines opened after January 2022 are not included in the analysis as the CFPB cannot observe a full two years after origination. The CFPB was able to identify the two-year performance of over 94 percent of the credit account tradelines opened before January 2022. The exceptions are accounts that stopped being reported by the furnisher before the end of two years.

The inquiry and performance datasets are structured at the inquiry or credit account tradeline level, and not at the consumer or medical collection level. This means the econometric analysis can be interpreted as modeling creditor decisions and creditor outcomes, as viewed from creditors' perspectives, rather than modeling the decisions of consumers or debt collectors.

When a consumer has multiple medical collections, the data contain duplicates of the inquiries and credit account tradelines if they occur within 180 days of different medical collections. For example, suppose a consumer has two medical collections that are first reported on May 1 and on September 1. Suppose a creditor makes an inquiry on August 1. This inquiry will appear in the inquiry dataset twice: once for the May 1 collection, and once for the September 1 collection. Inquiries and credit account tradelines are also duplicated when consumers have multiple medical collections reported on the same day.

4. Inquiry Summary Statistics

²⁸⁴ Credit account tradelines are matched over time either using the tradeline's account number or the tradeline's date of account opening and loan type. Tradelines are matched on origination date and loan type when there is no match on account number because account numbers can change when an account is lost or transferred, e.g., if a consumer loses their credit card and has a new card issued.

TABLE 5—INQUIRY SUMMARY STATISTICS²⁸⁵

	(1) Credit cards	(2) Mortgages	(3) Other inq. type
Panel A: Unsuccessful, Over \$500 Sample:			
Shopping window (days)	0.47	16.87	0.89
No. open mortgages	0.03	0.11	0.04
No. open credit cards	0.73	1.18	0.68
No. open other trades	0.61	0.82	0.64
Any D90+ trades	0.30	0.29	0.29
Credit score	563.89	613.81	566.76
Obs. (Unique Inquiries)	259532	44524	218127
Panel B: Successful, Over \$500 Sample:			
Shopping window (days)	1.00	42.74	1.11
No. open mortgages	0.07	0.23	0.07
No. open credit cards	1.36	1.85	1.11
No. open other trades	0.71	0.99	1.08
Any D90+ delinquent trades	0.26	0.20	0.29
Credit score	624.44	673.12	602.45
Credit amount	1645.96	244846.31	5374.88
Two-year D90+	0.21	0.03	0.25
Past due amount	145.19	304.43	661.84
Obs. (Unique Inquiries)	117147	11188	13160
Panel C: Unsuccessful, Full Sample:			
Shopping window (days)	0.46	16.09	0.86
No. open mortgages	0.03	0.12	0.04
No. open credit cards	0.69	1.15	0.64
No. open other trades	0.56	0.80	0.60
Any D90+ trades	0.30	0.30	0.30
Credit score	562.12	607.76	563.39
Obs. (Unique Inquiries)	892295	171704	761275
Panel D: Successful, Full Sample:			
Shopping window (days)	0.97	40.69	1.06
No. open mortgages	0.08	0.26	0.06
No. open credit cards	1.32	1.84	0.98
No. open other trades	0.70	0.96	1.04
Any D90+ trades	0.27	0.20	0.30
Credit score	621.08	670.13	597.12
Credit amount	1582.59	238199.13	5597.18
Two-year D90+	0.20	0.03	0.23
Past due amount	125.17	201.84	598.32
Obs. (Unique Inquiries)	409209	42138	52669

Table 5 provides summary statistics for the unique inquiries in the data. The

²⁸⁵ Each panel in the table includes one observation per inquiry. All values are means. Panels A and B limit the sample to consumers with at least one inquiry that is associated with a medical collection over \$500 and includes no medical collections on the consumer report under \$500 when the inquiry is made. Panels C and D include the full sample. Panels A and C include all inquiries that do not correspond to a tradeline opened within the inquiry type's origination window. Panels B and D include all inquiries that can be matched to an originated tradeline. "Shopping window (days)" provides the length of the shopping window for each inquiry, where the shopping window is equal to zero if all inquiries are made on the same day. Variables providing the number of open accounts for a given credit account type, "No. open", describe the number of accounts of a given type that appeared on the consumer report in the month before the inquiry. "Any D90+ trades" is equal to one if the consumer had at least one tradeline (open or closed) that had been at least 90+ days delinquent in the last seven years included on their consumer report in the month before the inquiry. "Credit score" is equal to the credit score in the month before the inquiry. "Credit amount", "Two-year D90+", and "Past due

summary statistics are provided separately for "unsuccessful" inquiries that do not result in originated credit account tradelines, which are provided in Panels A and C, and for "successful" inquiries that can be associated to originated tradelines, which are provided in Panels B and D. Panels A and B are limited to the over-\$500 sample, while Panels C and D provide summary statistics for the full sample. Table 5 shows that successful inquiries are associated with stronger credit profiles for every inquiry type and for both considered samples. The average

amount" describe tradelines that opened in response to the inquiry, where "Credit amount" provides the credit limit of revolving accounts or credit account principal of installment accounts, "Two-year D90+" is equal to one if the account is at least 90 days delinquent within two years of its origination date, and "Past due amount" is the dollar amount past due on the account after two years. These variables cannot be included in Panels A and C because no account was opened in response to unsuccessful inquiries.

successful credit applicant has more open pre-existing credit account tradelines, fewer seriously delinquent pre-existing credit account tradelines, and a higher credit score in the month or quarter before inquiry was made than the average unsuccessful credit applicant.²⁸⁶ The table also shows that successful credit applicants shop for longer than unsuccessful credit applicants in the sample. Panels B and D further include the average characteristics of credit accounts opened in response to successful inquiries, measuring the credit limit at time of origination, the past due amount, and serious delinquency status two years after origination, showing that

²⁸⁶ These characteristics are considered as of the month or quarter before the inquiry because they can be affected by the outcome of the inquiry. The month before the inquiry is used when data is available, but only quarterly data are available prior to 2020 for some variables.

credit cards are much more likely than mortgages to be seriously delinquent within two years from opening, perhaps in part because credit cards are

unsecured. However, the average past due amount is lower for credit cards, perhaps because average credit card monthly minimum payments are much

lower than mortgage monthly payment amounts.

5. Consumer Summary Statistics

TABLE 6—CONSUMER SUMMARY STATISTICS²⁸⁷

	(1) Mean	(2) Median	(3) Obs. (unique consumers)
Panel A: Over \$500 Sample:			
No. medical collections	2.24	1.00	266147
Months between date of last med. coll. and date of first med. coll.	20.47	0.00	266147
No. credit card inquiries	1.42	1.00	266147
No. mortgage inquiries	0.21	0.00	266147
No. other inquiries	1.11	1.00	266147
Credit score at first inquiry	594.52	588.00	214485
Missing credit score at first inquiry	0.19	0.00	266147
Consumer age at first inquiry	40.29	38.00	261488
Northeastern share at first inquiry	0.08	0.00	266147
Midwestern share at first inquiry	0.15	0.00	266147
Southern share at first inquiry	0.61	1.00	266147
Western share at first inquiry	0.14	0.00	266147
Panel B: Full sample:			
No. medical collections	4.08	2.00	688682
Months between date of last med. coll. and date of first med. coll. = ...	35.77	10.92	688682
No. credit card inquiries	1.89	1.00	688682
No. mortgage inquiries	0.31	0.00	688682
No. other inquiries	1.52	1.00	688682
Credit score at first inquiry	596.10	590.00	558362
Missing credit score at first inquiry	0.19	0.00	688682
Consumer age at first inquiry	41.89	40.00	676075
Northeastern share at first inquiry	0.10	0.00	688682
Midwestern share at first inquiry	0.19	0.00	688682
Southern share at first inquiry	0.54	1.00	688682
Western share at first inquiry	0.16	0.00	688682

Table 6 provides summary statistics at the consumer level, using the first

²⁸⁷ Each panel in the table includes one observation per consumer. All values are means. Panel A limits the sample to consumers with at least one inquiry that is associated with a medical collection over \$500 and includes no medical collections under \$500 on the consumer report when the inquiry is made. Panel B includes the full sample. “No. medical collections” provides the number of unique medical collections in the sample for each consumer. Because each observation in the analysis dataset corresponds to an inquiry, consumers may have additional medical collections that are not represented in the sample if there were no inquiries made in the 180 days before or after those medical collections were first reported. “Months between date of last med. coll. and date of first med. coll.” provides the number of months between each consumer’s medical collections, for those medical collections that are represented in the sample. The “No. inquiries” variables only include inquiries made in the 180 days before or after a medical collection was first reported; consumers may have other inquiries that are not included in the data if they did not fall within these 361-day windows. Variables “at first inquiry” are provided for each consumer’s earliest inclusion in the sample, as they may change within consumers over time. There are fewer consumer observations corresponding to average credit scores than for the other statistics in both panels because average credit score is only calculated using data from consumers whose credit scores are non-missing. There are also some consumers with missing birth year that are not included in the calculation of average age. State regional shares were calculated using Census Regions; see U.S. Census Bureau,

observation for each consumer observed in the inquiry dataset. On average, a consumer in the over-\$500 sample experiences 2.24 medical collections that appear within 180 days of an inquiry. These medical collections are, on average, approximately 20 months apart from the earliest to the latest reported. Nineteen percent of the consumers in the sample do not have a credit score in the month before their first inclusion in the sample; for consumers who do have a credit score, it is most often subprime.²⁸⁸ More than 60 percent of consumers in the sample are located in Southern States, reflecting the disproportionate share of consumers with medical debt in the South documented in prior research.²⁸⁹ These summary statistics support the generalizability of the results, as the

Geographic Levels, <https://www.census.gov/programs-surveys/economic-census/guidance-geographies/levels.html> (last revised Oct. 8, 2021).

²⁸⁸ Consumer Fin. Prot. Bureau, *Borrower risk profiles*, <https://www.consumerfinance.gov/data-research/consumer-credit-trends/student-loans/borrower-risk-profiles/> (last visited May 9, 2024).

²⁸⁹ U.S. Census Bureau, *19% of U.S. Households Could Not Afford to Pay for Medical Care Right Away* (Apr. 7, 2021), <https://www.census.gov/library/stories/2021/04/who-had-medical-debt-in-united-states.html>.

sample of consumers is generally similar to the overall population of consumers with medical collections during this time period.²⁹⁰ Furthermore, the summary statistics for consumers in the full sample are similar to those for the over-\$500 sample, but consumers in the over-\$500 have nearly two fewer medical collections reported within 180 days of an inquiry in the sample. Though this at first may seem counterintuitive, this is because consumers with several medical collections often have at least one medical collection valued under \$500 which removes them from the over-\$500 subsample.

6. Empirical Strategy

The CFPB used a regression discontinuity in time (RDIT) design to estimate the effect of reported medical collections on consumers’ access to credit and the performance of credit account tradelines resulting from creditors’ inquiries. Regression

²⁹⁰ Consumer Fin. Prot. Bureau, *Paid and Low-Balance Medical Collections on Consumer Credit Reports* (July 27, 2022), <https://www.consumerfinance.gov/data-research/research-reports/paid-and-low-balance-medical-collections-on-consumer-credit-reports/>.

discontinuity is a quasi-experimental design that, under certain assumptions, allows estimation of the causal effect of a treatment or intervention where a treatment is assigned by a threshold value of that variable.²⁹¹ In the present context, inquiries are “treated” when a medical collection tradeline is added to the NCRA’s database. The date that a medical collection is added to a consumer report is the “threshold” that potentially creates a discontinuous effect on the studied dependent variables: inquiry success and two-year serious delinquency. Before this date, creditors cannot observe the medical collection on the consumer report at the time an inquiry is made, but the CFPB can observe using the CCIP that the consumer did have a medical debt in collections that would eventually be reported. The proximity of each inquiry to the threshold, referred to as the “running variable” in regression discontinuity terminology, is equal to the number of days between the date that the collection was first included on the consumer report and the date that the inquiry was made. When the inquiry date occurred after the medical collection reported date (or in other words, the medical collection was included on the consumer report before the inquiry was made), this running variable is greater than or equal to the “threshold” zero; for values less than or equal to zero, the medical collection was not included on the consumer report when the inquiry was made. The key assumption of a regression discontinuity analysis is that nothing is changing discontinuously across the threshold besides the treatment.

To analyze inquiry success, the CFPB estimated Equation 1 using the inquiry dataset:

$$Y_{ijk} = \alpha + \gamma D_{ijk} + \beta Z_{ijk} + \delta D_{ijk} \times Z_{ijk} + \epsilon_{ijk} \quad (1)$$

Where i is a consumer, j is an inquiry, and k is the medical collection associated with the inquiry. Y_{ijk} is a binary variable equal to one if the inquiry is successful, *i.e.*, if a tradeline is originated within 14 days for a credit card or auto loan, 120 days for a mortgage, or 30 days for other loans. D_{ijk} is the running variable, *i.e.*, the number of days after medical collection k was added to the consumer report that inquiry j was made. D_{ijk} is negative if the inquiry was made before the medical collection was added, and positive if the inquiry was made after. Z_{ijk} is a binary

variable equal to one if the inquiry j was made after the date when collection k was reported. The coefficient of interest, β , represents the difference in the likelihood that an inquiry is successful for inquiries made after a medical collection is added, relative to inquiries made before. The intercept α allows estimation of a more flexible linear form.

The CFPB also estimated Equation 1 for the performance dataset, using the two-year performance of tradelines that can be traced to an inquiry included in the inquiry dataset as the dependent variable. The estimating equation is largely unchanged, though j is interpreted as a tradeline associated with an inquiry in the inquiry dataset (rather than the inquiry itself), and Y_{ijk} is a binary variable equal to one if the account is at least 90 days delinquent on the tradeline at any point within the first two years after the tradeline is originated (rather than if the inquiry is associated with a tradeline origination, as in the inquiry dataset regression).

In the results described below, the CFPB estimated six specifications to estimate impacts on inquiry success and account performance. The first specification is limited to the over-\$500 sample, as defined above. The second and third specifications separate the over-\$500 sample into two groups: inquiries that were made when the consumer had no nonmedical collections on their consumer report, and inquiries made when consumers had nonmedical collections on their consumer report. These specifications test whether reported medical collections affect inquiry success and better predict account performance for consumers with fewer signals of negative information. The hypothesis is that the effects of a reported medical collection should be larger for inquiries made without nonmedical collections on the consumer report. If a consumer already has nonmedical collections, the appearance of a medical collection likely implies a lower marginal change in expected delinquency risk. Finally, the CFPB then estimated each of these three specifications for all inquiries in the sample.

The CFPB only reports its estimates of the parameter β which provides the effect of medical collection furnishing on inquiry success and account performance. Combined across the main results and balance tests described later, the CFPB estimated a total of 192 β coefficients, so the reported standard errors were adjusted using the Benjamini-Hochberg procedure, a method for accounting for multiple comparisons (under which it is more

likely to find a statistically significant result by chance than in a one-off analysis).²⁹²

To justify the robustness of the main specification, the CFPB considers the potential threats to identification that can arise from RDIT specifications. RDIT varies from a standard regression discontinuity design because the running variable is not generally continuous. As summarized by an academic paper, RDIT designs can be biased if observations far from the threshold time period are used for identification, as there may be autoregressive properties or unobservable confounders.²⁹³ This is often required in RDIT designs that have little cross-sectional variation, as the sample size can only grow by adding observations further from the threshold, rather than by adding additional cross-sectional units. However, the data underlying the analysis discussed in this document contains ample cross-sectional variation, with 663,678 unique inquiries in the inquiry dataset and 401,027 unique tradelines in the performance dataset for the over-\$500 sample. Furthermore, the analysis considers observations that are no more than 180 days from the threshold, minimizing the extent of possible autoregression. In addition to these features of the datasets that limit the potential for bias arising from the RDIT design, the CFPB estimates the regressions using econometric best practices as implemented by a practitioner software package.²⁹⁴ Standard errors are clustered by consumer to account for correlation within consumer observations over time. Additionally, the CFPB conducted several robustness checks to support the validity of the main design, described in detail after the discussion of the main results.

²⁹² See Yoav Benjamini & Yosef Hochberg, *Controlling the False Discovery Rate: A Practical and Powerful Approach to Multiple Testing*, 57(1) J. of the Royal Stat. Soc’y Series B (Methodological), at 289–300 (1995), <http://www.jstor.org/stable/2346101>.

²⁹³ Catherine Hausman & David S. Rapson, *Regression Discontinuity in Time: Considerations for Empirical Applications*, 10 Ann. Rev. of Res. Econ. (2018), <https://www.annualreviews.org/content/journals/10.1146/annurev-resource-121517-033306>.

²⁹⁴ Specifically, the regressions are estimated using the Stata package *rdrobust*, implemented with a triangular kernel, a common mean-square-error-optimal bandwidth selector, and adjustments for mass points. Sebastian Calonico et al., *rdrobust: Software for regression-discontinuity designs*, 17:2 Stata J. (2017), https://rdpackages.github.io/references/Calonico-Cattaneo-Farrell-Titiunik_2017_Stata.pdf.

²⁹¹ Guido W. Imbens & Thomas Lemieux, *Regression discontinuity designs: A guide to practice*, 142(2) J. Econometrics, at 615–35 (Feb. 2008), <https://www.sciencedirect.com/science/article/abs/pii/S0304407607001091>.

7. Results on Inquiry Success

The CFPB first uses the inquiry dataset to consider how medical collection reporting affects inquiry success. Importantly, an unsuccessful inquiry does not necessarily imply that the lender denied the credit application. Consumers may be approved for credit with worse terms than they would have received absent medical collection

reporting and decline the offer of credit as a result, or consumers may choose not to take up approved credit for idiosyncratic reasons. However, this is less likely to be an issue with credit cards because the CFPB understands that credit card accounts are generally issued automatically if the creditor approves an application, with little opportunity for a consumer to decline.

The CFPB assumes that consumers' underlying demand for credit is unaffected by medical collection reporting, so changes in inquiry success across the reporting threshold can be attributed to creditors' denial of credit account applications or provision of worse terms, rather than changes in who applies. The CFPB justifies this assumption below.

TABLE 7—THE EFFECT OF MEDICAL COLLECTION REPORTING ON INQUIRY SUCCESS²⁹⁵

	(1) Over \$500	(2) Over \$500, no NMC	(3) Over \$500, NMC	(4) All	(5) No NMC	(6) NMC
Panel A: Credit cards: RD Estimate	*** − 0.047 (0.006) [− 0.059, − 0.036]	*** − 0.072 (0.009) [− 0.090, − 0.055]	*** − 0.029 (0.006) [− 0.041, − 0.018]	*** − 0.033 (0.003) [− 0.038, − 0.027]	*** − 0.049 (0.005) [− 0.059, − 0.040]	*** − 0.022 (0.003) [− 0.028, − 0.017]
Avg. success	0.294	0.381	0.222	0.275	0.364	0.214
Observations	601230	267276	333954	3026355	1233571	1792784
Panel B: Mortgages: RD Estimate	* − 0.026 (0.012) [− 0.049, − 0.004]	* − 0.040 (0.018) [− 0.074, − 0.006]	− 0.003 (0.012) [− 0.027, 0.022]	− 0.014 (0.009) [− 0.031, 0.004]	− 0.013 (0.015) [− 0.043, 0.017]	− 0.005 (0.006) [− 0.016, 0.006]
Avg. success	0.186	0.248	0.098	0.167	0.235	0.089
Observations	79372	46003	33369	439685	237413	202272
Panel C: Other credit accounts: RD Estimate	* − 0.014 (0.006) [− 0.026, − 0.003]	* − 0.020 (0.009) [− 0.038, − 0.002]	− 0.010 (0.007) [− 0.024, 0.004]	*** − 0.015 (0.003) [− 0.021, − 0.009]	*** − 0.024 (0.005) [− 0.033, − 0.015]	** − 0.010 (0.004) [− 0.017, − 0.003]
Avg. success	0.242	0.307	0.197	0.246	0.316	0.205
Observations	469290	190942	278348	2484030	908849	1575181

Standard errors in parentheses, 95 percent confidence intervals in brackets.

*p < 0.1, **p < 0.05, ***p < 0.01.

Table 7 provides the results of the main regression discontinuity analysis on inquiry success. Each panel represents a different loan type, as products generally have different underwriting procedures. At a high level, several summary observations can be made. First, just over half of the inquiries in the full sample of the inquiry dataset are for credit cards. Only

7.4 percent of the inquiries in this sample are for mortgages, compared to almost 17 percent of all inquiries in the CCIP. This likely reflects the fact that most consumers in the sample have thin credit files²⁹⁶ and subprime credit scores, and therefore may be less likely to apply for mortgages than for other types of credit, given the higher underwriting standards of mortgages.²⁹⁷ Inquiry success rates are higher for all loan types when inquiries are made without nonmedical collections on the consumer report than when nonmedical collections are present, with differences as large as 15.9 percentage points. This is expected because consumers with less

negative information on their consumer reports are more likely to be approved for credit or receive favorable terms. Perhaps less intuitively, average success rates for credit cards and mortgages are also generally higher for the subsample of inquiries made by consumers who only have medical collections valued over \$500, if they have any. As discussed above, inquiries made by consumers with many medical collections are often excluded from the over-\$500 sample because at least one of those medical collections is under \$500. The average number of medical collections on a consumer report when an inquiry is made in the full sample, in Column 4, across all loan types, is 5.03. Conversely, the average number of medical collections on a consumer report when an inquiry is made, for inquiries made with all medical collections greater than \$500, in Column 1 is 1.08. Thus, the over-\$500 sample is positively selected, *i.e.*, consumers in this sample have less negative information than consumers in the full sample, at least as measured by the number of medical collections present on their consumer reports. Despite the

²⁹⁵ The table provides the regression discontinuity estimates for the inquiry dataset, separately by credit account type. Each coefficient (RD Estimate) estimates a percentage point effect of having an additional medical collection reported on inquiry success. These effects can be represented as percent changes by comparing to the baseline "Avg. success", which is calculated as the success rate of all inquiries made to the left of the regression discontinuity threshold (or without medical collection reporting). Column 1 limits the sample to inquiries associated with medical collections over \$500 made when the consumer had no medical collections under \$500 on their consumer report, which is then subset into Columns 2 and 3. Column 2 limits the sample to inquiries made when the consumer did not have a nonmedical collection (NMC) on their consumer report; Column 3, when consumers did have a nonmedical collection on their consumer report. Column 4 includes the full sample. Columns 5 and 6 are defined equivalently to Columns 2 and 3 for the full sample. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

²⁹⁶ A thin credit file is a consumer report that contains fewer than five credit accounts. Jennifer White, Experian, *What is a Thin Credit File?* (May 25, 2022), <https://www.experian.com/blogs/ask-experian/what-is-a-thin-credit-file-and-how-will-it-impact-your-life/>.

²⁹⁷ Consumers with credit scores below 500 may not be approved for a mortgage but can usually access secured credit cards. Louis DeNicola, Experian, *How to Buy a House with Bad Credit* (Oct. 7, 2023), <https://www.experian.com/blogs/ask-experian/how-to-get-a-home-loan-with-bad-credit/>; Consumer Fin. Prot. Bureau, *How to rebuild your credit* (July 2020), https://files.consumerfinance.gov/f/documents/cfpb_how-to-rebuild-your-credit.pdf.

positive selection into the over-\$500 sample, the CFPB expects these results to most closely represent the effects of removing all medical collections from consumer reports given the parallel with the NCRAs' current practice for under-\$500 medical collections.

Turning to the regression estimates in Table 7, Column 1 of Panel A (credit cards) shows that a medical collection being reported causes a 4.7 percentage point decline in the likelihood of inquiry success for the over-\$500 sample. This represents a 16.0 percent decline from relative to the average success rate for inquiries to the left of the regression discontinuity threshold (*i.e.*, inquiries made before the medical collection was reported). The effect is larger in absolute value for inquiries made when the consumer had no nonmedical collections on their consumer report, shown in Column 2, than when consumers had nonmedical collections on their consumer report, shown in Column 3. This supports the hypothesis that medical collection reporting has a larger effect on consumers without outstanding nonmedical collections. Columns 4 through 6 repeat the groups from Columns 1 through 3 but include the full sample. The regression result shown in Column 4 of Panel A describes a 3.3 percentage point, or 12.0 percent, decline in inquiry success for inquiries made with these larger medical collections reported relative to inquiries made without these medical collections reported. Again, effects are larger in absolute value for inquiries made when consumers did not have nonmedical collections on their consumer report than when nonmedical collections were present.

The first three Columns of Panel B (mortgages) find relatively small and no more than marginally significant effects of medical collection reporting on mortgage inquiry success. Medical collection reporting reduces mortgage inquiry success by 2.6 percentage points, or 14.0 percent of its baseline level. The effect appears to be driven by inquiries made when there were no nonmedical collections on the consumer report, as the coefficient in Column 3 is statistically insignificant and small. However, the estimates in Columns 1 and 2 are only statistically significant at the 10 percent level.²⁹⁸ All estimates for the full sample in Columns 4 through 6 are statistically insignificant. Using the 95 percent confidence interval for the coefficient in Column 4 of Panel B, it is possible to reject effects larger than a 3.1 percentage point, or 18.6 percent, decline in inquiry success for the full sample.²⁹⁹

Panel C provides results for all other types of credit accounts. The estimated effects are all smaller in magnitude than the results for credit cards and vary in statistical significance. The coefficients imply that medical collection reporting causes a 1.4 percentage point decline in the likelihood of inquiry success for non-mortgage and non-credit-card credit accounts for the over-\$500 sample, or a 5.8 percent decline from the baseline inquiry success rate. Estimated effects are similar for the full sample. As with the effects on credit cards and mortgage inquiries, effects for both samples are larger for consumers without nonmedical collections.

8. Results on Account Performance

The estimated effects on inquiry success show that the underwriting

procedures for many credit types penalize consumers for having medical collections on their consumer reports, with generally larger effects for consumers with medical collections over \$500. The CFPB next considered whether this use of medical collections protects creditors from delinquency risk. If creditors use medical collection information to accurately predict whether consumers have high delinquency risk and deny their applications, then originated accounts resulting from a successful inquiry for a consumer with an unreported medical collection at the time of the inquiry would be more likely to be seriously delinquent than those resulting from a successful inquiry for a consumer with a reported medical collection. However, to the extent that creditors provide worse credit terms to consumers with reported medical collections and such worse credit terms increase the likelihood of serious delinquency, one might expect the opposite: Originated accounts resulting from an inquiry for a consumer with an unreported medical collection could be less likely to be seriously delinquent (because they received more affordable credit terms) than those resulting from an inquiry for a consumer with a reported medical collection (because they received worse credit terms). These opposing effects make it impossible to determine how the underlying delinquency risk of consumers with and without unreported medical collections varies. However, the results of this analysis are still informative as to how two-year delinquency rates are affected by medical collection reporting, net of the effects of application denials and the provision of worse terms.

TABLE 8—THE EFFECT OF MEDICAL COLLECTION REPORTING ON TWO-YEAR CREDIT ACCOUNT PERFORMANCE³⁰⁰

	(1) Over \$500	(2) Over \$500, no \$500, NMC	(3) Over NMC	(4) All	(5) No NMC	(6) NMC
Panel A: Credit cards:						
RD Estimate	−0.000 (0.012) [−0.023,0.023]	0.002 (0.014) [−0.026,0.031]	−0.003 (0.021) [−0.045,0.038]	0.002 (0.006) [−0.009,0.013]	0.004 (0.007) [−0.010,0.018]	−0.005 (0.008) [−0.021,0.011]
Avg. D90+	0.231	0.190	0.293	0.223	0.171	0.284

²⁹⁸ That is, given the variability in the data, if medical collections had no effect on inquiry success, one would expect an estimate as large as those show in Columns 1 and 2 less than 10 percent of the time, but more than 5 percent of the time, through chance alone.

²⁹⁹ The confidence intervals provided in brackets in the tables contain the true value of the parameter being estimated with 95 percent confidence, *i.e.*, if the CFPB had sufficient data to run this regression with 100 different samples, and estimated 100 different confidence intervals, one would expect 95 of these confidence intervals would contain the true value of the parameter. Therefore, the CFPB can reject coefficients outside of the bounds of its

estimated confidence intervals as unlikely to be consistent with the true effect of medical collections reporting on inquiry success with 95 percent confidence.

³⁰⁰ The table provides the regression discontinuity estimates for the performance dataset, separately by credit account type. The results estimate effects on two-year 90-day delinquency rate for all accounts originated from a successful inquiry in the inquiry dataset. Each coefficient (RD Estimate) estimates a percentage point effect of having an additional medical collection reported on inquiry success. These effects can be represented as percent changes using the baseline "Avg. D90+", which is calculated as the 90-day delinquency rate

of all inquiries made to the left of the regression discontinuity threshold (or without medical collection reporting). Column 1 limits the sample to inquiries associated with medical collections over \$500 made when the consumer had no medical collections under \$500 on their consumer report, which is then subset into Columns 2 and 3. Column 2 limits the sample to inquiries made when the consumer did not have a nonmedical collection (NMC) on their consumer report; Column 3, when consumers did have a nonmedical collection on their consumer report. Column 4 includes the full sample. Columns 5 and 6 are defined equivalently to Columns 2 and 3 for the full sample.

TABLE 8—THE EFFECT OF MEDICAL COLLECTION REPORTING ON TWO-YEAR CREDIT ACCOUNT PERFORMANCE ³⁰⁰—
Continued

	(1) Over \$500	(2) Over \$500, no \$500, NMC	(3) Over NMC	(4) All	(5) No NMC	(6) NMC
Observations	96297	56423	39874	565680	305980	259700
Panel B: Mortgages: RD Estimate	−0.011 (0.014) [−0.039,0.017]	−0.021 (0.014) [−0.049,0.007]	0.033 (0.034) [−0.033,0.100]	0.004 (0.007) [−0.009,0.017]	−0.006 (0.006) [−0.018,0.007]	0.034 (0.019) [−0.003,0.071]
Avg. D90+	0.035	0.025	0.069	0.038	0.029	0.065
Observations	10177	7944	2233	56976	43106	13870
Panel C: Other credit accounts: RD Estimate	−0.012 (0.014) [−0.040,0.015]	−0.011 (0.015) [−0.041,0.019]	−0.009 (0.021) [−0.050,0.033]	−0.001 (0.006) [−0.012,0.011]	−0.002 (0.006) [−0.014,0.011]	−0.002 (0.009) [−0.019,0.016]
Avg. D90+	0.182	0.135	0.235	0.171	0.120	0.216
Observations	71760	36951	34809	459094	213481	245613

Standard errors in parentheses, 95 percent confidence intervals in brackets.

*p < 0.1, **p < 0.05, ***p < 0.01.

Table 8 shows the results of the main regression discontinuity analysis in the performance dataset. Across all loan types and subsamples, the estimated effects of medical collection reporting on serious delinquency are small and statistically insignificant. Column 1 of Panel A shows that, in the over-\$500 sample, the CFPB can reject effects larger in absolute value than 2.3 percentage points, or 10.0 percent of the baseline delinquency rate, with 95 percent confidence. That is, it would be highly unlikely to find an estimate as small as what is reported in Table 8 through chance alone if having an unreported medical collection was associated with an increase in the rate of serious delinquency by 10 percent or more. The confidence interval is tighter and the central estimate more positive (*i.e.*, unreported medical collections associated with less delinquency) for inquiries made when consumers did not have nonmedical collections on their consumer report than when these collections were present. This means that the true effects for inquiries made without nonmedical collections are more likely to be positive. Further, if there is a difference in delinquency rate for consumers with unreported medical collections, these consumers are less likely to be delinquent than consumers with reported medical collections. This also holds for the full subsample in Columns 4 through 6.

These results broadly find that credit card lenders use medical collection information in underwriting, but do not reduce their two-year serious delinquency risk for originated credit account tradelines by doing so. Fewer accounts are originated to consumers with reported medical collections, but those that are originated are no less likely to be delinquent than accounts originated to consumers with unreported medical collections. This suggests that removing medical collections information from credit card underwriting would increase access to credit without negatively impacting the likelihood of serious delinquency for consumers with medical collections, all else equal.

The results in Panel B show qualitatively similar estimates for mortgages, but with less precisely estimated effects. The effects are less precise because the average serious delinquency rate is much lower for mortgages than for credit cards: only 3.5 percent of mortgages in the over-\$500 sample are seriously delinquent within two years, compared to 23.1 percent of credit cards. The lower frequency in the dependent variable as well as the smaller sample size will naturally lead to wider confidence intervals. Column 1 shows that the CFPB can only reject marginal reductions in mortgage delinquency rates with reported medical collections that are larger in absolute value than 3.9 percentage points, or 11.4 percent of the baseline delinquency rate, with 95 percent confidence. For the full sample, the CFPB can reject marginal reductions larger in absolute value than 0.9 percentage points, or 23.7 percent of baseline delinquency rate. Though these

results are too imprecise to allow the rejection of large effects, their statistical insignificance can be interpreted as suggestive that removing larger medical collections from mortgage underwriting would not cause increases in serious delinquency risk.

As for credit cards, the results for non-mortgage and non-credit-card accounts, shown in Table 8, are mostly statistically insignificant and small in magnitude. Again, the CFPB concludes that the use of medical collections information in underwriting does not reduce the delinquency risk of accounts originated to people with reported medical collections.

9. Results Related to Credit Demand and Selection

The results described in the previous two subsections confirm suggest that creditors use medical collections information in their underwriting procedures, but this information does not enable them to originate accounts that are less likely to become seriously delinquent. This interpretation of the regression discontinuity results relies on the identifying assumption discussed above: the only difference between the inquiries made before and after a medical collection is added to a consumer report is the medical collection reporting itself, rather than that the application delinquency risk (quality) is lower for consumers with reported medical collections. This section discusses evidence supporting this identifying assumption.

Though the analysis benefits from ample observations near the threshold, as discussed above, RDit specifications may still be affected by anticipation or selection effects if cross-sectional

³⁰¹ This figure plots the number of inquiries made in each week within 180 days of the medical collection's first reported date. The number of inquiries is provided as a ratio, relative to the number of inquiries made in the week before the associated medical collection's first reported date. The first and last week of the 180-day window include only six days and are not plotted.

observations can sort themselves on either side of the threshold. In this setting, consumers may be less likely to apply for credit after a medical collection is added to their consumer report. If consumers with lower delinquency risk have more knowledge about when a medical collection will be

added to their consumer report, they may be more likely to apply for credit immediately to the left of the threshold (*i.e.*, just before the medical collection is added to the consumer report). The CFPB first considered how the magnitude of credit demand changes across the reporting threshold by

plotting the number of inquiries made in each week relative to the week of the medical collection's addition to the consumer report.

Figure 1: Inquiry Distribution Across Weeks³⁰¹



Figure 1 plots the number of inquiries made in each week relative to the week before the date a medical collection was added to a consumer report, represented as week zero. For all credit account products, credit demand is largely stable through the 25 weeks before the medical collection is reported, but there is an immediate reduction in the week that the medical collection is reported. Credit demand rebounds quickly from this initial drop but remains persistently lower for the 25 weeks after the medical collection is reported, only approaching its pre-report level by the final considered week for credit cards and mortgages. Though the reduction in credit demand is sharp around the week of the medical collection's first report, it is not large; at most, credit demand falls by eight percent of the baseline (for mortgages).

Any reduction in credit demand corresponding to medical collection reporting may appear to threaten the identifying assumption, which requires that applications for credit made by

consumers with reported medical collections only differ from those made by consumers whose medical collections were not yet reported because of the medical collection reporting itself, and not because application quality differs. However, credit demand may fall for reasons that do not simultaneously affect credit application quality. For example, many NCRA's provide credit monitoring services that alert a consumer when a collection is added to their consumer report.³⁰² A consumer who planned to apply for credit may no longer do so if they are aware of a medical collection's negative effect on their credit score, which would affect their access to credit. The causality may also flow in the other direction if debt collectors track consumer reports and use "collection triggers" to focus their medical collection reporting after consumers apply for or open new credit accounts.³⁰³ These mechanisms cannot be observed in the data but could explain the observed discontinuous

decline in credit demand around medical collection reporting.

To estimate if credit application quality changes across the threshold, the CFPB estimated balance tests using Equation 1, where Y_{ijk} is equal to one of several variables that describe the consumer report at the time of the inquiry j . This estimates how inquiries made with reported medical collections differ from inquiries made with unreported medical collections. If such differences are large in absolute value and statistically significant, one might be concerned that there are underlying differences in the types of credit applications made when medical collections are reported that could be driving the regression discontinuity results, instead of the medical collection reporting itself. Finding small or imprecise coefficients would support the identifying assumption that the only difference in inquiries across the regression discontinuity threshold is the addition of a medical collection to the consumer report.

TABLE 9—INQUIRY BALANCE TESTS³⁰⁴

	(1) Credit card	(2) Mortgage	(3) Other credit accounts
Panel A: Over \$500 sample: RD Estimate	0.117 (0.172)	0.257 (0.464)	0.118 (0.172)

³⁰² See, e.g., Equifax, *Equifax Complete*TM, <https://www.equifax.com/personal/products/credit-monitoring-and-reports/> (last visited May 15, 2024).

³⁰³ See, e.g., Experian, *Collection Triggers*SM; Monitoring your collections accounts, <https://www.experian.com/business/products/collection-triggers> (last visited May 15, 2024).

³⁰⁴ The table includes balance tests for the inquiry sample. Panel A limits the sample to inquiries

associated with a medical collection over \$500 and no medical collections under \$500 on the consumer report when the inquiry is made. Panel B includes the full sample. These balance tests estimate Equation 1 using characteristics from the consumer's consumer report in the month before the creditor makes an inquiry. "RD Estimate" provides the estimate for β when the dependent variable is the variable whose average is provided.

Each column limits the sample by inquiry type. "Any D90+" describes whether any open or closed account on the consumer report is at least 90 days delinquent, and "tot. past due am." describes the total amount past due or charged off across all accounts. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

TABLE 9—INQUIRY BALANCE TESTS³⁰⁴—Continued

	(1) Credit card	(2) Mortgage	(3) Other credit accounts
Avg. consumer age	39.295	41.430	38.637
RD Estimate	** - 3.208 (1.192)	4.034 (3.572)	- 0.540 (1.255)
Avg. credit score	576.254	617.565	569.366
RD Estimate	**0.012 (0.005)	- 0.001 (0.009)	0.008 (0.005)
Avg. missing credit score	0.197	0.074	0.151
RD Estimate	0.032 (0.035)	0.050 (0.115)	0.026 (0.039)
Avg. num. open loans	1.328	1.997	1.275
RD Estimate	- 0.001 (0.005)	- 0.010 (0.012)	- 0.008 (0.006)
Avg. any D90+	0.265	0.256	0.268
RD Estimate	49.549 (63.234)	* - 259.894 (149.575)	29.122 (72.823)
Avg. tot. past due am	1131.626	1155.664	1276.969
Panel B: Full sample:			
RD Estimate	0.072 (0.077)	- 0.111 (0.235)	- 0.077 (0.087)
Avg. age	41.092	43.078	40.784
RD Estimate	* - 1.472 (0.590)	1.868 (1.990)	- 0.817 (0.642)
Avg. credit score	569.811	606.276	561.472
RD Estimate	**0.007 (0.003)	0.002 (0.004)	*0.005 (0.003)
Avg. missing credit score	0.171	0.073	0.134
RD Estimate	- 0.010 (0.020)	- 0.092 (0.047)	- 0.010 (0.018)
Avg. num. open loans	1.122	1.749	1.065
RD Estimate	0.001 (0.003)	- 0.000 (0.006)	0.000 (0.004)
Avg. any D90+	0.262	0.260	0.267
RD Estimate	- 33.152 (42.478)	- 72.382 (76.899)	70.836 (40.274)
Avg. tot. past due am.	1073.628	1135.919	1190.611

Standard errors in parentheses.

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$.TABLE 10—PERFORMANCE BALANCE TESTS³⁰⁵

	(1) Credit card	(2) Mortgage	(3) Other credit accounts
Panel A: Over \$500 sample:			
RD Estimate	0.261 (0.296)	0.294 (0.894)	0.200 (0.366)
Avg. consumer age	41.404	42.692	40.184
RD Estimate	- 3.694 (2.012)	7.807 (7.099)	0.502 (2.608)
Avg. credit score	618.329	668.427	601.025
RD Estimate	- 0.005 (0.006)	0.005 (0.010)	0.002 (0.007)
Avg. missing credit score	0.078	0.014	0.099
RD Estimate	***0.286 (0.092)	*0.564 (0.340)	0.089 (0.092)
Avg. num. open loans	1.884	2.834	1.804
RD Estimate	0.017 (0.009)	- 0.019 (0.027)	- 0.002 (0.013)
Avg. any D90+	0.248	0.191	0.268
RD Estimate	175.228 (112.690)	- 332.580 (302.978)	16.765 (180.777)
Avg. tot. past due am	1034.492	673.171	1220.532
Panel B: Full sample:			
RD Estimate	**0.411 (0.154)	0.871 (0.630)	0.068 (0.200)
Avg. consumer age	43.264	44.083	42.246

TABLE 10—PERFORMANCE BALANCE TESTS ³⁰⁵—Continued

	(1) Credit card	(2) Mortgage	(3) Other credit accounts
RD Estimate	– 1.670 (0.921)	– 0.602 (3.340)	– 1.194 (1.197)
Avg. credit score	611.625	660.599	590.484
RD Estimate	– 0.001 (0.003)	0.002 (0.005)	– 0.000 (0.004)
Avg. missing credit score	0.057	0.016	0.087
RD Estimate	– 0.027 (0.042)	– 0.162 (0.157)	0.029 (0.045)
Avg. num. open loans	1.671	2.588	1.530
RD Estimate	0.003 (0.005)	– 0.028 (0.016)	0.007 (0.007)
Avg. any D90+	0.256	0.189	0.274
RD Estimate	82.685 (88.985)	– 135.890 (138.828)	35.141 (76.515)
Avg. tot. past due am	1005.487	609.676	1191.860

Standard errors in parentheses.

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$.

Table 9 provides results for the inquiry dataset and Table 10 provides results for the performance dataset. Nearly all coefficients are not statistically significant, and where there is statistical significance, the magnitude of the coefficient is never larger than 20 percent of the mean value. This implies that credit applications submitted by consumers with reported medical collections are similar to those submitted by consumers whose medical collections are not yet on their consumer reports at the time of application, and differences in inquiry success and account performance can be attributed to the medical collection reporting itself.

To further test for the presence of anticipation or selection effects, the CFPB estimated a “donut” regression that removes from the sample all inquiries made within seven days of their associated medical collection’s addition to the consumer report. If the regression estimates are driven by anticipation or selection, the effects would be much smaller when estimated without observations near the reporting threshold, as application quality would be less selected from the threshold. In addition, medical collections may not be reported to all three NCRA on precisely the same date. The creditors that make inquiries to the NCRA that provides the CFPB’s CCIP may observe a medical collection on an inquiry they

make to a different NCRA and use this information, even though it appears in the CCIP that the medical collection was not reported. Additionally, the construction of inquiry shopping windows and inherent imprecision in connecting inquiries to opened tradelines may further limit the accuracy of calculating the running variable. This is especially important near the reporting threshold because a one-day error in assigning the date a medical collection was reported or an inquiry was made could be sufficient to erroneously categorize the medical collection reporting status of an inquiry. The CFPB further considered variation in dates within inquiry shopping windows below.

TABLE 11—THE EFFECT OF MEDICAL COLLECTION REPORTING ON INQUIRY SUCCESS AND CREDIT ACCOUNT PERFORMANCE, USING A 14-DAY DONUT ³⁰⁶

	(1) Over \$500, success	(2) Over \$500, D90+	(3) All, success	(4) All, D90+
Panel A: Credit cards:				
RD Estimate	*** – 0.060 (0.0080) [– 0.075, – 0.045]	– 0.006 (0.015) [– 0.036, 0.024]	*** – 0.041 (0.005) [– 0.050, – 0.032]	0.008 (0.008) [– 0.009, 0.024]
Avg. dep. var	0.294	0.232	0.275	0.223
Observations	578088	92708	2908047	543865

³⁰⁵ The table includes balance tests for the performance sample. Panel A limits the sample to inquiries associated with a medical collection over \$500 and no medical collections under \$500 on the consumer report when the inquiry is made. Panel B includes the full sample. These balance tests estimate Equation 1 using characteristics from the consumer’s consumer report in the month before the creditor makes an inquiry. “RD Estimate” provides the estimate for β when the dependent variable is the variable whose average is provided. Each column limits the sample by inquiry type. “Any D90+” describes whether any open or closed account on the consumer report is at least 90 days delinquent, and “tot. past due am.” describes the

total amount past due or charged off across all accounts. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

³⁰⁶ The table provides regression discontinuity estimates for the inquiry and performance datasets, separately by credit account type, and omitting all inquiries made within seven days of the associated medical collection’s reporting date, making a 14-day “donut hole” of omitted inquiries. Each coefficient (RD Estimate) estimates a percentage point effect of having an additional medical collection reported on inquiry success (in Columns 1 and 3) using the inquiry dataset or 90-day delinquency (in Columns 2 and 4) using the

performance dataset. These effects can be represented as percent changes by comparing to a baseline “Avg. dep. var.”, which is calculated as the success rate or 90-day delinquency rate of all inquiries made to the left of the regression discontinuity threshold (or without medical collection reporting). Columns 1 and 2 limit the sample to inquiries associated with medical collections over \$500 made when the consumer had no medical collections under \$500 on their consumer report. Columns 3 and 4 include the full sample. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

TABLE 11—THE EFFECT OF MEDICAL COLLECTION REPORTING ON INQUIRY SUCCESS AND CREDIT ACCOUNT PERFORMANCE, USING A 14-DAY DONUT ³⁰⁶—Continued

	(1) Over \$500, success	(2) Over \$500, D90+	(3) All, success	(4) All, D90+
Panel B: Mortgages:				
RD Estimate	** – 0.037 (0.017) [– 0.071, – 0.004]	– 0.022 (0.025) [– 0.071]	*** – 0.043 (0.008) [– 0.060, – 0.027]	– 0.003 (0.011) [– 0.026, 0.019]
Avg. dep. var	0.186	0.035	0.167	0.038
Observations	76358	9797	422584	54818
Panel C: Other Credit Accounts:				
RD Estimate	– 0.009 (0.009) [– 0.027, 0.009]	– 0.038 (0.025) [– 0.087, 0.012]	* – 0.010 (0.004) [– 0.018, – 0.002]	0.008 (0.010) [– 0.012, 0.027]
Avg. dep. var	0.242	0.182	0.245	0.171
Observations	451474	69159	2387333	441523

Standard errors in parentheses, 95 percent confidence intervals in brackets.

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$.

Table 11 provides the “donut” specification regression results. By comparing Column 1 of Table 7 to Column 1 of Table 11 and comparing Column 4 of Table 7 to Column 3 of Table 11, one can observe that effects on inquiry success are larger in absolute magnitude and more statistically significant for credit cards and mortgages in the donut specification than in the main specification. This shows that the main results using the inquiry data are not driven by selection or anticipation effects. Instead, the results in the main specification may be attenuated by fuzziness in the date that the medical collection was reported or that the inquiry was made, as discussed above.

Despite the modest differences between Table 11 and Table 7 for the inquiry dataset, there are no meaningful differences in the magnitude or statistical significance of effects for the performance datasets, as shown by

comparing Column 1 of Table 8 to Column 2 of Table 11 and comparing Column 4 of Table 8 to Column 4 of Table 11. This provides further evidence that the use of medical collection reporting in underwriting does not improve account performance.

A final concern is that it could be problematic if there is a hidden effect to the number of days between the first date a medical collection tradeline is reported and the date of an inquiry as the running variable. The potential issue is that there may be bunching at certain values of the running variable if the likelihood of a medical collection being reported, or an inquiry being made, differs across days of the week. For example, fewer than four percent of the medical collections associated with inquiries in the inquiry dataset were reported on a Sunday, compared to nearly 28 percent reported on a Tuesday. The distribution of inquiries in the inquiry dataset (across all inquiry

product types) is more even, with a low of 8.5 percent on Sunday, just over 15 percent on Monday through Friday, and nearly 14 percent on Saturday. Combining these two features, an inquiry made on a Monday is more likely to correspond to a medical collection on the subsequent day than an inquiry made on a Saturday. If the types of inquiries made on Mondays differ from those made on Saturdays, there may disproportionately more inquiries made on Monday for the running variable value immediately before the threshold (equal to -1), which could cause selection bias in the estimated effect. To test whether this selection biases the regression results, the CFPB estimated an additional specification that adds binary indicator variables to the main specification for the day of the week of each observation’s inquiry date and date of the medical collection report.

TABLE 12—THE EFFECT OF MEDICAL COLLECTION REPORTING ON INQUIRY SUCCESS AND CREDIT ACCOUNT PERFORMANCE, CONTROLLING FOR DAY-OF-WEEK EFFECTS ³⁰⁷

	(1) Over \$500, success	(2) Over \$500, D90+	(3) All, success	(4) All, D90+
Panel A: Credit cards:				
RD Estimate	*** – 0.048 (0.006) [– 0.059, – 0.038]	– 0.002 (0.012) [– 0.024, 0.021]	*** – 0.034 (0.003) [– 0.039, – 0.028]	0.001 (0.006) [– 0.010, 0.012]
Avg. dep. var	0.294	0.231	0.275	0.223

³⁰⁷ The table provides regression discontinuity estimates for the inquiry and performance datasets, separately by credit account type, and including binary control variables for the day of the week that the inquiry was made (or the inquiry shopping window’s last date) and the day of the week of the associated medical collection’s addition to the consumer report. Each coefficient (RD Estimate) estimates a percentage point effect of having an

additional medical collection reported on inquiry success (in Columns 1 and 3) in the inquiry dataset or 90-day delinquency (in Columns 2 and 4) in the performance dataset. These effects can be represented as percent changes by comparing to a baseline “Avg. dep. var.”, which is calculated as the success rate or 90-day delinquency rate of all inquiries made to the left of the regression discontinuity threshold (or without medical

collection reporting). Columns 1 and 2 limit the sample to inquiries associated with medical collections over \$500 made when the consumer had no medical collections under \$500 on their consumer report. Columns 3 and 4 include the full sample. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

TABLE 12—THE EFFECT OF MEDICAL COLLECTION REPORTING ON INQUIRY SUCCESS AND CREDIT ACCOUNT PERFORMANCE, CONTROLLING FOR DAY-OF-WEEK EFFECTS³⁰⁷—Continued

	(1) Over \$500, success	(2) Over \$500, D90+	(3) All, success	(4) All, D90+
Observations	601230	96297	3026355	565680
Panel B: Mortgages: RD Estimate	* − 0.027 (0.011) [− 0.049, − 0.004]	− 0.017 (0.015) [− 0.045, 0.012]	− 0.014 (0.009) [− 0.032, 0.003]	0.005 (0.007) [− 0.008, 0.018]
Avg. dep. var	0.186	0.035	0.167	0.038
Observations	79372	10177	439685	56976
Panel C: Other credit accounts: RD Estimate	* − 0.014 (0.006) [− 0.026, − 0.003]	− 0.015 (0.014) [− 0.042, 0.013]	*** − 0.015 (0.003) [− 0.021, − 0.010]	− 0.002 (0.006) [− 0.013, 0.010]
Avg. dep. var	0.242	0.182	0.246	0.171
Observations	469290	71760	2484030	459094

Standard errors in parentheses, 95 percent confidence intervals in brackets.

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$.

Table 12 provides the regression results for a version of Equation 1 that includes day-of-the-week controls. Results are very similar to the main specification, as can be seen by comparing Column 1 of Table 7 to Column 1 of Table 12, Column 4 of Table 7 to Column 3 of Table 12, Column 1 of Table 8 to Column 2 of Table 12 and comparing Column 4 of Table 8 to Column 4 of Table 12. The CFPB concluded that the main results are not caused by bias in the

distribution of inquiry or medical collection timing across days of the week.

10. Results Related to Credit Shopping

As described above, the main specification defines the running variable using the date of the last inquiry observed within the inquiry shopping window. This creates imprecision in the measurement of the inquiry date for inquiry observations that reflect shopping windows with

multiple inquiries if they were not made on the same date.³⁰⁸ Because this imprecision could attenuate results, the CFPB estimated Equation 1 separately for inquiry observations that reflect multi-inquiry-date shopping windows (Shopping) and for inquiry observations that reflect shopping windows that only contain one inquiry date (No Shopping). The CFPB estimated this robustness check for the inquiry dataset first, and then for the performance dataset.

TABLE 13—THE EFFECT OF MEDICAL COLLECTION REPORTING ON INQUIRY SUCCESS, SEPARATED BY SHOPPING BEHAVIOR³⁰⁹

	(1) Over \$500, shopping	(2) Over \$500, no shopping	(3) All, shopping	(4) All, no shopping
Panel A: Credit cards: RD Estimate	− 0.043 (0.020) [− 0.082, − 0.003]	*** − 0.050 (0.005) [− 0.060, − 0.039]	0.000 (0.013) [− 0.025, 0.026]	*** − 0.035 (0.003) [− 0.040, − 0.030]
Avg. success	0.445	0.279	0.422	0.262
Observations	51481	549749	250319	2776036
Panel B: Mortgages: RD Estimate	− 0.019 (0.028) [− 0.074, 0.037]	− 0.022 (0.011) [− 0.043, − 0.001]	*** − 0.041 (0.014) [− 0.068, − 0.014]	− 0.002 (0.011) [− 0.024, 0.020]
Avg. success	0.329	0.123	0.308	0.111
Observations	24266	55106	126393	313292
Panel C: Other credit accounts:				

³⁰⁸ Note that there may be imprecision in assignment of inquiry date for all inquiries, even those associated with no other inquiries within a shopping window, because the CFPB's CCIP only contains inquiries made to one NCRA.

³⁰⁹ The table provides regression discontinuity estimates for the inquiry and performance datasets, separately by credit account type, and separately by shopping behavior. Each coefficient (RD Estimate) estimates a percentage point effect of having an additional medical collection reported on inquiry

success (in Columns 1 and 3) in the inquiry dataset or 90-day delinquency (in Columns 2 and 4) in the performance dataset. These effects can be represented as percent changes by comparing to a baseline "Avg. dep. var.", which is calculated as the success rate or 90-day delinquency rate of all inquiries made to the left of the regression discontinuity threshold (or without medical collection reporting). Columns 1 and 2 limit the sample to inquiries associated with medical collections over \$500 made when the consumer had

no medical collections under \$500 on their consumer report. Columns 3 and 4 include the full sample. Columns 1 and 3 include only inquiries with shopping windows that contained inquiries made on different dates. Columns 2 and 4 include only inquiries with sole-inquiry shopping windows or inquiry shopping windows where all inquiries were made on the same date. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

TABLE 13—THE EFFECT OF MEDICAL COLLECTION REPORTING ON INQUIRY SUCCESS, SEPARATED BY SHOPPING BEHAVIOR ³⁰⁹—Continued

	(1) Over \$500, shopping	(2) Over \$500, no shopping	(3) All, shopping	(4) All, no shopping
RD Estimate	0.002 (0.015) [−0.030,0.027]	* −0.016 (0.006) [−0.029,−0.004]	−0.015 (0.007) [−0.029,−0.001]	*** −0.015 (0.003) [−0.021,−0.008]
Avg. success	0.391	0.213	0.394	0.217
Observations	77603	391687	400620	2083410

Standard errors in parentheses, 95 percent confidence intervals in brackets.

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$.

Table 13 shows results for inquiry success for inquiries associated with multi-date versus single-date shopping windows. For credit cards and other non-mortgage accounts, the results are only statistically significant for single-date shopping windows and are also larger in absolute magnitude. Fewer than 10 percent of credit card inquiries are associated with multi-date shopping

windows, which is expected given the small average shopping windows for credit cards shown in Table 5. Alternatively, the only statistically significant result for mortgages appears for inquiries associated with multi-date shopping windows in the full sample. This limited ability to identify a precise effect is reflected in the main specification as well, as shown in Table

7. The CFPB concluded that, for non-mortgage products, the inability to observe the exact date that an inquiry was made may attenuate the results in the main specification, and the true effect of having a medical collection reported may be a larger decrease in inquiry success than what is reported in Table 7.

TABLE 14—THE EFFECT OF MEDICAL COLLECTION REPORTING ON TWO-YEAR CREDIT ACCOUNT PERFORMANCE, SEPARATED BY SHOPPING BEHAVIOR ³¹⁰

	(1) Over \$500, shop- ping	(2) Over \$500, no shopping	(3) All, shopping	(4) All, no shopping
Panel A: Credit cards:				
RD Estimate	−0.010 (0.035) [−0.079,0.059]	−0.000 (0.013) [−0.025,0.025]	0.023 (0.018) [−0.013,0.059]	−0.001 (0.006) [−0.013,0.011]
Avg. D90+	0.320	0.218	0.313	0.210
Observations	12288	84009	70222	495458
Panel B: Mortgages:				
RD Estimate	−0.005 (0.020) [−0.045,0.036]	−0.025 (0.020) [−0.063,0.014]	0.009 (0.011) [−0.012,0.030]	0.001 (0.008) [−0.015,0.018]
Avg. D90+	0.041	0.027	0.046	0.030
Observations	5673	4504	30756	26220
Panel C: Other credit Accounts:				
RD Estimate	−0.013 (0.026) [−0.065,0.039]	−0.003 (0.014) [−0.030,0.025]	−0.000 (0.012) [−0.023,0.023]	−0.001 (0.007) [−0.014,0.012]
Avg. D90+	0.216	0.170	0.207	0.158
Observations	19879	51881	122953	336141

Standard errors in parentheses, 95 percent confidence intervals in brackets.

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$.

Table 14 provides the same robustness check as Table 13 but estimates effects on serious delinquency using the performance dataset. As in previous robustness checks, the estimated results on account performance are all statistically insignificant, and nearly all are small in comparison to the baseline average delinquency rate. The CFPB considers these results as evidence that

imprecision in assigning inquiry dates does not drive the lack of statistical significance in the main specification.

³¹⁰ The table provides regression discontinuity estimates for the performance dataset, separately by credit account type, and separating the sample by shopping behavior. Each coefficient (RD Estimate) estimates a percentage point effect of having an additional medical collection reported on inquiry success. These effects can be represented as percent changes by comparing to a baseline “Avg. D90+”, which is calculated as the 90-day delinquency rate

of all inquiries made to the left of the regression discontinuity threshold (or without medical collection reporting). Columns 1 and 2 limit the sample to inquiries associated with medical collections over \$500 made when the consumer had no medical collections under \$500 on their consumer report. Columns 3 and 4 include the full sample. Columns 1 and 3 include only inquiries with shopping windows that contained inquiries made on different dates. Columns 2 and 4 include only inquiries with sole-inquiry shopping windows or inquiry shopping windows where all inquiries were made on the same date. Standard errors are

Finally, the CFPB tested whether classifying the timing of an inquiry shopping window using the last inquiry makes a difference to the results. Although it makes intuitive sense to focus on the last inquiry—a consumer finishes shopping, then either gets a new account or does not, this could impact whether a consumer is considered treated or not by having a medical collection reported or not. For

example, if a consumer applied for accounts that created inquiries on March 5 and March 17, had an account opened on March 19, and had a medical collections tradeline reported on March 15, in the main specification described above, they would be considered to have a medical collection at the time of the inquiry. This may be accurate, if the March 17 inquiry (or another inquiry after March 15 that was made with a

difference NCRA) resulted in the open account, but it also may be inaccurate, and influence the results reported above. To further test how the definition of shopping windows may affect the main results, the CFPB estimated a version of the analysis using the first date of the shopping window instead of its last date to define the running variable.

TABLE 15—THE EFFECT OF MEDICAL COLLECTION REPORTING ON INQUIRY SUCCESS AND CREDIT ACCOUNT PERFORMANCE, CLASSIFYING SHOPPING WINDOWS BY FIRST INQUIRY DATE ³¹¹

	(1) Over \$500, success	(2) Over \$500, D90+	(3) All, success	(4) All, D90+
Panel A: Credit cards:				
RD Estimate	*** − 0.049 (0.004) [− 0.058, − 0.041]	0.002 (0.012) [− 0.021, 0.025]	*** − 0.035 (0.003) [− 0.040, − 0.030]	0.004 (0.006) [− 0.008, 0.016]
Avg. dep. var	0.294	0.231	0.275	0.222
Observations	600209	95973	3021234	563942
Panel B: Mortgages:				
RD Estimate	− 0.010 (0.012) [− 0.033, 0.014]	0.003 (0.013) [− 0.022, 0.028]	− 0.010 (0.008) [− 0.026, 0.006]	0.003 (0.006) [− 0.009, 0.015]
Avg. dep. var	0.182	0.033	0.163	0.035
Observations	74674	8836	415412	49986
Panel C: Other credit Accounts:				
RD Estimate	− 0.010 (0.006) [− 0.021, 0.002]	− 0.020 (0.014) [− 0.048, 0.008]	*** − 0.012 (0.003) [− 0.018, − 0.006]	− 0.003 (0.006) [− 0.015, 0.008]
Avg. dep. var	0.242	0.182	0.246	0.171
Observations	467949	71401	2476494	456828

Standard errors in parentheses, 95 percent confidence intervals in brackets.

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$.

The results in Table 15 are very similar in size to those in the main specification, as seen by comparing Column 1 of Table 7 to Column 1 of Table 15, Column 4 of Table 7 to Column 3 of Table 15, Column 1 of Table 8 to Column 2 of Table 15 and comparing Column 4 of Table 8 to Column 4 of Table 15. The coefficients in Column 1 of Table 15, estimating the impact of medical collection reporting on inquiry success, are no longer marginally significant for mortgages and other credit accounts. This may be because the last inquiry observed within an inquiry shopping window is a better proxy for the date that the creditor

observed the consumer report for these products, which is sensible if consumers continue to shop when they reject an earlier credit offer, or their application is rejected. Earlier pulls of consumer reports, and the information contained on them, do not have any bearing on inquiry success if those earlier inquiries did not lead to originated account. The CFPB considers these results as evidence that, given the inherent challenges in assigning inquiry dates, the method of using the last date that an inquiry was observed within a shopping window is the best available classification.

11. Results Related to Alternative Measures of Account Performance and Inquiry Success

Moving on from statistical and data construction considerations, the CFPB returns to the applicability of the results to the considered equilibrium in which all medical collections are removed from consumer reports. Creditors may respond to reported medical collections by providing lower amounts of credit, especially for products whose applications do not typically request a certain amount of credit, such as credit cards (and unlike mortgages). The CCIP does not contain data on the dollar

clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

³¹¹ The table provides regression discontinuity estimates for the inquiry and performance datasets, separately by credit account type, and using the date of the first inquiry observed within an inquiry shopping window instead of the date of the last inquiry observed, as in the primary specification. The sample is limited to inquiries whose first date of the inquiry shopping window was within 180

days of the medical collection's inclusion on the consumer report. Each coefficient (RD Estimate) estimates a percentage point effect having an additional medical collection reported on inquiry success (in Columns 1 and 3) in the inquiry dataset or 90-day delinquency (in Columns 2 and 4) in the performance dataset. These effects can be represented as percent changes by comparing to a baseline "Avg. dep. var.", which is calculated as the success rate or 90-day delinquency rate of all

inquiries made to the left of the regression discontinuity threshold (or without medical collection reporting). Columns 1 and 2 limit the sample to inquiries associated with medical collections over \$500 made when the consumer had no medical collections under \$500 on their consumer report. Columns 3 and 4 include the full sample. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

amount of credit that consumers were offered if consumers decided not to open an account, but it can observe credit limits and loan principals for originated accounts. The CFPB

estimated Equation 1 using the account's credit limit (for revolving accounts) or loan principal (for installment accounts) as the dependent variable. This regression can only be run

for the performance dataset because credit limits and loan principals cannot be observed for unsuccessful inquiries.

TABLE 16—THE EFFECT OF MEDICAL COLLECTION REPORTING ON CREDIT ACCOUNT LIMITS AND LOAN PRINCIPALS³¹²

	(1) Over 500	(2) All
Panel A: Credit cards:		
RD Estimate	*** – 384.312 (80.367) [– 541.829, – 226.795]	*** – 247.492 (33.855) [– 313.848, – 181.137]
Avg. credit am	1481.169	1312.252
Observations	96208	565222
Panel B: Mortgages:		
RD Estimate	– 12746.532 (11952.690) [– 36173.374, 10680.309]	– 15734.984 (11952.690) [– 33208.174, 1738.206]
Avg. credit am	232565.905	225877.236
Observations	10163	56918
Panel C: Other credit accounts:		
RD Estimate	254.621 (398.877) [– 527.164, 1036.407]	– 195.017 (220.971) [– 628.113, 238.078]
Avg. credit am	20994.097	20380.048
Observations	71739	458968

Standard error in parentheses, 95 percent confidence intervals in brackets.

*p < 0.1, **p < 0.05, ***p < 0.01.

Table 16 provides estimates for the effect of medical collection reporting on credit limits and loan principals. The results in Panel A show that medical collection reporting leads to lower credit limits for originated credit cards, with an average reduction in provided credit limits of \$384 for the over-\$500 sample and \$247 for the full sample. This represents a meaningful reduction in consumer access to credit, as baseline credit limits are lower than \$1,500 for both samples. As expected, the CFPB does not find statistically significant effects for mortgages or other non-credit-card account types. Consumers generally apply for a specific dollar amount of credit for installment products, and the dollar amount of

credit provided is not a margin that would generally be affected by medical collection reporting.

Furthermore, the CFPB understands that the classification of serious delinquency is not the sole determinant of account performance. Three other measures of performance are considered in this final set of regressions, estimated on the performance dataset: whether the account is ever 30 days or more delinquent within two years of its origination, whether the account is 90 days or more delinquent at the end of its first two years after origination (instead of whether it was ever 90 days or more delinquent within that two-year period), and the dollar amount past due or charged off for accounts with nonzero

past due or charged off amounts at the end of its first two years after origination. If the primary classification of serious delinquency is a good proxy for account performance, then results for the first two alternative measures should be similar to their counterparts in the main performance results in direction and statistical significance. The results for past due amounts may be more nuanced, as Table 16 above shows that medical collection reporting lowers the credit limits of credit cards. This may cause lower past due amounts in response to medical collection reporting because consumers cannot borrow as much as they can absent medical collection reporting.

³¹² The table provides regression discontinuity estimates for the performance dataset, separately by credit account type, and using the credit limit or loan principal at time of origination as the dependent variable. Each coefficient (RD Estimate) estimates a percentage point effect of having an additional medical collection reported on the account's credit limit or loan principal. These effects can be represented as percent changes by

comparing to a baseline "Avg. credit am.", which is calculated as the average of the credit limit or loan principal for all inquiries made to the left of the regression discontinuity threshold (or without medical collection reporting). Column 1 limits the sample to inquiries associated with medical collections over \$500 made when the consumer had no medical collections under \$500 on their consumer report. Column 2 includes the full

sample. The dependent variable is equal to the credit limit at the time of account origination for credit cards and other revolving accounts. The dependent variable is equal to the loan principal at the time of account origination for mortgages and other installment products. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

TABLE 17—THE EFFECT OF MEDICAL COLLECTION REPORTING ON TWO-YEAR CREDIT ACCOUNT PERFORMANCE, ALTERNATIVE CLASSIFICATIONS³¹³

	(1) Over \$500, D30+	(2) Over \$500, D90+ alt.	(3) Over \$500, Past due am.	(4) All, D30+	(5) All, D90+ alt.	(6) All, past due am.
Panel A: Credit cards:						
RD Estimate	0.008 (0.013) [−0.017, 0.032]	−0.006 (0.011) [−0.027, 0.015]	** −215.199 (86.597) [−384.926, −45.472]	0.002 (0.006) [−0.010, 0.015]	−0.003 (0.005) [−0.013, 0.008]	* −62.830 (29.197) [−120.055, −5.604]
Avg. dep. var	0.321	0.164	713.724	0.316	0.153	643.677
Observations	96297	96297	19945	565680	565680	111342
Panel B: Mortgages:						
RD Estimate	−0.034 (0.027) [−0.087, 0.018]	0.002 (0.010) [−0.018, 0.022]	4477.430 (2894.862) [−1196.394, 10151.255]	0.012 (0.012) [−0.012, 0.036]	0.001 (0.005) [−0.009, 0.012]	261.686 (1682.921) [−3036.779, 3560.152]
Avg. dep. var	0.125	0.021	7511.005	0.118	0.019	6018.840
Observations	10177	10177	409	56976	56976	1954
Panel C: Other credit Ac- counts:						
RD Estimate	−0.006 (0.016) [−0.037, 0.025]	−0.002 (0.013) [−0.027, 0.023]	−803.533 (732.117) [−2238.455, 631390]	−0.000 (0.008) [−0.016, 0.015]	0.000 (0.005) [−0.009, 0.010]	−562.913 (301.400) [−1153.647, 27.821]
Avg. dep. var	0.322	0.156	7012.189	0.316	0.145	6510.499
Observations	71760	71760	13777	459094	459094	81546

Standard errors in parentheses, 95 percent confidence intervals in brackets.

*p < 0.1, **p < 0.05, ***p < 0.01.

Table 17 estimates Equation 1 on the performance dataset using alternative measures of account performance. Columns 1, 2, 4, and 5 show small and statistically significant effects of medical collection reporting on account performance, as in Columns 1 and 4 of Table 8. In Panel A, Columns 3 and 6 provide relatively small but at least marginally significant effects, suggesting

³¹³ The table provides regression discontinuity estimates for the performance dataset, separately by credit account type, and using alternative classifications of account performance. Each coefficient (RD Estimate) estimates a percentage point effect of having an additional medical collection reported on the account's credit limit or loan principal. These effects can be represented as percent changes by comparing to a baseline "Avg. credit am.", which is calculated as the average of the credit limit or loan principal for all inquiries made to the left of the regression discontinuity threshold (or without medical collection reporting). Columns 1 through 3 limit the sample to inquiries associated with medical collections over \$500 made when the consumer had no medical collections under \$500 on their consumer report. Columns 4 through 6 includes the full sample. The dependent variable in Columns 1 and 4, "D30+", is whether the account was ever at least 30 days delinquent within two years of its origination. The dependent variable in Columns 2 and 5, "D90+ alt.", is whether the account was at least 90 days delinquent exactly two years after the origination date, in contrast to the primary classification which considers whether the account was ever at least 90 days delinquent within two years of the origination date. The dependent variable in Columns 3 and 6 is the total amount past due or charged off on the account exactly two years after the account's origination date if either value is positive and non-missing. If accounts have positive and non-missing past-due amounts and charged-off amounts, the classification uses the charged-off amount. Standard errors are clustered by consumer and adjusted using the Benjamini-Hochberg procedure.

that medical collection reporting may lead to lower past-due or charged-off amounts for credit cards, when those amounts are nonzero. This may be caused by the lower credit limits provided to consumers with reported medical collections, as shown in Table 16. Though credit cards originated to consumers with unreported medical collections may be no more likely to become seriously delinquent within two years, the dollar amount past due when the account is delinquent may be higher because consumers with unreported medical collections receive higher credit limits. Additionally, creditors can earn higher revenues when providing higher credit limits to consumers who revolve their balance from month-to-month and pay interest fees. The results in Panels B and C show no statistically significant effects on past-due or charged-off amounts for mortgages, as expected because there were no differences in serious delinquency or in the dollar amount of credit provided.

List of Subjects in 12 CFR Part 1022

Banks, Banking, Consumer protection, Credit unions, Holding companies, National banks, Privacy, Reporting and recordkeeping requirements, Savings associations.

Authority and Issuance

For the reasons set forth in the preamble, the CFPB proposes to amend 12 CFR part 1022, as set forth below:

PART 1022—FAIR CREDIT REPORTING (REGULATION V)

■ 1. The authority citation for part 1022 continues to read as follows:

Authority: 12 U.S.C. 5512, 5581; 15 U.S.C. 1681a, 1681b, 1681c, 1681c–1, 1681c–3, 1681e, 1681g, 1681i, 1681j, 1681m, 1681s, 1681s–2, 1681s–3, and 1681t; Sec. 214, Pub. L. 108–159, 117 Stat. 1952.

Subpart A—General Provisions

■ 2. Amend § 1022.3 by adding paragraph (j) to read as follows:

§ 1022.3 Definitions.

* * * * *

(j) *Medical debt information* means medical information that pertains to a debt owed by a consumer to a person whose primary business is providing medical services, products, or devices, or to such person's agent or assignee, for the provision of such medical services, products, or devices. Medical debt information includes but is not limited to medical bills that are not past due or that have been paid.

* * * * *

Subpart D—Medical Information

■ 3. Amend § 1022.30 by:

- a. Revising paragraph (c);
- b. Removing and reserving paragraph (d);
- c. Revising paragraphs (e)(1)(viii) and (ix); and
- d. Adding paragraphs (e)(1)(x)(A) through (C) and (e)(6) and (7).

The revisions and additions read as follows:

§ 1022.30 Obtaining or using medical information in connection with a determination of eligibility for credit.

* * * * *

(c) *Rule of construction for obtaining and using unsolicited medical information*—(1) *In general.* A creditor does not obtain medical information in violation of the prohibition if it receives medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information.

(2) *Use of unsolicited medical information.* A creditor that receives unsolicited medical information in the manner described in paragraph (c)(1) of this section may use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit to the extent the creditor can rely on at least one of the exceptions in § 1022.30(e).

(3) *Examples.* A creditor does not obtain medical information in violation of the prohibition if, for example:

(i) In response to a general question regarding a consumer's debts or expenses, the creditor receives information that the consumer owes a debt to a hospital.

(ii) In a conversation with the creditor's loan officer, the consumer informs the creditor that the consumer has a particular medical condition.

(d) [Reserved].

(e) * * *

(1) * * *

(viii) To determine the consumer's eligibility for, the triggering of, or the reactivation of a debt cancellation contract or debt suspension agreement if a medical condition or event is a triggering event for the provision of benefits under the contract or agreement;

(ix) To determine the consumer's eligibility for, the triggering of, or the reactivation of a credit insurance product if a medical condition or event is a triggering event for the provision of benefits under the product; or

(x) So long as the conditions in paragraphs (e)(1)(x)(A) through (C) of this section are met:

(A) The medical information relates to income, benefits, or the purpose of the loan, including the use of proceeds. Medical information relating to income and benefits include, for example, the dollar amount and continued eligibility for disability income, workers' compensation income, or other benefits related to health or a medical condition

that is relied on as a source of repayment.

(B) The creditor uses the medical information in a manner and to an extent that is no less favorable than it would use comparable information that is not medical information in a credit transaction.

(C) The creditor does not take the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of the determination of the consumer's eligibility, or continued eligibility, for credit.

* * * * *

(6) *Example to comply with applicable requirements of local, State, or Federal laws.* A consumer applies for a mortgage loan subject to §§ 1026.43(c) or 1026.34(a)(4) of this chapter, or an open-end (not home-secured) credit card account subject to § 1026.51(a) of this chapter. The application does not specifically request medical information, but the consumer provides unsolicited medical information on the application. The creditor or the card issuer is permitted to use such medical information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit only to the extent required by the applicable Federal law and implementing regulation. For example, assume a consumer applies for a mortgage loan subject to § 1026.43(c) of this chapter. Assume further that the creditor has not specifically requested medical information on the application, but the consumer provides information on a current debt obligation, such as a monthly medical payment plan, that is medical information. The creditor is permitted to consider the existence and the amount of the medical payment plan as required in considering factors under § 1026.43(c)(2) of this chapter, such as the current debt obligations, consumer's monthly debt-to-income ratio, and residual income, in making the repayment ability determination required under § 1026.43(c)(1) of this chapter. In this circumstance, the creditor would not be required to independently verify the existence and amount of the monthly medical payment plan, as provided for under § 1026.43(c)(3)(iii) of this chapter. See also comment 43(c)(3)–6, describing a situation in which a consumer provides a creditor with information on a debt obligation that is not listed on a consumer report. Further, a creditor or card issuer is not permitted to obtain or use any medical information from a consumer reporting agency to comply with the ability-to-repay rule under

§ 1026.43(c) of this chapter for closed-end mortgages, the repayment ability rule under § 1026.34(a)(4) of this chapter for open-end, high-cost mortgages, or the ability-to-pay rule under § 1026.51(a) of this chapter for open-end (not home-secured) credit card accounts, because the creditor or card issuer can comply with those rules using information provided by the consumer.

(7) *Example of medical information relating to income and benefits.* A consumer indicates on an application for a \$200,000 mortgage loan that she receives \$15,000 in long-term disability income each year from her former employer and has no other income. Annual income of \$15,000, regardless of source, would not be sufficient to support the requested amount of credit. The creditor denies the application on the basis that the projected debt-to-income ratio of the consumer does not meet the creditor's underwriting criteria. The creditor has used medical information in a manner and to an extent that is no less favorable than it would use comparable non-medical information.

■ 4. Add reserved §§ 1022.33 through 1022.37, and add § 1022.38 to read as follows:

§§ 1022.33–1022.37 [Reserved]

§ 1022.38 Duty of consumer reporting agencies regarding medical debt information.

(a) *Scope.* This section applies to any consumer reporting agency as defined in section 603(f) of the FCRA, 15 U.S.C. 1681a(f).

(b) *Limitation regarding prohibited medical debt information.* A consumer reporting agency may include medical debt information, as defined in § 1022.3(j), in a consumer report furnished to a creditor only if the consumer reporting agency:

(1) Has reason to believe the creditor intends to use the medical debt information in a manner not prohibited by § 1022.30; and

(2) Is not otherwise prohibited from furnishing to the creditor a consumer report containing the medical debt information, including by a State law that prohibits furnishing to the creditor a consumer report containing medical debt information.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

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Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 4, 16, 201, et al.

Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 4, 16, 201, 210, 211, 213, 230, 314, and 514

[Docket No. FDA-2021-N-1333]

RIN 0910-AH96

Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases

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

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule revising the requirements concerning current good manufacturing practice (CGMP), postmarketing safety reporting, and labeling that apply to certain medical gases. This final rule also establishes regulations regarding certification of designated medical gases. This final rule satisfies the medical gas rulemaking requirements of the Consolidated Appropriations Act, 2017.

DATES: This rule is effective December 18, 2025, except for the amendments to §§ 4.2 (amendatory instruction 2), 4.3 (amendatory instruction 3), and 4.4 (amendatory instruction 4) (21 CFR 4.2, 4.3, and 4.4), which are effective February 2, 2026. The incorporation by reference of certain material listed in this rule has been approved by the Director of the Federal Register as of February 2, 2026.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
 - A. Purpose of the Final Rule
 - B. Summary of the Four Major Provisions of the Final Rule
 - C. Legal Authority
 - D. Costs and Benefits
- II. Table of Abbreviations/Commonly Used Acronyms in This Document
- III. Background
 - A. Need for the Regulation/History of the Rulemaking
 - B. Summary of Comments to the Proposed Rule
- IV. Legal Authority
- V. Comments on the Proposed Rule and FDA Response
 - A. Introduction
 - B. Description of General Comments and FDA Response
 - C. Description of Part 4 Comments and FDA Response
 - D. Part 16
 - E. Description of Part 201 Comments and FDA Response
 - F. Part 210
 - G. Part 211
 - H. Description of Part 213 Comments and FDA Response
 - I. Description of Part 230 Comments and FDA Response
 - J. Description of Part 314 Comments and FDA Response
 - K. Part 514
- VI. Effective Date
- VII. Economic Analysis of Impacts
- VIII. Analysis of Environmental Impact
- IX. Paperwork Reduction Act of 1995
- X. Federalism
- XI. Consultation and Coordination With Indian Tribal Governments
- XII. References

I. Executive Summary

A. Purpose of the Final Rule

On May 23, 2022, FDA issued a proposed rule to amend requirements concerning CGMP, postmarketing safety reporting, and labeling that apply to certain medical gases, and to establish regulations regarding certification of designated medical gases (87 FR 31302). This rule satisfies the requirement in section 756 of the Consolidated Appropriations Act, 2017 (Pub. L. 115-31) that FDA issue final regulations revising the Federal drug regulations with respect to medical gases by July 15, 2017.

By tailoring certain labeling, CGMP, certification, and postmarketing safety reporting requirements more narrowly to medical gases, FDA intends to better address the unique characteristics of medical gases. Specifically, the final rule is intended to provide clarity and consistency regarding how information is presented in the labeling of certain medical gases, as well as to ensure important safety information is

included. The CGMP requirements in this final rule are intended to reflect appropriate requirements for the manufacturing, processing, packing, and holding of such products. The certification requirements in this final rule implement and clarify the certification process for designated medical gases described in section 576 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ddd-1). Lastly, the new postmarketing safety reporting regulations for designated medical gases address human and animal use and better reflect the development, manufacturing, and distribution of designated medical gases. Independently and collectively, FDA anticipates that these four categories of regulatory changes will promote greater efficiency in the regulation of medical gases while helping to ensure that they adhere to all applicable safety and quality standards.

Following consideration of comments received and further internal deliberation, we are finalizing this rule as described in this document.

B. Summary of the Four Major Provisions of the Final Rule

We received fewer than 25 comments on the proposed rule. The most detailed comments were from industry trade associations and consultants. The other comments were from individuals. Comments addressed many of the labeling, CGMP, certification, and safety reporting provisions, as well as general considerations, including general support, definitions, timing of the rule, and the effective date.

The remainder of this subsection includes a brief description of the four major provisions of this rule.

1. Labeling Provisions

This rule includes several changes to FDA's drug labeling regulations, including the addition of certain operations required to produce a medical gas to the list of operations that are performed by its manufacturer. We are revising the requirements for stating the ingredients in the labeling of a designated medical gas or medically appropriate combination of designated medical gases (referred to hereafter in this preamble as “medically appropriate combination”).¹ We also specify

¹ Section 576(a)(3)(A)(i) of the FD&C Act provides that “[a] designated medical gas for which a certification is granted under paragraph (2) is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved application under section [505 or 512], subject to all applicable postapproval requirements,” for certain indications for use. FDA interprets the term

requirements for the declaration of net quantity of contents in the labeling of designated medical gases and medically appropriate combinations.

We are requiring that all designated medical gases—whether certified for human use, animal use, or both—and medically appropriate combinations bear labeling that is in a standardized format.

FDA is revising the requirements for warning statements for certain medical gases including that the labeling of medical air and carbon monoxide bear certain warning statements. We are including different labeling requirements for final use containers and bulk or transport containers. We also are requiring a new oxygen warning statement and graphic warning symbol to alert users of the risks of smoking, vaping, and open flames near an oxygen container.

FDA is revising the medical gas container labeling regulations to clarify that the owner of a designated medical gas container or a container of a medically appropriate combination can be mentioned on the container to facilitate return of the container to the owner, and to ensure that product quality issues are directed to the appropriate entity. This rule also includes clarifying revisions to the definition of “portable cryogenic medical gas container” for purposes of FDA’s labeling regulations.

2. CGMP Provisions

FDA is issuing new CGMP regulations specific to medical gases. These regulations include many of the same categories of provisions as the general drug CGMP regulations but reflect differences in how medical gases are manufactured, processed, packed, and held. These regulations represent the minimum CGMP for medical gases. Of note, we include different cleaning requirements for medical gases because these gases are generally manufactured in a sealed, closed system, and because cleaning at inappropriate times can introduce contaminants.

FDA is including requirements for medical gas containers and closures that are similar to the general drug CGMP regulations, with an additional

requirement that portable cryogenic medical gas containers and small cryogenic gas containers for use by individual patients have a working gauge to assist the user in determining whether the container contains an adequate supply of medical gas for continued use (minor revisions were made to the version of this provision in the proposed rule). This will help users determine when a container must be refilled or replaced and when a leaking or venting container is empty. We are not including time limitations on production because medical gases are generally not expected to expire or degrade. Additionally, unlike the salvaging requirements under the general drug CGMP regulations, medical gases that have been stored improperly may be salvaged unless their containers have been subjected to adverse conditions that negatively impact the identity, strength, quality, or purity of the product or the integrity of the product’s container closure.

3. Certification Provisions

FDA is issuing new regulations regarding the certification process for designated medical gases that are intended to codify the certification process and provide additional clarity where necessary. These requirements govern the process for applicants to file a certification request and supplements as well as the contents of such a request. The regulations also set forth requirements concerning the transfer of ownership of a certification from one entity to another.

We are requiring the submission of a streamlined annual report, to include certain required contents and submission timing. Changes to the proposed rule include requiring submission on a calendar year basis, rather than based on the anniversary of the date the certification request was deemed granted, and clarifying revisions to the list of facilities to be included in the annual report.

These regulations set forth requirements that are similar to the recommendations described in the November 2015 draft guidance for industry “Certification Process for Designated Medical Gases” (November 25, 2015, 80 FR 73771) (Ref. 1).

4. Postmarketing Quality and Safety Reporting Provisions

FDA is issuing new postmarketing quality and safety reporting requirements for designated medical gases.

We are including requirements for submitting field alert reports (FARs), including revised submission timelines

to allow applicants time to compile sufficient information to complete their FAR.

We are including adverse event reporting requirements related to the use of designated medical gases in humans and animals. For designated medical gases that are certified for human use and deemed to have in effect an approved application under section 505 of the FD&C Act (21 U.S.C. 355), we are requiring that applicants and nonapplicants report serious adverse events within 15 calendar days from when the applicant or nonapplicant has met certain reporting criteria and acquired certain minimum data.

We are issuing requirements for the contents and format of submissions, including an electronic submission requirement, the process for requesting a waiver of the electronic submission requirement, recordkeeping requirements, written procedures requirements, and patient privacy provisions.

For designated medical gases that are certified for animal use and deemed to have in effect an approved application under section 512 of the FD&C Act (21 U.S.C. 360b), we are requiring that applicants and nonapplicants submit serious adverse event reports to FDA within 15 calendar days from when the applicant or nonapplicant has met certain reporting criteria and that recordkeeping requirements related to adverse events are maintained.

C. Legal Authority

Sections 501, 502, 505, 512, 575, 576, and 704 of the FD&C Act (21 U.S.C. 351, 352, 355, 360b, 360ddd, 360ddd–1, and 374), in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as our principal legal authority for this final rule.

D. Costs and Benefits

This final rule establishes CGMP regulations specific to medical gases. These regulations include many of the same categories of requirements as the general drug product CGMP regulations but are tailored to reflect differences in how medical gases are manufactured, packaged, labeled, stored, and distributed. We quantify benefits to industry from removing CGMP requirements that would not apply to medical gases, such as removing certain building and facility requirements, including more limited equipment maintenance and cleaning requirements, and codifying some existing practices, which may streamline inspections. Additional benefits will include a potentially small reduction in fires from

“combination” in this section to mean two or more distinct designated medical gases that are mixed together. For example, a mixture of oxygen and nitrous oxide that each meet the standards set forth in an official compendium could constitute a medically appropriate combination of designated medical gases. However, the addition of oxygen to a container that already contains oxygen would not result in a medically appropriate combination of designated medical gases because only one kind of designated medical gas would be present in the container.

graphic warning labels on oxygen containers, and clarification that adverse events generally are not required to be submitted for reports of the death of a patient or animal who was administered oxygen, nor when fires associated with the administration of oxygen occur but do not include an adverse event experienced by the patient or animal.

We quantify costs to industry from new labeling requirements, regulatory clarification leading to firms becoming

compliant with existing requirements, and added CGMP requirements including a requirement for portable cryogenic containers to have a working gauge. Additional costs will include maintaining resumes for consultants, and potential cost of relabeling medical air containers. We estimate that the annualized benefits over 10 years will range from \$0.00 million to \$7.02 million at a 7 percent discount rate, with a primary estimate of \$3.51

million, and from \$0.00 million to \$7.43 million at a 3 percent discount rate, with a primary estimate of \$3.72 million. The annualized costs will range from \$1.52 million to \$5.30 million at a 7 percent discount rate, with a primary estimate of \$3.24 million, and from \$1.36 million to \$5.11 million at a 3 percent discount rate, with a primary estimate of \$3.07 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
ANDA	Abbreviated New Drug Application.
CDER	Center for Drug Evaluation and Research.
CFR	Code of Federal Regulations.
CGMP	Current Good Manufacturing Practice.
COA	Certificate of Analysis.
CVM	Center for Veterinary Medicine.
FAR	Field Alert Report.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA or Agency	Food and Drug Administration.
FR	Federal Register.
ICSR	Individual Case Safety Report.
NADA	New Animal Drug Application.
NDA	New Drug Application.
NDC	National Drug Code.
OMB	Office of Management and Budget.
PET	Positron Emission Tomography.
PRIA	Preliminary Regulatory Impact Analysis.
USP	United States Pharmacopeia.

III. Background

A. Need for the Regulation/History of the Rulemaking

Medical gases have historically been manufactured, labeled, and distributed in a manner different than most other drugs. Under section 576 of the FD&C Act, the process for obtaining marketing authorization for a designated medical gas also differs from the process for obtaining marketing authorization for other human and animal drugs. Moreover, because of these differences, FDA believes that the likelihood of identifying new safety issues for medical gases is low. Thus, some existing regulations are not well-tailored to addressing designated medical gases and other medical gases. FDA undertook this rulemaking to address these differences, and to decrease regulatory burden where appropriate. On May 23, 2022, FDA issued a proposed rule to amend requirements concerning CGMP, postmarketing safety reporting, and labeling that apply to certain medical gases, and to establish regulations regarding certification of designated medical gases.

Although we believe that these four categories of regulatory changes will best help to address the unique characteristics of medical gases when

implemented collectively, each provision independently improves the clarity of the regulations and requirements applicable to medical gases. In the event of a stay or invalidation of any major provision(s), those that remain in effect would continue to function sensibly ² to advance the statutory requirements applicable to medical gases and provide useful, clear standards for firms to meet their existing statutory obligations. For example, invalidation of the major provisions related to certification of a designated medical gas would have no effect on those addressing CGMP for medical gases. Likewise, in the absence of new provisions specific to postmarketing safety reporting for medical gases, each of the other major provisions would continue to contribute to greater clarity and efficiency for the medical gas industry, while helping to maintain a high standard of safety and quality. Finally, because medical gases have historically been regulated as drugs rather than as a specialized subset

² See, e.g., *Belmont Mun. Light Dep’t v. FERC*, 38 F.4th 173, 188 (D.C. Cir. 2022) (finding severability of a portion of an administrative action, applying the principle that severability is appropriate where “the agency prefers severability to overturning the entire regulation” and where the remainder of the regulation “could function sensibly without the stricken provision”) (citations omitted).

thereof, were any major provision in this regulation invalidated, medical gases would continue to be regulated under the existing general regulatory regime corresponding to that provision (e.g., if medical gas CGMP requirements are invalidated, medical gases would remain subject to the general drug CGMP requirements in parts 210 and 211 (21 CFR parts 210 and 211)). Therefore, it is FDA’s intent to preserve each of the rule’s four major provisions to the fullest possible extent, to help address the unique aspects of medical gases that set them apart from most other drugs.

B. Summary of Comments to the Proposed Rule

We received fewer than 25 comments on the proposed rule. The most detailed comments were from industry trade associations and consultants. The other comments were from individuals. Comments covered many aspects of the proposed rule, including:

- General considerations, including general support, definitions, timing of the rule, and the effective date;
- Labeling requirements, including labeling statements and the applicability of labeling provisions to different types of containers;

- CGMP requirements, including buildings and facilities, equipment, control of incoming products, packaging and labeling control, holding and distribution, laboratory controls, records, and returned medical gases;

- Certification requirements, including annual reporting, withdrawal, and the applicability of current requirements in part 314 (21 CFR part 314); and

- Postmarketing quality and safety reporting requirements, including submitting FARs, reporting of individual case safety reports (ICSRs) related to human use, and reporting of adverse events related to animal use.

IV. Legal Authority

We are issuing this final rule under sections 501, 502, 505, 512, 575, 576, 701, and 704 of the FD&C Act. Medical gases are generally regulated as prescription drugs under sections 201(g)(1) and 503(b)(1) of the FD&C Act (21 U.S.C. 321(g)(1) and 353(b)(1)) (although oxygen may be provided without a prescription for certain uses specified at section 576(b)(2) of the FD&C Act).

Section 501 of the FD&C Act describes the circumstances under which a drug is deemed to be adulterated. Under section 501(a)(2)(B) of the FD&C Act, a drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice. For purposes of section 501(a)(2)(B), “current good manufacturing practice” includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.

Section 502 of the FD&C Act describes the circumstances under which a drug is deemed to be misbranded. Under section 502(f) of the FD&C Act, a drug is deemed to be misbranded unless its labeling bears adequate directions for use and such adequate warnings against use where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users. Under section 704 of the FD&C Act, FDA is authorized to inspect, among other things, records in any establishment in which prescription drugs or nonprescription drugs intended for human use are manufactured, processed, packed, or held bearing on

whether such products are in violation of the FD&C Act.

Section 576 of the FD&C Act describes the certification process for designated medical gases (as defined in section 575 of the FD&C Act) and the effect of certification, the applicability of FDA’s prescription requirements, and certain labeling requirements. Under section 576(a)(3)(A)(i) of the FD&C Act, a certified designated medical gas is subject to all applicable postapproval requirements. Under section 505(k) of the FD&C Act, FDA has the authority to establish certain postmarketing safety reporting regulations for human drugs to enable FDA to determine or facilitate a determination as to whether there are or may be grounds to invoke section 505(e) of the FD&C Act, which concerns the withdrawal or suspension of approval of a new drug application (NDA) or abbreviated new drug application (ANDA). Section 512(l) of the FD&C Act authorizes FDA to establish postmarketing safety reporting regulations for new animal drugs to enable FDA to determine or facilitate a determination as to whether there are or may be grounds to withdraw approval of an application pursuant to section 512(e) or 512(m)(4) of the FD&C Act.

Thus, sections 501, 502, 505, 512, 575, 576, and 704 of the FD&C Act, in conjunction with our general authority in section 701(a) of the FD&C Act to issue regulations for the efficient enforcement of the FD&C Act, serve as our principal legal authority for this final rule.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received fewer than 25 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from individuals, trade organizations, and industry consultants.

We describe and respond to the comments in sections V.B. through V.G. of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment’s value or importance or the order in which comments were received.

Additionally, on its own initiative, FDA is making minor technical and grammatical changes to the rule to improve clarity.

B. Description of General Comments and FDA Response

(Comment 1) Some comments make general remarks supporting the proposed rule without focusing on a particular proposed provision. One comment also notes that the COVID–19 pandemic highlighted the need for updated medical gas regulations.

(Response 1) We appreciate these comments of support and agree that this rulemaking is needed.

(Comment 2) One comment encourages FDA to publish this rule widely to ensure that all affected entities access it.

(Response 2) FDA is publishing this final rule publicly consistent with requirements under the Administrative Procedure Act and Agency practice. We believe this sufficiently addresses the need to make regulatory changes widely accessible to the public.

(Comment 3) One comment discusses when to publish the final rule, urging FDA to issue the final rule swiftly.

(Response 3) FDA acknowledges the public interest in finalizing this rule promptly. The Agency works within its defined processes to draft, clear, and issue regulations. During the rulemaking process, FDA published in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda) its estimated timeline for completion of the final rule.

C. Description of Part 4 Comments and FDA Response

FDA proposed changes to part 4, subpart A (21 CFR part 4, subpart A) to reflect the new CGMP requirements for medical gases proposed in part 213 (21 CFR part 213). FDA proposed definitions of “medical gas” and “medical gas CGMPs” in § 4.2, and conforming changes to account for combination products that contain a medical gas in § 4.3. FDA also proposed in § 4.4 conforming changes to account for combination products that contain a medical gas, as well as a list of CGMP provisions from part 213 that must be satisfied if the CGMP operating system for a combination product containing a medical gas has been shown to comply with the device quality system regulations. We received one comment on these provisions, which we discuss below.

(Comment 4) One comment notes that some manufacturers of designated medical gases will not know whether their product will ultimately be used as

a drug constituent part of a combination product. As such, the comment asks whether such designated medical gases are subject to the CGMP regulations in part 4.

(Response 4) In the example in the comment, if the entities are manufacturing only the gas, they would not be subject to the CGMP regulations in part 4, which only apply to combination product manufacturers (§ 4.1). Such original manufacturers of designated medical gases only have to comply with part 213. However, for example, a third party manufacturing a combination product that includes such a designated medical gas would be subject to these part 4 CGMP requirements.

D. Part 16

FDA proposed to revise § 16.1(b)(2) (21 CFR 16.1(b)(2)) to broaden the scope of regulatory hearings to include hearings relating to revocation of a grant of a certification for a designated medical gas. We did not receive comments on the proposed revision and are finalizing the provision as proposed with minor technical changes made on our own initiative.

E. Description of Part 201 Comments and FDA Response

1. General Comments

(Comment 5) One comment makes general remarks supporting the proposed revisions to the labeling regulations in part 201 (21 CFR part 201) without focusing on a particular proposed provision.

(Response 5) We appreciate this comment of support.

2. Manufacturer Definition (Proposed § 201.1)

FDA proposed revisions to the “manufacturer” definition in § 201.1(b), adding proposed paragraph (11) to address medical gas manufacturing activities for purposes of part 201 and section 502(a) and (b)(1) of the FD&C Act. We proposed to specify that, with respect to a medical gas, the manufacturer is the person fabricating the gas by chemical reaction, physical separation, compression of atmospheric air, purification (e.g., reprocessing an industrial gas into a medical gas), by combining two or more distinct medical gases, or by other process.

(Comment 6) One comment recommends that FDA remove the catchall “other processes” and include filling a medical gas container in the list of manufacturing operations. The comment expresses that this change would capture operations performed post-fabrication.

(Response 6) FDA does not agree with this recommendation. The operations listed in § 201.1(b)(11) focus on methods of “fabricating the gas,” rather than downstream processes. While certain downstream processes will be subject to the CGMP requirements in part 213 when in effect, the purpose of § 201.1(b) is to capture the primary activities conducted to initially produce a drug product.

3. Adequate Directions for Use (§ 201.100)

Although FDA did not propose revisions to § 201.100, the Agency received comments proposing revisions to the current text.

(Comment 7) One comment proposes a new § 201.100(a)(1)(iv) to specify that a designated medical gas used to clean or purge medical gas containers, including medical gas pipelines, is exempt from the requirement in section 502(f)(1) of the FD&C Act that its labeling bear adequate directions for use. The comment adds that this would allow individuals to obtain designated medical gases for such use (for example, nitrogen for purging medical pipelines).

(Response 7) FDA does not agree with this comment. Revisions to § 201.100(a)(1) are not necessary because gases used for the purposes described in the comment do not meet the definition of a drug under section 201(g)(1) of the FD&C Act. Therefore FDA’s drug labeling requirements, including the requirement to bear adequate directions for use, would not apply to a gas intended only for these uses.

(Comment 8) One comment proposes revisions to § 201.100(b) exempting designated medical gases in compliance with § 201.161 from the labeling requirements in § 201.100(b) because § 201.161 as revised by this rulemaking includes specific requirements for designated medical gas labeling.

(Response 8) FDA does not believe these revisions are needed. The purpose of § 201.100 is to exempt prescription drugs from the requirements in section 502(f)(1) of the FD&C Act if certain requirements are met. For designated medical gases, section 576(a)(3)(A)(ii) of the FD&C Act already addresses this requirement by stating that, for such gases, the requirements of sections 503(b)(4) and 502(f) of the FD&C Act are deemed to have been met for a designated medical gas if the labeling on its final use container bears the information required by section 503(b)(4), a warning statement concerning the use of the medical gas (as determined by the Secretary by regulation), and appropriate directions

and warnings concerning storage and handling.

The revisions to § 201.161 in this rulemaking further satisfy this requirement, as sections 503(b)(4) and 502(f) of the FD&C Act are deemed to have been met for a designated medical gas if the final use container bears the information required in § 201.161(a).

4. Medical Gas Labeling Statements (Proposed § 201.161)

FDA proposed several changes to the medical gas labeling requirements in § 201.161. We proposed moving the warning statement requirements for oxygen in § 201.161(a)(1)(i) to § 201.161(a)(1), without proposing any changes to the requirements. We also proposed moving the warning statement requirements for nitrogen, carbon dioxide, helium, nitrous oxide, and medically appropriate combinations of oxygen, nitrogen, carbon dioxide, helium, and nitrous oxide in § 201.161(a)(1)(ii) to § 201.161(a)(2) and proposed expanding their scope to all designated medical gases other than oxygen as well as medically appropriate combinations of any medical gases. We also proposed adding a requirement that the final use container bears the symbol “Rx only.” In proposed § 201.161(a)(3), we proposed requiring that the final use container bears appropriate directions and warnings concerning storage and handling.

In proposed § 201.161(b), we proposed requirements that a designated medical gas or medically appropriate combination of designated medical gases in a bulk or transport container be identified with the name of the product contained therein and accompanied by documentation identifying the product as meeting applicable compendial standards.

Lastly, proposed § 201.161(c) included several definitions. We received no comments on the proposed definitions of “designated medical gas” (proposed § 201.161(c)(1)) or “bulk or transport container” (proposed § 201.161(c)(3)) and are finalizing these definitions as proposed with minor technical changes made on our own initiative. We proposed to define “final use container” as a container that is for direct use or access by a patient or healthcare provider to administer a designated medical gas or medically appropriate combination of designated medical gases, not including bulk or transport containers or containers that are described in § 868.5655 (21 CFR 868.5655).

We respond to the comments on proposed § 201.161 in the following paragraphs.

(Comment 9) One comment recommends that the oxygen warning statement in proposed § 201.161(a)(1)(i) include additional instances in which oxygen may be provided without a prescription aside from depressurization or environmental oxygen deficiency, or emergency resuscitation. As an example of such an additional use, the comment suggests the emergency use of oxygen for hyperbaric oxygen therapy for decompression sickness.

(Response 9) FDA disagrees. The uses described in § 201.161(a)(1)(i) of the proposed rule are consistent with the circumstances described in section 576(b)(2)(A) of the FD&C Act under which oxygen may be provided without a prescription. FDA does not believe it would be appropriate to include additional uses in this provision.

(Comment 10) Regarding FDA's proposed requirement in § 201.161(a)(1)(ii) that final use containers bear a "No Smoking" and "No Vaping" warning statement and a graphic symbol conveying that smoking, vaping, and open flames near oxygen are dangerous, one comment notes that industry may need time to develop graphic symbols and text.

(Response 10) FDA recognizes the concerns expressed in this comment, and we note, as stated in section VI of this document, that firms will have 18 months to develop the required warning statement and graphic symbol. The Agency is happy to discuss the matter further with industry as firms develop graphics to address this requirement.

(Comment 11) One comment proposes adding a new § 201.161(a)(1)(iii) to state that, if oxygen is provided as a designated medical gas in the form of a cryogenic liquid in a cryogenic final use container meeting the definition of a device, the warning statements in § 201.161 are not required. The comment conditions this on the device label providing adequate directions for use in accordance with the device approval. The comment notes that this would reflect the current labeling appearing on home oxygen units.

(Response 11) FDA does not agree that this revision is needed. The definition of "final use container" in § 201.161(c)(2) already makes clear that the term does not include containers meeting the definition of a medical device and classified under § 868.5655. As devices, these containers have separate labeling requirements. Therefore, further clarification in § 201.161 is not necessary.

(Comment 12) In response to FDA's request for feedback regarding the inclusion in § 201.161(a)(2) of medical air in the proposed labeling

requirements for designated medical gases other than oxygen and medically appropriate combinations of designated medical gases, one comment responds that they do not oppose this.

(Response 12) FDA appreciates the feedback on this request.

(Comment 13) One comment requests that FDA add language to § 201.161(a)(2) explaining that the required statements in § 201.161 are not required for cryogenic nitrogen in an open top dewar. The comment notes that certain uses of cryogenic nitrogen, such as dermatological use, are device uses rather than drug uses.

(Response 13) While FDA agrees that cryogenic nitrogen being used for certain dermatological purposes is a device use, and therefore not subject to § 201.161, the Agency declines to add the requested language. As revised by this rule, § 201.161(a) states that section 503(b)(4) of the FD&C Act, which only applies to drugs, is deemed to have been met if a designated medical gas is in compliance with § 201.161(a). Therefore, it is clear that the requirements in § 201.161 only apply to medical gases that are drugs, and that if a gas is a device, it is subject to applicable device labeling requirements. This position is consistent with FDA's draft guidance for industry entitled "Certification Process for Designated Medical Gases"³ (Ref. 1).

(Comment 14) One comment requests that FDA revise § 201.161(b) to require that a designated medical gas or medically appropriate combination of designated medical gases in a bulk or transport container must be "provided with" documentation identifying the product as meeting applicable compendial standards, rather than "accompanied by" such documentation. This comment is intended to allow for current industry practices of electronic delivery of such documentation.

(Response 14) FDA believes that this change is unnecessary. Information promptly transmitted electronically would be considered to accompany a drug. Therefore, revisions are not necessary to address the concern expressed in this comment.

(Comment 15) One comment recommends that the definition of "final use container" in § 201.161(c)(2) be revised to mean a container that is "labeled" for direct use, rather than a container that is "for" direct use. The comment notes that the proposed definition of "bulk or transport

container" includes cylinders that are connected to a medical gas supply system, such as a hospital's oxygen system. However, the comment asserts that cylinder banks may contain individual labeled cylinders.

(Response 15) FDA disagrees with the proposed revision. First, specifying that a container is a final use container if it is "labeled" for direct use would be circular, and a firm could avoid being regulated as a final use container simply by not labeling its containers accordingly. Second, FDA believes that the purpose of the container should determine the appropriate labeling. If the container is intended to be used as a final use container, it must be labeled in compliance with § 201.161(a), and if a container is intended to be used as a bulk or transport container, it must be labeled in compliance with § 201.161(b).

5. Labeling of Medical Gas Containers (Proposed § 201.328)

FDA proposed changes to § 201.328(a)(1) to reference § 213.94(e)(3) instead of § 211.94(e)(2). We also proposed to add § 201.328(d) to clarify that a container filled with a designated medical gas or medically appropriate combination of designated medical gases may bear a statement identifying the name of the owner of the container or the address to which the container should be returned after use, noting that this statement may appear on a separate sticker or decal. We further proposed that if the owner of the container is not the manufacturer, packer, or distributor of the designated medical gas or medically appropriate combination of designated medical gases, that shall be clearly stated on the container. Proposed § 201.328(d) further notes that the addition of such statement shall not cause the owner of the cylinder to be a "relabeler" for purposes of FDA's registration and listing requirements.

(Comment 16) Although FDA did not propose changes to the definition of "portable cryogenic medical gas container" in § 201.328(a), one comment did suggest changes. This provision refers to a container that is capable of being transported and is intended to be attached to a medical gas supply system within a hospital, health care entity, nursing home, other facility, or home health care setting, or is a base unit used to fill small cryogenic gas containers for use by individual patients. The term does not include cryogenic containers that are not designed to be connected to a medical gas supply system, including portable liquid oxygen units as defined in § 868.5655. First, the comment requests to remove the term "base unit"

³ "Gases not intended for human or animal drug use . . . do not fall within the definition of 'medical gas' provided in section 575(2) of the FD&C Act, and are not subject to the certification process described in this guidance."

because the term is commonly used to refer to the device maintained at a patient's home that is filled with oxygen. The comment notes that these containers are not typically moved. Second, the comment suggests removing "small" before "cryogenic gas containers" in the exclusionary language, as well as including language clarifying that cryogenic gas containers utilize proprietary connections. Third, the comment suggests removing from the exclusionary language the reference to devices defined in § 868.5655.

(Response 16) FDA agrees that the term "base unit" should be removed from the definition. Because there may be confusion over what a "base unit" includes, we believe it is more appropriate to focus on the purpose of the container. As such, we are revising the definition to include, among other things, a container that "is used to fill small cryogenic gas containers for use by individual patients."

However, we disagree with the other requested changes. Because portable cryogenic medical gas containers can be in patients' homes, we believe that it is critical that they include proper labeling. Removing "small" before "cryogenic gas containers" would unnecessarily expand the exclusionary language and limit the scope of products subject to the labeling requirements described in part 201. We also do not believe adding the qualifier that cryogenic gas containers utilize proprietary connections to the exclusionary language is appropriate, as it is not clear why the exclusion should depend on the type of connections used. We also note that these requested revisions are not consistent with similar revisions proposed for § 213.94(e)(1) (concerning requirements for medical gas containers and closures) (see response 30).

We do not believe it is appropriate to remove the reference to § 868.5655 from the exclusionary language. It is unclear why the comment suggests removing this language while also noting that base units are considered devices; if the reference to § 868.5655 were removed from the exclusionary language, the definition might arguably be read to consider such devices to be portable cryogenic medical gas containers subject to the wraparound labeling requirement. This distinction between containers that are devices, and those that are not, is important, and FDA believes that the definition as revised makes clear which containers are devices subject to applicable device requirements, and which are portable cryogenic medical gas containers subject to applicable drug requirements.

Lastly, we are revising "does not include" to "exclude," consistent with the revisions discussed in response 31 below. As finalized, the term "portable cryogenic medical gas containers" excludes cryogenic containers that are not designed to be connected to a medical gas supply system.

(Comment 17) One comment requests that § 201.328(d) be revised to clarify that, if information identifying the name of the owner of the container or the address to which the container should be returned after use appears on a separate sticker or decal, such sticker or decal should not cover up other language on the label.

(Response 17) FDA appreciates the concern that labeling information should be clearly displayed and not covered up, but the Agency does not believe the proposed revisions are necessary because other provisions address this issue. In particular, section 502(c) of the FD&C Act states that a drug shall be misbranded if any word, statement, or other information required by or under authority of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Additionally, § 201.15(a)(6) of FDA's labeling regulations makes clear that "obscuring designs or vignettes" may cause required information to lack the prominence and conspicuousness required by section 502(c) of the FD&C Act.

F. Part 210

FDA proposed conforming edits to the general provisions concerning drug CGMP requirements in part 210 to reflect the proposed establishment of medical gas CGMP requirements in part 213. We did not receive comments on the proposed revisions and are finalizing the provisions as proposed with minor technical changes made on our own initiative.

G. Part 211

FDA proposed conforming edits to the drug CGMP requirements in part 211 to reflect that medical gases would no longer be subject to this part. We did not receive comments on the proposed revisions and are finalizing the provisions as proposed.

H. Description of Part 213 Comments and FDA Response

1. General Comments

(Comment 18) Some comments make general remarks supporting the

proposed CGMP regulations without focusing on a particular proposed provision.

(Response 18) We appreciate these comments of support.

2. Definitions (Proposed § 213.3)

FDA proposed definitions of several terms used in part 213. We received comments on several of those proposed definitions, as discussed below. We are finalizing as proposed (with minor technical and grammatical changes made on our own initiative) those definitions for which we received no comments.

a. Acceptance Criteria (Proposed § 213.3(b)(1))

We proposed to define "acceptance criteria" as the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).

(Comment 19) One comment requests that the "acceptance criteria" definition in proposed § 213.3(b)(1) be consistent not only with the acceptance criteria definition in part 210, but also the corresponding definitions in other regulations and guidance. For example, the comment notes that the "acceptance criteria" definition in part 212 (21 CFR part 212) concerning positron emission tomography (PET) drugs differs from the proposed definition for medical gases.

(Response 19) FDA does not believe that revisions are necessary. The proposed "acceptance criteria" definition in § 213.3(b)(1) is identical to the current "acceptance criteria" definition in § 210.3(b)(20), and FDA further believes that it is generally consistent with the "acceptance criteria" definition in § 212.1. In any case, PET drugs are outside the scope of this rulemaking, as FDA did not propose any revisions to part 212 in the proposed rule.

b. Batch (Proposed § 213.3(b)(2))

We proposed to define "batch" as a specific quantity of a medical gas or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(Comment 20) One comment suggests that batches, as defined in proposed § 213.3(b)(2), and lot numbers, as defined in § 213.3(b)(10), be defined per day. The comment argues that this

would provide sufficient information for downstream tracking and reporting.

(Response 20) FDA disagrees. As discussed in the proposed rule, we believe the proposed “batch” definition allows for significant flexibility in defining a batch to address considerations raised by different types of firms and different manufacturing, processing, packing, and holding activities (87 FR 31302 at 31310). We do not believe the term should restrict batches to a quantity produced in a single day. As such, we also do not believe that any revisions to the definition in § 213.3(b)(10) for “lot number, control number, or batch number” are necessary.

c. Commingling or Commingled (Proposed § 213.3(b)(3))

We proposed to define “commingling or commingled” as the act of combining one lot of designated medical gas or component with another lot or lots of the same designated medical gas or component.

(Comment 21) One comment concurs with the definition of “commingling or commingled” in proposed § 213.3(b)(3), but notes that, in the event lots are combined, firms should maintain tracking information at the container level to record which lots are included in the combined product and when they were added.

(Response 21) We believe that the tracking requirements established in this final rule sufficiently address any risks associated with the receipt of gases from multiple suppliers. Specifically, § 213.82 contains requirements for the receipt of incoming designated medical gases, including that either a signed certificate of analysis (COA) must accompany the gas or that the receiving firm must conduct full compendial testing (all tests necessary to ensure compliance with an official compendium), and that an identity test must be performed (see response 26 below for more information regarding revisions to § 213.82). Additionally, § 213.101(b) requires that in-process and final product containers of components and incoming designated medical gases shall identify the name of the component or designated medical gas or the name and percentage of each component or designated medical gas if they contain multiple components or designated medical gases, and the unique lot number assigned.

d. Original Manufacturer (Proposed § 213.3(b)(13))

We proposed to define “original manufacturer” as the person or entity that initially produces a designated

medical gas by chemical reaction, physical separation, compression of atmospheric air, purification (e.g., re-processing an industrial gas into a medical gas), or other means.

(Comment 22) One comment suggests that the “original manufacturer” definition in § 213.3(b)(13) be revised to exclude processing agents such as nitrogen used in bottle purging and product overlay because these gases are not a part of the drug product and are not considered medical gases.

(Response 22) FDA does not believe that revisions are necessary to address this concern. We agree that gases used in the production of drugs that are not medical gases are not subject to part 213. Such gases may be subject to part 211 if the drug product is subject to those regulations depending on the use of the gas, but that is outside the scope of this rulemaking. We also note that, as discussed below in response 45, we do not believe it is necessary for the definition to include “or entity” because the word “person” captures all relevant entities. As such, we have revised the definition to remove “or entity.”

(Comment 23) One comment proposes adding a definition of “subsequent manufacturer” in § 213.3(b) to resolve regulatory uncertainty that may exist without distinguishing between subsequent manufacturers and original manufacturers.

(Response 23) FDA does not believe that this definition is necessary. We understand “subsequent manufacturer” to refer to a person that performs manufacturing operations after the initial production of a designated medical gas, such as transfilling and curbside filling. We agree that subsequent manufacturers that are not engaged in the activities described in § 213.3(b)(13) are not original manufacturers. However, the proposed rule preamble clarified what kinds of entities would not be considered an original manufacturer (87 FR 31302 at 31311). If a provision does not specify that it applies only to original manufacturers, then subsequent manufacturers subject to part 213 would need to comply as applicable. Moreover, part 213 does not use the term “subsequent manufacturer,” and the comment’s proposed revisions would only use the term in the definition section.

3. Buildings and Facilities (Proposed Part 213, Subpart C)

FDA proposed to establish requirements for the design and construction features of buildings and facilities for the manufacture, processing, packing, or holding of

medical gases (proposed § 213.42). We received one comment on these provisions, which we discuss below.

(Comment 24) One comment asks for clarification regarding what FDA considers to be “adequate space” in proposed § 213.42(a), which would require that buildings and facilities used in the manufacture, processing, packing, or holding of a medical gas be of adequate design, including adequate space, for the orderly placement of equipment and materials to prevent mix-ups and allow for adequate cleaning, maintenance, and proper operations. The comment asserts that the term is ambiguous and proper equipment, operations, and labeling should allow firms to mitigate the risk of mix-ups.

(Response 24) The use of the term “adequate space” is intended to allow for flexibility in designing a manufacturing facility that prevents mix-ups and allows for adequate cleaning, maintenance, and proper operations. We agree that there are not necessarily size restrictions and that using proper equipment and processes are key to ensuring that the space is appropriate for the operations. We do not believe that revisions to § 213.42(a) are necessary.

4. Equipment (Proposed Part 213, Subpart D)

FDA proposed to establish several requirements concerning equipment used in the manufacture, processing, packing, or holding of medical gases (proposed §§ 213.63, 213.65, 213.67, and 213.68). We received no comments on proposed §§ 213.63, 213.65, and 213.67 and are finalizing them as proposed with a minor technical change made on our own initiative. We received comment only on proposed § 213.68(a), which specified that automatic, mechanical, and electronic equipment used in the manufacture of medical gases shall be routinely calibrated, inspected, and checked according to a written program designed to ensure proper performance, and that written procedures and records of calibration, inspections, and checks shall be maintained.

(Comment 25) One comment suggests that proposed § 213.68(a) be revised to include a minimum frequency for calibration, inspection, and checking of automatic, mechanical, and electronic equipment.

(Response 25) FDA does not believe it is necessary to include specific frequency requirements for such calibration, inspection, and checking of equipment. This is also consistent with § 211.68(a) and affords flexibility to

firms to take steps that will ensure proper performance based on the operations conducted and equipment used.

5. Control of Incoming Designated Medical Gas, Components, and Medical Gas Containers and Closures (Proposed Part 213, Subpart E)

FDA proposed to establish several requirements concerning the control of incoming designated medical gas, components, and medical gas containers and closures (proposed §§ 213.80, 213.82, 213.84, 213.89, and 213.94). We received no comments on proposed §§ 213.80 and 213.89 and are finalizing them as proposed. We respond to the comments on proposed §§ 213.82, 213.84, and 213.94 below.

a. Receipt and Storage of Incoming Designated Medical Gases (Proposed § 213.82)

FDA proposed that, upon receipt of an incoming designated medical gas, the firm shall verify and record that a signed certificate of analysis from the supplier accompanies each different designated medical gas in a shipment, including the supplier's name; name of the incoming designated medical gas; lot number or other unique identification number; actual analytical result obtained for strength, as well as the results of other tests performed; identification of the test method(s) used for analysis; NDA or new animal drug application (NADA) number of the incoming designated medical gas; and the supplier representative's signature and the date of signature (proposed § 213.82(a)(1)). If the incoming designated medical gas is obtained from a supplier other than the original manufacturer, FDA proposed requiring the shipment to include complete information from the original manufacturer's COA, and that the firm establish and maintain a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures (proposed § 213.82(a)(2)). Lastly, FDA proposed requiring that an identity test be performed upon receipt (proposed § 213.82(b)).

(Comment 26) One comment asks that § 213.82(a)(1) be revised to allow receiving firms to conduct full compendial testing on the commingled product as an alternative to verifying that a COA accompanies the shipment. The comment maintains that this is consistent with industry practice.

(Response 26) FDA generally agrees with this comment. The Agency believes that both proposed approaches are appropriate for ensuring that each

shipment of each incoming designated medical gas is verified as meeting relevant standards and is appropriate for use. However, FDA does not believe it is appropriate to specify that the full compendial testing be of the commingled product because testing of the gas before it is commingled would also confirm that it meets compendial standards. Further, § 213.82(a)(2) requires that, for incoming designated medical gas from a supplier other than the original manufacturer, each shipment shall also include complete information from the original manufacturer's COA. We are revising § 213.82(a)(1) accordingly to state that, upon receipt of each shipment of each incoming designated medical gas, the firm shall either perform full compendial testing on the gas and record the results, or verify and record that a signed COA from the supplier accompanies each different designated medical gas in a shipment.

(Comment 27) One comment requests that, instead of requiring that "a signed certificate of analysis from the supplier accompanies each different designated medical gas," § 213.82(a)(1) should state that "a signed *document* from the supplier *is provided* for each different designated medical gas" The comment suggests additional edits, including that the document must identify the product as meeting compendial standards, that a COA may be used to satisfy these requirements, and that only if a COA is used would paragraphs (a)(1)(i) through (vii) apply.

(Response 27) FDA does not agree that the term "certificate of analysis" should be replaced with the term "document." First, by retaining the term "certificate of analysis" after using the more general term "document," the suggested revisions would create ambiguity concerning what requirements would apply to a "document" that is not a COA. Second, our intent is that the entity providing this documentation certify the information accompanying the shipment. Therefore, "document" is less clear than the term "certificate of analysis." We similarly disagree with including a statement that a COA may be used to satisfy these requirements because FDA is already using that term to refer to the applicable documentation.

FDA disagrees with revising "accompanies" to read "is provided for." In general, we believe the terms can be read similarly, and FDA generally intends to interpret "accompany" broadly enough to include prompt electronic transmission, as discussed above in response 14.

FDA does not agree that it is necessary to add that the COA identifies the product as meeting applicable compendial standards. This is already covered by § 213.82(a)(1)(ii), (iv), and (vii), which require that the COA identify the name of the designated medical gas, its analytical test results, and a signature from the supplier's representative. For example, a supplier of Oxygen, USP (United States Pharmacopeia) would be certifying that the gas meets compendial standards for Oxygen, USP by identifying the gas by its compendial name and including test results demonstrating that the gas meets applicable standards.

(Comment 28) One comment asks that FDA delete proposed § 213.82(a)(1)(vi) because the inclusion of NDA or NADA information does not provide support for the quality or traceability of the product in addition to the other information provided. The comment maintains that NDA or NADA information may not be accurate in the case of commingled or combined gases, or gases from subsequent manufacturers.

(Response 28) FDA disagrees with the requested deletion. The Agency's intent in § 213.82 is to ensure that adequate information accompanies incoming designated medical gases shipped from original manufacturers to downstream entities, not combined or commingled gases from one subsequent manufacturer to another. However, we recognize that there may be confusion regarding the proposed definition of "incoming designated medical gas." Therefore, we are revising that definition in § 213.3(b)(8) to state that an "incoming designated medical gas" is a designated medical gas received from one source that, *after receipt*, is commingled with the same gas from another source, used in a medically appropriate combination of designated medical gases or in the production of another medical gas, or further distributed.

b. Testing and Approval or Rejection of Components, Containers, and Closures (Proposed § 213.84)

FDA proposed requirements for testing and approval or rejection of components, containers, and closures. Proposed § 213.84(a) included requirements either to examine components, containers, and closures prior to manufacturing or filling, or ensure that a statement of verification is provided from the supplier, provided that the firm establishes and maintains a program to ensure the reliability of the supplier's capabilities. Under proposed § 213.84(b), firms shall take appropriate actions to protect against container and closure leaks, including performing leak

tests on containers and closures at the time of fill and after fill but prior to release. Under proposed § 213.84(c), each component shall be sampled, tested, and approved or rejected as appropriate prior to use, either by performing testing for conformance with written specifications or by an identity test on the component accompanied by an acceptable COA from the supplier, provided that the firm establishes and maintains a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures.

(Comment 29) FDA specifically sought comments on the proposed requirement in § 213.84(b) that firms take appropriate actions to protect against container and closure leaks, including performing leak tests on containers and closures at the time of fill and after fill but prior to release. One comment maintains that FDA's proposed requirements would be sufficient. However, one comment asserts that leak testing upon pickup of a container would not be appropriate, both because of staffing and due to the varied timing at which the container is returned.

(Response 29) FDA appreciates this feedback and agrees that, unless an establishment is in receipt of a complaint or complaints of leaking or empty containers, the proposed language and associated testing described in § 213.84(b) is sufficient. Regarding the comment concerning leak testing upon pickup, FDA did not propose to require such testing, but rather noted in the preamble to the proposed rule that such testing may be needed to further protect against container and closure leaks to provide sufficient assurance of the durability of the container closure system throughout its period of use (87 FR 31302 at 31314). FDA does not believe that such testing will always be necessary, and other testing (or no additional testing) could be appropriate depending on the manufacturer's circumstances.

However, we continue to believe that leaking and empty container complaints is a serious concern, in light of the numerous instances of leaking and empty containers described in the proposed rule (87 FR 31302 at 31314) (see also Ref. 2). In several instances, firms did not appropriately evaluate the complaints in that the investigation conducted was inadequate, even when similar complaints were received, lacking steps such as evaluating the durability and suitability of containers and closures to identify a root cause. Therefore, we are adding to the complaint files provision at § 213.198(a)

a requirement that all complaints involving leaking containers or closures be reviewed, evaluated, and investigated in accordance with § 213.192.

The level of effort, formality, and documentation of the investigation of complaints should be commensurate with the level of risk. For complaints of leaking and empty containers, an appropriate investigation should include a review of production and testing procedures and records, and will often include additional testing and actions, such as use of more sensitive leak testing methods and use of mechanisms that allow for identification of containers that are the subject of a complaint. Based on the result of the investigation, the firm must take appropriate corrective action under § 213.192 (e.g., additional leak testing, removal of container or closure from circulation, addition of periodic leak testing to support container and closure durability). When there are no complaints of leaking or empty containers, we do not anticipate the need for additional leak testing. But in the event a firm becomes aware of repeated or trending leaks or empty containers, or other information indicating a production issue or container or closure issue that may result in leaking or empty containers, it is important that root causes are identified and corrective actions are taken that result in product and process improvements to ensure that the container closure system operates correctly, and that the gas will be available to the patient when needed.

c. Medical Gas Containers and Closures (Proposed § 213.94)

FDA proposed that medical gas containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the gas beyond the official or established requirements (proposed § 213.94(a)). We also proposed to require that container closure systems provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the gas (proposed § 213.94(b)). Under proposed § 213.94(c), medical gas containers and closures shall be clean to assure that they are suitable for their intended use. Additionally, we proposed that standards or specifications, testing methods, and where indicated, cleaning methods shall be written and followed (proposed § 213.94(d)).

Proposed § 213.94(e) included revisions to the requirements in § 211.94(e), including new proposed

requirements. Under proposed § 213.94(e)(1), portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (e.g., those that have been silver-brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the container's use) except by the manufacturer. FDA proposed to define "manufacturer" for purposes of § 213.94(e)(1) to include any individual or firm that fills high-pressure medical gas cylinders or cryogenic medical gas containers. FDA proposed to define "portable cryogenic medical gas container" for purposes of § 213.94(e)(1) as one that is capable of being transported and is intended to be attached to a medical gas supply system within a hospital, healthcare entity, nursing home, other facility, or home healthcare setting, or is a base unit used to fill small cryogenic gas containers for use by individual patients. The term would not include cryogenic containers that are not designed to be connected to a medical gas supply system, e.g., tank trucks, trailers, rail cars, or small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined in § 868.5655).

Under proposed § 213.94(e)(2), portable cryogenic medical gas containers as defined in proposed § 213.94(e)(1) as well as small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined in § 868.5655) must have a working gauge sufficient to indicate whether the container has an adequate supply of medical gas for continued use.

Finally, proposed § 213.94(e)(3) required that the labeling specified at § 201.328(a) be affixed to the container in a manner that does not interfere with other labeling, and each label as well as materials used for coloring medical gas containers must be reasonably resistant to fading, durable when exposed to atmospheric conditions, and not readily soluble in water.

(Comment 30) Regarding the proposed requirements for gas-specific use outlet connections in § 213.94(e)(1), one comment recommends adding "home healthcare" before "base unit" in the definition of "portable cryogenic medical gas container." The comment intends for this to clarify the term "base unit" and to achieve consistency with current safe practices.

(Response 30) FDA does not agree. As discussed above in response 16, although the proposed language for the

definition of “portable cryogenic medical gas container” in § 213.94(e)(1) is identical to the current definition in §§ 201.328(a) and 211.94(e)(1), different revisions were proposed for §§ 201.328(a) and 213.94(e)(1). Rather than adding “home healthcare” before “base unit,” FDA believes that it is most appropriate to remove “base unit” to focus on the purpose of the container.

(Comment 31) One comment recommends that the exclusionary language in the last sentence in § 213.94(e)(1) be revised such that “does not include” would be revised to “exclude” and that “not” would be removed before “designed.” The comment’s requested revisions would read “[t]he term excludes cryogenic containers that are designed to be connected to a medical gas supply system” The comment asserts that these changes would remove the double negative and provide clarity.

(Response 31) FDA agrees that revising “does not include” to “exclude” is clearer and has made that change in the final rule. However, FDA does not agree with removing “not” before “designed,” as that revision would change the meaning of the sentence. The first revision is sufficient to remove the double negative. We are also making this change in § 201.328(a). As finalized, the term “portable cryogenic medical gas container” excludes cryogenic containers that are not designed to be connected to a medical gas supply system.

(Comment 32) Multiple comments discuss the proposed requirement in § 213.94(e)(2) that portable cryogenic medical gas containers and small cryogenic gas containers for use by individual patients have a working gauge sufficient to indicate whether the container contains an adequate supply of medical gas for continued use. One comment expresses general support but maintains that the gauge should be subject to the testing provisions for components in § 213.84(c). Another comment suggests deleting the phrase “sufficient to indicate whether the container contains an adequate supply of medical gas for continued use” because patient use is subjective and determined on an individual basis. Instead, the comment requests that the gauge should indicate container pressure or the amount of liquid in the container.

(Response 32) We appreciate the comment of support and agree that the gauge would be subject to the testing provisions for components, as the gauge is part of the container closure system. Regarding the comment recommending that we revise proposed § 213.94(e)(2),

FDA would like to clarify that the intent of this language is to ensure that the gauge allows the user to understand how much of the medical gas remains in the tank. We recognize that it is not possible for a gauge to display patient-specific information. To help clarify this we are revising the codified to read, in pertinent part, that portable cryogenic medical gas containers and small cryogenic gas containers for use by individual patients have a working gauge sufficient to *assist the user in determining* whether the container contains an adequate supply of medical gas for continued use. We agree with the comment that a gauge capable of displaying container pressure or liquid level would satisfy this requirement.

6. Production and Process Controls (Proposed Part 213, Subpart F)

FDA proposed to establish several requirements concerning production and process controls for medical gases (proposed §§ 213.100, 213.101, and 213.110). We received no comments on the proposed provisions and are finalizing them as proposed.

7. Packaging and Labeling Control (Proposed Part 213, Subpart G)

FDA proposed to establish several requirements concerning packaging and labeling controls for medical gases (proposed §§ 213.122, 213.125, and 213.130). We received no comments on proposed §§ 213.122 and 213.130 and are finalizing them as proposed.

In proposed § 213.125(a), we proposed that labeling and packaging operations must be controlled to prevent labeling and product mix-ups, and that procedures shall be written and followed describing in sufficient detail the control procedures employed for the issuance of labeling. In proposed § 213.125(b), we proposed requiring that procedures be used to reconcile the quantities of labeling issued, used, and returned, and that procedures require evaluation of discrepancies when such discrepancies are outside narrow preset limits based on historical operating data (FDA proposed that labeling reconciliation be waived for cut or roll labeling if a 100-percent examination is performed in accordance with § 213.122(f)(2), and for 360° wraparound labels on portable cryogenic medical gas containers). Proposed § 213.125(c) states that all excess lot number stickers or decals bearing lot or control numbers shall be discarded. Lastly, proposed § 213.125(d) exempted bulk or transport containers from § 213.125. We respond to the comments on proposed § 213.125 below.

(Comment 33) Regarding proposed § 213.125(c), one comment requests clarification regarding what constitutes excess lot number stickers or decals. The comment asserts that, if the intent is for a container to only have one label, the wear and tear of medical gas labels may justify multiple labels including the same content.

(Response 33) FDA’s intent in proposed § 213.125(c) is to address the risks of excess labeling materials that are unused. FDA does not object to including lot number information in more than one location on the container closure. Rather, our concern is that extra stickers will be inadvertently used for another batch, which would lead to mix-ups. We believe the provision as drafted addresses this concern and do not believe that changes are needed.

8. Holding and Distribution (Proposed Part 213, Subpart H)

FDA proposed to establish warehousing and distribution procedure requirements. Specifically, FDA proposed that written procedures be established and followed describing the distribution of medical gases, including a system by which the distribution of each lot can be readily determined to facilitate its recall (proposed § 213.150(a)). Additionally, FDA proposed that written procedures be established and followed describing the warehousing of medical gases, including quarantine before release by the quality unit (proposed § 213.150(b)).

(Comment 34) Although not directed at a specific provision, one comment discusses the transfilling process and the information that should be tracked. The comment maintains that transfillers should record which lots of medical gas were added as well as the date. The comment further asserts that once transfilling occurs, this information can no longer be tracked.

(Response 34) FDA does not believe that changes are needed to address this issue. Although tracking this information upon adding gas to a transfilling container may enhance traceability to some degree, FDA expects that the benefits would be minimal while the added burden of tracking this information would be significant. Moreover, it would be unclear in the long term what lots are in the cylinder because the gases from multiple batches would commingle and the transfiller would not be able to determine when a lot is no longer present in the container. Therefore, the list of lots could become quite long and unmanageable over time.

9. Laboratory Controls (Proposed Part 213, Subpart I)

FDA proposed to establish several laboratory control requirements (proposed §§ 213.160, 213.165, and 213.166). We received no comments on proposed §§ 213.160 and 213.166 and are finalizing them as proposed.

FDA proposed testing and release requirements in § 213.165. Under proposed § 213.165(a), for each batch of medical gas, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the gas, including the identity and strength, prior to release. Additionally, FDA proposed that any sampling and testing plans shall be described in written procedures that shall be followed, including the method of sampling, the number of units per batch to be tested, and acceptance criteria (proposed § 213.165(b)). Under proposed § 213.165(c), the accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented, and such validation and documentation may be accomplished in accordance with § 213.194(a)(2). Also under proposed § 213.165(c), the suitability of all testing methods shall be verified under actual conditions of use. Proposed § 213.165(d) would require rejection of medical gases that fail to meet established standards or specifications and any other relevant quality criteria. This proposal is generally consistent with the requirements described in § 211.165(f), but FDA did not propose to include in § 213.165(d) the provision stating that reprocessing may be performed or the requirements for using reprocessed material because the Agency is not aware of reprocessing that occurs for medical gases. FDA solicited comment on this issue, including any example scenarios in which medical gases are reprocessed. Finally, proposed § 213.165(e) would exempt from this section filling of designated medical gases and medically appropriate combinations of medical gases via liquid to liquid into a container at a delivery site.

(Comment 35) Regarding § 213.165(d)'s proposed requirement to reject medical gases that fail to meet established standards or specifications, one comment notes that they are not aware of any reprocessing of medical gases.

(Response 35) FDA appreciates the additional information. In light of the response received, we do not believe revisions to § 213.165(d) are necessary.

10. Records (Proposed Part 213, Subpart J)

FDA proposed to establish records requirements (proposed §§ 213.180, 213.182, 213.184, 213.186, 213.189, 213.192, 213.194, 213.196, and 213.198). We received no comments on proposed §§ 213.180, 213.184, 213.186, 213.192, 213.194, and 213.198 and are finalizing them as proposed with minor technical and grammatical changes made on our own initiative. We respond to the comments on proposed §§ 213.182, 213.189, and 213.196 below.

a. Equipment Cleaning and Use Log (Proposed § 213.182)

We proposed that a written record of major equipment cleaning, maintenance (except routine maintenance), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed (proposed § 213.182). If equipment is dedicated to manufacture of one product, then individual equipment logs would not be required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, we proposed that the records of cleaning, maintenance, and use shall be part of the batch record. We proposed that the persons performing and double-checking the cleaning and maintenance (or, if using automated equipment under § 213.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Lastly, we proposed that entries in the log shall be in chronological order.

(Comment 36) One comment suggests revising § 213.182 to state that cleaning and maintenance is performed on a periodic basis or when there is suspected contamination and is not associated with a batch or lot process. The comment further requests that this provision state that equipment cleaning and non-routine maintenance is documented on separate cleaning or maintenance records. While the comment agrees that keeping a record of maintenance performed on production equipment is necessary, the comment maintains that, because these gases are manufactured and filled in a closed, pressurized system, equipment should not be cleaned between batches and lots. Otherwise, the comment asserts, contaminants could be introduced. Additionally, the comment states that the requirement to keep a use log of production equipment is not needed

because this information is included on batch production records and would only increase manufacturers' burden.

(Response 36) FDA disagrees with this comment. The comment's suggested revisions go beyond recordkeeping requirements. The underlying cleaning and maintenance requirements are already addressed in §§ 213.42(c) and 213.67. Additionally, FDA does not believe that this provision as originally proposed suggests or requires cleaning at inappropriate times.

We also do not believe that the proposed requirements in § 213.182 are overly burdensome. Because the requirements in § 213.182 are intended to support good recordkeeping practices, such as the ability to locate records related to the equipment used in medical gas production (without needing to review one or more batch records), we decline to make the suggested revisions.

b. Batch Production and Control Records (Proposed § 213.189)

We proposed to require that batch production and control records be prepared for each batch of medical gas produced (proposed § 213.189(a)). We further proposed in § 213.189(b) that these records shall include documentation that each significant step in the manufacture, processing, packing, or holding of the medical gas produced was accomplished, including dates and times of each significant step, including in-process and laboratory tests as applicable; a description of the container for the medical gas, including the number and size of the containers filled as applicable; specific identification of each component and its source or in-process material used as applicable; measures of components used in the course of processing as applicable; testing results, including any in-process test results and finished product test results; dated signature or initials of the persons performing and directly supervising or checking each significant event in the operation; inspection of the packaging and labeling area before and after use; complete labeling control records, including specimens or copies of all labeling used and label application and reconciliation records as appropriate; and any investigation made according to § 213.192.

(Comment 37) One comment requests that the Agency revise § 213.189(b)(1) by deleting the words "and times" from the provision requiring that batch production and control records include "[d]ates and times of each significant step, including in-process and laboratory tests as applicable." The

comment asserts that recording the time of production would not improve medical gas safety in light of the manufacturing processes used for medical gases.

(Response 37) FDA agrees with this comment. The Agency also notes that, considering the long, continuous production processes associated with many of these gases (for example, air separation used to produce oxygen and nitrogen), recording time as part of a firm's batch production and control records may be challenging. Therefore, the Agency is revising § 213.189(b)(1) to delete the reference to the time of significant steps. The finalized language requires that batch production records include the dates of each significant step, including in-process and laboratory tests as applicable.

(Comment 38) One comment asks that we delete § 213.189(b)(8), which would require batch production and control records to include complete labeling control records, including specimens or copies of all labeling used and label application and reconciliation records as appropriate. The comment maintains that the inclusion of labeling information would not provide added safety assurance, as would be the case for other drugs. Additionally, the comment notes that labels are reused, and industry performs a 100 percent inspection of cylinder labels during production.

(Response 38) We decline to delete § 213.189(b)(8). As discussed in the preamble to the proposed rule, because labeling does not always need to be applied due to the reuse of labels, documentation of these labeling control activities is important to help prevent mix-ups and the incorrect application of labeling (87 FR 31302 at 31319). Moreover, the inclusion of labeling control records can help facilitate investigations of complaints and other post-market activities. Due to the industry practice of the reuse of the labels, it is possible that no labels are applied during the manufacturing of a batch. In these instances, a copy of the label or a reproduction of the label is reasonable to include as part of the labeling control activities.

c. Distribution Records (Proposed § 213.196)

We proposed in § 213.196 to require that distribution records contain the name of the product, lot or batch number, name and address of the consignee, and date and quantity shipped, and that, for medical air and medically appropriate combinations of designated medical gases, the

distribution record include the percentage of each gas.

(Comment 39) Multiple comments discuss the proposed requirement to include lot or batch number information in distribution records in § 213.196. One comment expresses concern that the exemption in § 211.196 (stating that compressed medical gas products do not need to include lot or control numbers in distribution records) would limit the ability to track a safety event. Another comment requests that "lot or batch number" be removed from § 213.196 to be consistent with the current requirements in § 211.196.

(Response 39) FDA declines to revise § 213.196. Regarding the concern about handling safety events, FDA proposed deletion of the exemption in § 211.196 for compressed medical gas products specifically because § 213.196 would fully address this requirement for medical gases. Regarding the proposed revision to § 213.196 to remove "lot or batch number," FDA continues to believe that including the lot or batch number is essential to properly tracking and tracing product in the event a safety issue is discovered (see proposed rule discussion, 87 FR 31302 at 31320).

(Comment 40) One comment requests that FDA revise § 213.196 to explain that distribution records shall contain the required information (the name of the product, lot or batch number, name and address of the consignee, and date and quantity shipped) "to facilitate a recall if needed." The comment asserts this would help achieve FDA's objective of improved traceability.

(Response 40) FDA does not agree. Because distribution records can serve many purposes aside from facilitating a recall, the suggested revision would unduly narrow the provision. As proposed (and finalized), § 213.196 can help a firm facilitate a recall and address other safety concerns that arise.

(Comment 41) One comment maintains that distribution records for medical air should not be required to include the percentage of each gas. The comment contends that, because the compendial standard for medical air specifies the range for the quantity of oxygen in nitrogen, including the specific percentage of oxygen for a shipment would not provide a benefit.

(Response 41) FDA agrees. Because medical air must be shown to meet compendial standards in order to be released, it is not necessary to state the amount of oxygen within the allowable range in the distribution records. Therefore, we have deleted "medical air and" from the second sentence of § 213.196 such that the requirement that the distribution record include the

percentage of each gas only applies to medically appropriate combinations of designated medical gases.

11. Returned and Salvaged Medical Gases (Proposed Part 213, Subpart K)

FDA proposed to establish requirements for returned and salvaged medical gases (proposed §§ 213.204 and 213.208). We received no comments on proposed § 213.208 and are finalizing it as proposed with a minor grammatical change made on our own initiative.

FDA proposed in § 213.204 to require that returned medical gases be identified as such and held, and that, if the conditions under which the returned gases have been held, stored, or shipped before or during their return, or if the condition of the gas, its container, carton, or labeling, as a result of storage or shipping, cast doubt on its safety, identity, strength, quality, or purity, the returned medical gas shall be destroyed unless examination, testing, or other investigations prove the gas meets appropriate standards of safety, identity, strength, quality, or purity. Moreover, FDA proposed to require that firms maintain certain records of returned medical gases, and if the reason for a medical gas being returned implicates associated batches, an appropriate investigation pursuant to proposed § 213.192 shall be conducted. Procedures for holding, testing, and use of returned medical gases would need to be in writing and followed. FDA proposed that § 213.204 would not apply to the routine refilling of cryogenic medical gas containers in the normal course of business unless the container was returned for a quality issue.

(Comment 42) One comment requests that FDA exempt containers that assure the quality of the residual product prior to refill from the returned medical gases requirements in proposed § 213.204. The comment maintains that certain cylinders have residual pressure valves that prevent backflow.

(Response 42) FDA does not believe this change is necessary to address the comment's concern. As noted in the proposed rule, § 213.204 would apply to situations in which a distributed medical gas is sent back to a firm due to a quality issue (87 FR 31302 at 31321). Proposed § 213.204 included an exception for the routine refilling of cryogenic medical gas containers in the normal course of business because we understand that small amounts of gas are expected to remain in a returned container that will be reused (Id.). In the event a cylinder with a residual pressure valve is returned in the normal course of business for refilling and

redistribution, the requirements in § 213.204 would not apply. We note, however, that such valves could nonetheless fail, and if, for any reason, a cylinder with such a valve were returned and any of the conditions in the second sentence of § 213.204 are present, then the returned gas must be destroyed unless examination, testing, or other investigations prove the gas meets appropriate standards of safety, identity, strength, quality, or purity.

I. Description of Part 230 Comments and FDA Response

1. General Comments

We proposed a new part 230 (21 CFR part 230) to include requirements concerning the certification of designated medical gases and postmarketing safety reporting.

(Comment 43) Some comments make general remarks supporting the proposed certification and safety reporting regulations without focusing on a particular proposed provision.

(Response 43) We appreciate these comments of support.

2. Definitions (Proposed § 230.3)

FDA proposed definitions of several terms used in part 230. We received comments on several of those proposed definitions, as discussed below. We are finalizing as proposed those definitions for which we received no comments with minor technical changes made on our own initiative.

a. Applicant (Proposed § 230.3(b)(2))

We proposed to define “applicant” as any person or entity who submits a certification request for a designated medical gas under part 230, including a supplement, and any person or entity who owns a granted certification for a designated medical gas under part 230 (proposed § 230.3(b)(2)).

(Comment 44) One comment asks that we add language to clarify that the applicant is a person or entity who submits a certification request “as an original manufacturer” as defined in the medical gas CGMP regulations at § 213.3(b)(13). The comment asserts that this would be consistent with parts 201 and 213 and account for applicants that are both original manufacturers and subsequent manufacturers.

(Response 44) FDA does not agree with these requested revisions. Consistent with section 576(a)(1) of the FD&C Act, § 230.50(a)(1) of the designated medical gas certification regulations makes clear that any person who seeks to *initially* introduce or deliver for introduction a designated medical gas into interstate commerce is

the entity that shall file a certification request. We agree that subsequent manufacturers are not required to submit certification requests, but revising the “applicant” definition is unnecessary because the applicant is *any* person or entity who submits a certification request. If a subsequent manufacturer erroneously submitted a certification request, FDA may determine that the request was unnecessary and not grant it, but the subsequent manufacturer would still be considered the applicant for purposes of all interactions with the Agency related to the certification request. Moreover, as stated in response 45, FDA does believe it is appropriate to remove “or entity” from the definition of “applicant,” as the word “person” captures all relevant entities.

b. Nonapplicant (Proposed § 230.3(b)(9))

We proposed to define “nonapplicant” as any person other than the applicant whose name appears on the label of a designated medical gas container as a manufacturer, packer, or distributor (proposed § 230.3(b)(9)).

(Comment 45) One comment suggests revisions to the proposed “nonapplicant” definition in § 230.3(b)(9) for consistency across the regulations applicable to designated medical gases. First, the comment asks that the definition be revised to include any person *or entity*, rather than just any person, meeting the criteria in the definition. This suggested revision is intended to be consistent with the “applicant” definition in § 230.3(b)(2). Second, the comment asks that the definition be revised to refer to entities that appear on the label of a designated medical gas container as a subsequent manufacturer or distributor, rather than as a manufacturer, packer, or distributor. The comment asserts that these revisions are intended to account for nonapplicants that are also original manufacturers. The comment maintains that removal of the term “packer” would be consistent with industry terminology.

(Response 45) We do not believe that changes are necessary to the “nonapplicant” definition. First, FDA routinely uses the word “person” to include entities and organizations that are not individuals. The term “person” as defined in section 201(e) of the FD&C Act includes an individual, partnership, corporation, and association. Additionally, the definition of “applicant” in § 314.3 “is any person who submits an NDA . . . or ANDA” As discussed in response 44 above, FDA also concludes it is not necessary to include “or entity” in the

definition of “applicant” in § 230.3(b)(2). Section 230.50(b)(1) has also been revised to refer to “person” and not “entity.”

Second, we do not agree with the use of the term “subsequent manufacturer” or the removal of the term “packer.” If an entity is an original manufacturer of a designated medical gas, FDA expects that it would be the applicant as opposed to a nonapplicant. Nonetheless, for a given designated medical gas, whether a firm is the applicant or a nonapplicant will depend on the activities performed for that product. We also note that the terminology used in the proposed definition is consistent with existing § 314.80(c)(1)(iii). While the medical gas industry may not ordinarily use the term “packing” to refer to its operations, the activities that subsequent manufacturers perform (such as transfilling, mixing, or filling at a delivery site) are expected to fall within the term “manufacturer, packer, or distributor.”

3. General Requirements for All Submission Types (Proposed § 230.50)

FDA proposed requirements for all types of certification submissions (proposed § 230.50). We received no comments on the proposed requirements and are finalizing them as proposed with minor technical edits made on our own initiative for clarity.

4. Withdrawal by the Applicant of a Certification Request Before It Is Deemed Granted (Proposed § 230.65)

FDA proposed requirements regarding withdrawal of a certification request prior to it being deemed granted (proposed § 230.65). We received no comments on the proposed requirements and are finalizing them as proposed.

5. Supplements and Other Changes to a Granted Certification (Proposed § 230.70)

FDA proposed requirements regarding supplements and other changes to a granted certification (proposed § 230.70). We received no comments on the proposed requirements and are finalizing them as proposed.

6. Change in Ownership of a Granted Certification (Proposed § 230.72)

FDA proposed requirements regarding the change in ownership of a granted certification (proposed § 230.72). We received no comments on the proposed requirements and are finalizing them as proposed.

7. Annual Report (Proposed § 230.80)

FDA proposed to establish annual report requirements in proposed § 230.80. First, FDA proposed that applicants must submit an annual report each year within 60 calendar days of the anniversary of the date the certification was granted, and that the annual report form must be signed and completed and submitted in an electronic format that FDA can process, review, and archive, or in hard copy by submitting two paper copies to CDER's Central Document Room (proposed § 213.80(a)). Under proposed § 213.80(b), the annual report would contain, for the prior 12 months, a brief summary of significant new information that might affect the safety, effectiveness, or labeling of the designated medical gas, including any actions the applicant has taken or intends to take as a result of this new information; information about the quantity of the designated medical gas distributed by the applicant, including the National Drug Code (NDC) numbers and quantities distributed for domestic use and the quantities distributed for foreign use; any changes to the applicant's name or contact information; and a list of current facilities, as well as a list of facilities that are no longer in use.

(Comment 46) One comment requests that annual reports be submitted after the start of the new calendar year, rather than on the anniversary of the date the certification request was deemed granted. The comment asserts that this would align the annual reporting requirements with reporting requirements stemming from the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136). The comment also states that annual reports are provided for activities related to the original manufacturing operations of the applicant, and not for subsequent manufacturing activities.

(Response 46) FDA agrees with this comment. In particular, section 3112(e) of the CARES Act established new section 510(j)(3) of the FD&C Act (21 U.S.C. 360(j)(3)), which requires all drug registrants to report annually on the amount of each listed drug manufactured, prepared, propagated, compounded, or processed for commercial distribution. We recognize that it may create efficiencies for firms to track information across multiple reports if the reports are submitted on the same reporting schedule. Therefore, we have revised § 230.80(a) to require annual reports to be submitted within 60 calendar days of the new calendar year. We also agree that annual reports

cover activities related to the original manufacture of the designated medical gas.

(Comment 47) One comment requests deletion of the requirement in proposed § 230.80(b)(2) that annual reports include distribution data because, as required by the CARES Act, section 510(j)(3) of the FD&C Act requires similar distribution data. Specifically, section 510(j)(3)(A) requires that each person who registers with FDA under section 510 of the FD&C Act with regard to a drug must report annually to FDA on the amount of each drug listed that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.

(Response 47) FDA appreciates the need to avoid duplicate submissions of information. However, we conclude it is appropriate to retain the proposed requirement that distribution data be included in designated medical gas annual reports. Certain information, such as the NDC number and quantities of gas distributed for domestic and foreign use, is important to retain.

FDA considers the requirement to submit distribution data in annual reports under § 230.80(b)(2) to have been met if: (1) the registrant of establishments identified in the application submits a timely and complete report under section 510(j)(3) of the FD&C Act; (2) the registrant of establishments identified in the application includes in its section 510(j)(3) report the amount of listed drug product (organized by NDC number) that was distributed for foreign use during the reporting period (in addition to the amount distributed in the United States); (3) the applicant's annual report provides the date(s) of the report(s) submitted under section 510(j)(3) of the FD&C Act that includes the domestic and foreign distribution information; and (4) the applicant's annual report submitted under § 230.80 contains all other information required in § 230.80(b). FDA believes that this would maintain the Agency's access to information that would enhance the Agency's ability to assess, prevent, and mitigate possible drug shortages, and would also address the potential reporting burden for applicants that are subject to both § 230.80 and section 510(j)(3) of the FD&C Act.

(Comment 48) One comment requests that the proposed requirement in § 230.80(b)(4) that the annual report contain a list of "current facilities" be revised to require a list of "the applicant's current original manufacturing facilities" because only

original manufacturing locations are required to be listed.

(Response 48) Our intent in § 230.80(b)(4) is for applicants to submit information regarding their original manufacturing facilities, as opposed to any subsequent manufacturing facilities they operate. In light of the comment received, we have revised § 230.80(b)(4) consistent with the requirement in section 576(a)(1)(C) of the FD&C Act and what we proposed for § 230.50(b)(4), which both address information to be submitted as part of a certification request. Because the purpose of § 230.80(b)(4) is to receive updates of the same information, we have revised the provision to require that the annual report include a list of current facilities *where the designated medical gas is initially produced*, and a list of facilities that are no longer in use.

8. FDA Review of Submissions (Proposed § 230.100)

FDA proposed requirements regarding FDA's review of submissions (proposed § 230.100). We received no comments on the proposed requirements and are finalizing them as proposed with minor technical edits made on our own initiative.

9. When a Submission Is Deemed Granted (Proposed § 230.105)

FDA proposed requirements regarding when a submission is deemed granted (proposed § 230.105). We received no comments on the proposed requirements and are finalizing them as proposed.

10. Withdrawal (Proposed § 230.150)

FDA proposed withdrawal and revocation requirements in proposed § 230.150. We did not receive comments on the proposed revocation requirements in § 230.150(b) and are finalizing those requirements as proposed with minor technical and grammatical changes made on our own initiative.

FDA proposed in § 230.150(a)(1) and (2) several grounds for withdrawing approval of a designated medical gas application, subject to FDA notifying the applicant and affording an opportunity for a hearing. Under proposed § 230.150(a)(3), FDA will withdraw approval of an application if the applicant requests its withdrawal because the designated medical gas subject to the application is no longer being marketed, provided none of the conditions listed in § 230.150(a)(1) and (2) apply. FDA would consider such a written request to be a waiver of an opportunity for hearing, and such withdrawal would be without prejudice

to refiling. FDA proposed in § 230.150(a)(4) that we may notify an applicant that we believe a potential problem associated with a designated medical gas is sufficiently serious that the designated medical gas should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application for the product, and to remove voluntarily the product from the market. Lastly, FDA proposed under § 230.150(a)(5) that, if FDA withdraws an approval, FDA will publish a notice in the **Federal Register** announcing the withdrawal.

(Comment 49) Regarding the proposed withdrawal requirements in § 230.150, one comment states that FDA should include a reason for voluntary withdrawals to clarify whether the designated medical gas was withdrawn for safety reasons. The comment asserts that, without such information, an applicant's reputation may be harmed.

(Response 49) FDA does not believe that posting a withdrawal notification without a rationale would necessarily be interpreted as a statement that the designated medical gas was withdrawn for safety or effectiveness reasons. Because designated medical gases are generally considered appropriate for the uses stated in the statute, many of the considerations relevant to drugs approved under section 505 of the FD&C Act are not applicable. Moreover, the withdrawal of a designated medical gas does not create the same follow-on considerations that the withdrawal of an NDA approved under section 505 of the FD&C Act would create for current and future ANDAs that reference the withdrawn NDA. Therefore, we decline to make the suggested revisions to § 230.150.

However, as discussed in response 61 below, FDA is revising § 230.150(a)(2)(i) to include failure to submit reports under § 314.81(b)(3). Because of this revision, it is unnecessary for § 314.81(d) to continue to apply to designated medical gases.

11. Field Alert Report (Proposed § 230.205)

We proposed field alert reporting requirements for designated medical gases in § 230.205. Specifically, FDA proposed that applicants be required to submit FARs to the FDA district office responsible for the facility involved within 3 working days of receipt by the applicant, and that the information may be provided by telephone or other rapid communication, with prompt written followup. FDA also proposed formatting

requirements for the FAR and its mailing cover. In proposed § 230.205(a), FDA proposed that a FAR is required for information concerning any incident that causes the designated medical gas or its labeling to be mistaken for, or applied to, another article. In proposed § 230.205(b), FDA proposed that a FAR is required for information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed designated medical gas, or any failure of one or more distributed batches of the designated medical gas to meet established specifications.

(Comment 50) One comment requests that the field alert reporting requirements apply to nonapplicants as well as applicants. The comment asserts that downstream entities are more directly linked to the end user and would have the most current and detailed information about any issues that might require a FAR.

(Response 50) FDA disagrees. We note that the proposed field alert reporting requirements are drafted for designated medical gases, as opposed to combinations of designated medical gases. This scope is also consistent with the field alert reporting requirements in § 314.81(b)(1), which require that applicants submit reports to the Agency. It is worth noting that the field alert reporting requirements in § 514.80(b)(1) (21 CFR 514.80(b)(1)) require the applicant, or the nonapplicant through the applicant, to report, so in either case the applicant would submit the FAR to FDA.

(Comment 51) One comment expresses support for the proposed 3-working-day reporting period, but asserts that FARs may still be incomplete at that timepoint.

(Response 51) FDA acknowledges the concern that more information may be available after 3 working days, and thus, under the proposed reporting timeframe, FARs may be incomplete in some instances. FDA believes that a 45-day reporting deadline for certain FARs for designated medical gases is appropriate. The 3-working-day reporting period originally proposed would apply if the information suggests that the reportable incident may require a rapid response to address a public health risk. Therefore, as finalized, § 230.205 requires that an applicant submit a FAR as soon as possible but no later than 45 calendar days from the date the applicant, or its agent or contractor, obtained information suggesting that a reportable incident has occurred, and if the information suggests that the reportable incident may require a rapid response to address

a public health risk, the applicant must submit the FAR as soon as possible, but no later than 3 working days from obtaining the information. Reporting as soon as possible but no later than 45 calendar days from the date the applicant, or its agent or contractor, obtained information suggesting that a reportable incident has occurred appropriately balances the need to report quickly with helping to ensure that the applicant collects sufficient information to enable an appropriate response.

FDA is not making further revisions to the field alert reporting requirements for designated medical gases to reflect the proposed changes to part 314. The Agency has not received many FARs for designated medical gases. Considering certain characteristics of these drug products (including that they are generally manufactured in a sealed, closed system, which makes contamination and stability less of a concern), we conclude that further revisions are unnecessary. However, as we gain more experience with designated medical gases and with any future revisions to the field alert reporting requirements in part 314, we will consider whether revisions to § 230.205 are needed.

12. General Reporting Requirements for Designated Medical Gas Adverse Events (Proposed § 230.210)

FDA proposed general reporting requirements for designated medical gas adverse events (proposed § 230.210). We received no comments on the proposed requirements and are finalizing them as proposed.

13. Human Postmarketing Safety Reporting (Proposed § 230.220)

FDA proposed human postmarketing safety reporting requirements in § 230.220. Under proposed § 230.220(a)(1), applicants and nonapplicants must submit each ICSR associated with the use of a designated medical gas in humans described in § 230.220(b) as soon as possible but no later than 15 calendar days from the date the applicant or nonapplicant met the reporting criteria and acquired a minimum data set for an ICSR for that adverse event. FDA further proposed that applicants and nonapplicants should not resubmit any ICSRs obtained from FDA's adverse event reporting database or forwarded to the applicant or nonapplicant by FDA (proposed § 230.220(a)(2)). Additionally, FDA proposed that applicants and nonapplicants must submit new information related to a previously submitted ICSR or an ICSR sent to the

applicant by FDA no later than 15 calendar days after the information is received or otherwise obtained (proposed § 230.220(a)(3)).

FDA proposed in § 230.220(b) to specify which adverse events must be reported in an ICSR. FDA proposed that applicants and nonapplicants must submit ICSRs for serious adverse events reported to the applicant or nonapplicant spontaneously (such as a report initiated by a patient, consumer, or healthcare provider) or obtained from published scientific and medical journals (either as case reports or as the result of a formal clinical trial) (proposed § 230.220(b)(1)(i) and (ii)). Proposed § 230.220(b)(1)(iii) explains that ICSRs are not required for reports of the death of a patient who was administered oxygen, unless the applicant or nonapplicant is aware of evidence to suggest that the death was caused by the administration of oxygen. In addition, under proposed § 230.220(b)(2), upon notification by FDA, applicants and nonapplicants must submit, in a timeframe established by FDA, ICSRs for any adverse event that are not required under § 230.220(b)(1).

Under proposed § 230.220(c), FDA proposed to specify how to complete and submit ICSRs required under § 230.220. FDA proposed to require that ICSRs and ICSR attachments be submitted in an electronic format that FDA can process, review, and archive, though applicants and nonapplicants may request, in writing, a temporary waiver of this requirement (proposed § 230.220(c)(1)). FDA further proposed to require that each ICSR be submitted only once, that separate ICSRs be submitted for each patient who experiences a reportable adverse event, that adverse event terms must be coded using standardized medical terminology, that all ICSRs must contain at least the minimum data set for an ICSR, that the applicant or nonapplicant must complete all known, available elements of an ICSR as specified in § 230.220(d), and that an applicant must submit autopsy reports, hospital discharge summaries, or published articles as specified (proposed § 230.220(c)(2)).

Proposed § 230.220(d) sets forth the information that must be included in an ICSR, including patient information, adverse event information, information about the suspect designated medical gas(es), information about the initial reporter, and applicant or nonapplicant information.

Under proposed § 230.220(e), FDA proposed recordkeeping requirements, including that applicants and

nonapplicants maintain records of information relating to adverse events for 10 years, whether or not submitted to FDA (proposed § 230.220(e)(1)). FDA further proposed that such records must include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse event information that is received or otherwise obtained by the applicant or nonapplicant (proposed § 230.220(e)(2)). Lastly, FDA proposed that, upon written notice by FDA, the applicant or nonapplicant must submit any or all of these records to FDA within 5 calendar days after receipt of the notice, and the applicant or nonapplicant must permit any authorized FDA employee, at reasonable times, to access, copy, and verify these established and maintained records (proposed § 230.220(e)(3)).

Proposed § 230.220(f) specified that applicants and nonapplicants must develop written procedures needed to fulfill the requirements of § 230.220 for the surveillance, receipt, evaluation, and reporting to FDA of adverse event information.

Proposed § 230.220(g) would establish requirements concerning patient privacy. Specifically, FDA proposed that an applicant or nonapplicant should not include in reports under § 230.220 the names and addresses of individual patients; instead, the applicant or nonapplicant should assign a unique code for identification of the patient. FDA further proposed that the applicant or nonapplicant should include the name of the reporter from whom the information was received as part of the initial reporter information, even when the reporter is the patient. Proposed § 230.220(g) further states that as set forth in FDA's public information regulations in 21 CFR part 20, the Agency generally may not disclose the names of patients, individual reporters, healthcare professionals, hospitals, and geographical identifiers submitted to FDA in adverse event reports.

Before discussing the comments received regarding FDA's proposed human postmarketing safety reporting requirements, the Agency notes an additional set of revisions we are making to § 230.220 on our own initiative. We are revising proposed § 230.220(b)(1)(i) to describe more clearly the requirement that applicants and nonapplicants must submit ICSRs for serious adverse events reported to or otherwise received by the applicant or nonapplicant. This revision aligns with the requirement in § 230.210(a) for prompt review of all safety information that the applicant or nonapplicant receives or otherwise obtains from any source and is intended to help ensure

that reports of serious adverse events otherwise received (or obtained) by the applicant or nonapplicant are submitted to the Agency. Accordingly, this requirement includes, for example, serious adverse event reports received at the request of the applicant or nonapplicant (such as reports received as part of a patient support program), in addition to unsolicited communications such as reports initiated by a patient, consumer, or healthcare professional.

In the proposed rule, FDA proposed that § 314.80(g) would continue to apply to designated medical gases, and proposed § 230.220(c)(1)(i) and (ii) included cross-references to § 314.80(g). After further consideration, the Agency believes that it would be most helpful and efficient to set forth the electronic format requirements in § 230.220 rather than referencing § 314.80(g). Therefore, we have revised § 230.220(c)(1)(i) to directly include the requirement that ICSRs and ICSR attachments be in an electronic format that FDA can process, review, and archive, rather than cross-reference § 314.80(g)(1). FDA intends to issue guidance on how to provide the electronic submission (*e.g.*, method of transmission, media, file formats, preparation and organization of files). We have also revised § 230.220(c)(1)(ii) to directly state that an applicant or nonapplicant may request, in writing, a temporary waiver of the electronic reporting requirements, and that these waivers will be granted on a limited basis for good cause shown, rather than cross-reference § 314.80(g)(2). FDA intends to issue guidance on requesting a waiver of the requirements in § 230.220(c)(1)(i).

Furthermore, we have revised § 314.1(c) to state that § 314.80, as a whole, does not apply to designated medical gases. These revisions have the same regulatory effect as the language included in the proposed rule on this issue.

(Comment 52) One comment maintains that some nonapplicants may be unable to comply with the proposed ICSR requirements.

(Response 52) FDA believes it is appropriate to apply the proposed ICSR requirements to nonapplicants. We note that nonapplicants are currently required to comply with the postmarketing safety reporting requirements in § 314.80(c)(1)(i) and (ii), although nonapplicants may comply by submitting all reports of serious adverse drug experiences to the applicant. Under § 230.220, the only difference will be that nonapplicants for designated medical gases must report to FDA, rather than the applicant.

Therefore, we do not believe that revisions are necessary.

(Comment 53) Regarding the proposed exception to the ICSR requirements for serious adverse events in proposed § 230.220(b)(1)(iii), one comment recommends expanding the exception to serious injuries of patients administered oxygen, unless the applicant or nonapplicant is aware of evidence to suggest that the serious injury was caused by the administration of oxygen. The comment references the proposed “no smoking” and “no vaping” warning statements in § 201.161(a)(1)(ii) and maintains that its suggested changes would be consistent with the warning statements.

(Response 53) FDA does not agree that this change is necessary. The purpose of the exception in § 230.220(b)(1)(iii) is to address cases where a patient being administered oxygen dies and there is no reason to believe that the oxygen contributed to the patient’s death. This is very common because, as discussed in the proposed rule, oxygen is commonly administered during end-of-life care or to patients with a life-threatening disease or who are otherwise in critical condition (87 FR 31302 at 31329). This provision is not intended to address fire-related injuries.

(Comment 54) One comment expresses support for the proposed minimum data set requirements for human postmarketing safety reporting but asserts that the burden could be significant for firms. The comment maintains that, for purposes of complying with § 230.220(c)(2) or § 230.220 more generally, firms may need to hire or contract with medical professionals to evaluate potential ICSRs.

(Response 54) FDA appreciates the feedback regarding the proposed minimum data set requirements and acknowledges the concern regarding compliance burden. (Section VII below discusses the economic burden of compliance with § 230.220, including § 230.220(c)(2).) Nonetheless, FDA does not believe that firms will need to hire medical professionals. We further note that applicants (and nonapplicants by way of applicants) are currently required to submit adverse event reports to FDA under §§ 314.80 and 514.80 for human adverse drug experiences and animal adverse drug events, respectively. In both cases, this requires determining whether the event is unexpected, something that generally would not be required under § 230.220 or § 230.230. Required reports of serious adverse events must be submitted regardless of expectedness, and a causality assessment is only required in

the event there is evidence to suggest that the death of a patient being administered oxygen was caused by such administration of oxygen.

(Comment 55) Regarding the proposed requirement in § 230.220(c)(2)(iii) that event terms in ICSRs be coded using standardized medical terminology, one comment requests that the word “must” be revised to “should.” The comment also requests that the recommendation that standardized medical terminology be used should only apply if the terminology is provided by the reporter. The comment maintains that medical gas firms do not necessarily have medical expertise available to code ICSR events.

(Response 55) FDA disagrees with these suggested revisions. We do not believe that coding using standardized medical terminology is a significant burden, nor do we believe that medical professionals are needed to code an event correctly. Standardized medical terminology generally includes terms commonly used by laypersons when describing adverse events. Moreover, because the reporter may be the patient or a relative, and thus not necessarily familiar with ICSR reporting or FDA regulation more broadly, it would be unreasonable to rely on the original reporter to properly code an event. Because the use of standardized medical terminology helps FDA track, evaluate, and respond to safety signals, we do not believe the requested revisions are appropriate.

(Comment 56) FDA received one comment concerning proposed § 230.220(c)(2)(vi)(B). The comment states that applicants and nonapplicants should be required to submit a reference to published articles, rather than the articles themselves, due to copyright restrictions. As an alternative, the comment suggests that FDA could require that the article be provided upon request, subject to copyright.

In light of these recommendations, the comment also requests deletion of the provisions requiring translation of the abstract of foreign language articles and describing the requirements for submitting more than one ICSR from the same published article. The comment maintains that the burden of these requirements would be significant, as firms would need to hire medical professionals to evaluate ICSRs.

(Response 56) FDA does not agree with these suggested changes. First, it is unclear why medical professionals would be needed to help an applicant or nonapplicant comply with the requirements in § 230.220(c)(2)(vi)(B). Additionally, we note that § 314.80(d) currently requires that a 15-day Alert

report based on information in the scientific literature be accompanied by a copy of the published article.

Regarding the submission of foreign language articles, FDA recognizes that there may be additional burden associated with translating foreign language documents, but we proposed that only the abstract be translated and expect that the burden associated with this activity would be minimal. As such, we believe that requiring translation of only the abstract of a foreign language article is appropriate.

Because we are requiring in this final rule that the applicant or nonapplicant provide a copy of published articles as an attachment, we believe it is important to retain the language concerning the submission of multiple ICSRs from the same article.

(Comment 57) One comment asks that proposed § 230.220(g) be revised to create an exception to the recommendation that the applicant or nonapplicant should include the name of the reporter from whom the information was received as part of the initial reporter information, even when the reporter is the patient. Specifically, the comment requests an exception for when the reporter is the patient out of concern for disclosing the patient’s personal information.

(Response 57) FDA disagrees. As noted in the sentence that immediately follows the referenced provision in § 230.220(g), FDA acknowledges that, as addressed in the Agency’s public information regulations, FDA generally may not disclose the names of patients, individual reporters, healthcare professionals, hospitals, and geographical identifiers submitted to FDA in adverse event reports. Moreover, in situations in which the reporter is the patient, nothing in the submission necessarily makes that fact evident to the reader. Lastly, the language at issue is consistent with the current text of § 314.80(i) indicating that the name of the reporter be included even when the reporter is the patient.

(Comment 58) FDA sought comment on the Agency’s decision not to propose periodic safety reporting requirements for designated medical gases and received comments in support and in opposition. Some comments maintain that this decision is consistent with FDA’s March 2015 Compliance Program Guidance Manual 7356.002E (Ref. 3), while other comments assert that periodic safety reporting enables cumulative review of safety information.

(Response 58) After considering the comments, FDA does not believe it is necessary to include a periodic safety reporting requirement in this

rulemaking. Medical gases have historically been manufactured, labeled, and distributed in a manner different than most other drugs. Because of these differences, FDA believes that the likelihood of identifying new safety issues for medical gases is low, and that ICSRs are an adequate and efficient means of identifying any new safety issues for these products.

14. Animal Postmarketing Safety Reporting (Proposed § 230.230)

FDA proposed animal postmarketing safety reporting requirements in § 230.230. Under proposed § 230.230(a), applicants and nonapplicants must submit serious adverse events to FDA as soon as possible but no later than within 15 calendar days of first receiving the information. FDA proposed that applicants and nonapplicants must submit reports for each serious adverse event reported to the applicant or nonapplicant spontaneously (such as reports initiated by a patient, consumer, veterinarian, or other healthcare professional), regardless of whether the applicant or nonapplicant believes the events are related to the designated medical gas (proposed § 230.230(a)(1)(i)). FDA also proposed that applicants and nonapplicants must submit reports for each serious adverse event obtained from published scientific and medical literature regardless of whether the applicant or nonapplicant believes the events are related to the designated medical gas (proposed § 230.230(a)(1)(ii)). FDA proposed that adverse event reports not be required for reports of the death of an animal who was administered oxygen, unless the applicant or nonapplicant is aware of evidence to suggest that the death was caused by the administration of oxygen (proposed § 230.230(a)(1)(iii)). Under proposed § 230.230(a)(2), upon notification by FDA, applicants and nonapplicants must submit reports of adverse events associated with the use of a designated medical gas in animals that do not qualify for reporting under § 230.230(a)(1). FDA proposed under § 230.230(a)(3) that applicants and nonapplicants should not resubmit adverse event reports obtained from FDA's adverse event reporting database or forwarded to the applicant or nonapplicant by FDA.

FDA proposed in § 230.230(b) to require that adverse event reports be submitted in an electronic format that FDA can process, review, and archive, and that data provided in electronic submissions must be in conformance with the data elements in Form FDA 1932 and FDA technical documents describing transmission (proposed

§ 230.230(b)(1)). FDA further proposed that applicants and nonapplicants may request, in writing, a temporary waiver of this requirement (proposed § 230.230(b)(2)).

Under proposed § 230.230(c), FDA proposed recordkeeping requirements, including that applicants and nonapplicants maintain records of information relating to adverse event reports for 5 years, whether or not submitted to FDA (proposed § 230.230(c)(1)). FDA further proposed that such records must include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse event information that is received or otherwise obtained by the applicant or nonapplicant (proposed § 230.230(c)(2)). Lastly, FDA proposed that, upon written notice by FDA, the applicant or nonapplicant must submit any or all of these records to FDA within 5 calendar days after receipt of the notice, and the applicant or nonapplicant must permit any authorized FDA employee, at reasonable times, to access, copy, and verify these established and maintained records (proposed § 230.230(c)(3)).

Before responding to a comment we received regarding the proposed animal postmarketing safety reporting requirements, the Agency notes a revision we have made on our own initiative. We have revised § 230.230(a)(1)(i) to more clearly specify that applicants and nonapplicants must submit reports for serious adverse events reported to or otherwise received by the applicant or nonapplicant. This revision aligns § 230.230(a)(1)(i) with the requirement in § 230.210(a) for prompt review of all safety information that the applicant or nonapplicant receives or otherwise obtains from any source, and helps ensure that reports of serious adverse events otherwise received (or obtained) by the applicant or nonapplicant are submitted to the Agency. Accordingly, § 230.230(a)(1)(i) includes, for example, serious adverse event reports received at the request of the applicant or nonapplicant, in addition to unsolicited communications such as reports initiated by a patient, consumer, veterinarian, or other healthcare professional.

(Comment 59) Regarding the proposed exception to the reporting requirements for serious adverse events in proposed § 230.230(a)(1)(iii), one comment recommends expanding the exception to serious injuries of animals administered oxygen, unless the applicant or nonapplicant is aware of evidence to suggest that the serious injury was caused by the administration of oxygen. The comment references the “no

smoking” and “no vaping” warning statements in proposed § 201.161(a)(1)(ii) and maintains that the suggested changes would be consistent with the warning statements.

(Response 59) As discussed above, FDA does not agree that this change is necessary. The purpose of the exception in § 230.230(a)(1)(iii) is to address cases where an animal being administered oxygen dies and there is no reason to believe that the oxygen contributed to the animal's death. This is very common because, as discussed in the proposed rule, we expect that oxygen will be administered to animals that are in critical condition, and death is expected to be a common outcome (87 FR 31302 at 31331). This provision is not intended to address fire-related injuries.

J. Description of Part 314 Comments and FDA Response

FDA proposed carving out designated medical gases from certain provisions in part 314, either because a corresponding provision specific to designated medical gases was proposed to be added to part 230, or because the provision is not relevant to designated medical gases. Specifically, FDA proposed exempting designated medical gases from §§ 314.50 through 314.72 (concerning certain information required in NDAs); § 314.80, except paragraph (g) (concerning certain postmarketing reporting requirements); § 314.81(a) and (b)(1) and (2) (concerning certain other postmarketing reports); § 314.90 (concerning waivers); subpart C (concerning ANDAs); §§ 314.100 through 314.162 (concerning certain requirements related to FDA action on NDAs and ANDAs; subpart H (concerning accelerated approval); and subpart I (concerning approval of new drugs when human efficacy studies are not ethical or feasible). FDA received comments related to some of these proposed changes, to which we respond below.

(Comment 60) One comment requests that designated medical gases be exempted from § 314.81(b)(3), which includes requirements for submitting advertisements and promotional labeling, special reports requested by the Agency, the process for notifying FDA of a permanent discontinuance of manufacture of a drug product, and withdrawal of an approved drug product from sale. The comment asserts that, in light of the proposed revisions to the labeling requirements in part 201, it is not necessary for these provisions to apply to designated medical gases.

(Response 60) FDA does not agree that designated medical gases should be exempted from § 314.81(b)(3). The

Agency assumes that the comment is primarily focused on § 314.81(b)(3)(i), which concerns the submission of advertisements and promotional labeling, because of the comment's discussion of part 201. The other provisions in § 314.81(b)(3) are unrelated to labeling, and it is not clear how the changes FDA proposed to part 201 would address these requirements. Furthermore, we do not believe that the changes FDA is making to part 201 address the requirements in § 314.81(b)(3)(i), as part 201 does not include requirements for promotional labeling. Because FDA believes it is still important for promotional materials to be submitted to the Agency, we believe it is important to retain this provision.

(Comment 61) One comment requests that designated medical gases be exempted from § 314.81(c) because an original manufacturer will only have one application for each designated medical gas.

(Response 61) We assume the comment concerns only § 314.81(c)(1), regarding the submission of information common to more than one application, as the comment does not discuss the requirements of § 314.81(c)(2). FDA does not expect that designated medical gas applicants will have information common to more than one application. In addition, upon further consideration, FDA concludes it is not necessary to retain the requirements in § 314.81(c)(2) for designated medical gases because patient privacy information is not expected to be included in reports for designated medical gases submitted under § 314.81. For these reasons, we are revising the codified at § 314.1(c) such that § 314.81(c) no longer applies to designated medical gases.

In addition, because § 230.150 now provides for withdrawal of an application for a designated medical gas based on failure to submit reports required under § 314.81(b)(3) (see section V.I.11), it is not necessary for § 314.81(d) (which concerns withdrawal of approval for failure to make required reports) to continue to apply to designated medical gases. Accordingly, FDA has revised § 314.1(c)(3) to read "Section 314.81, except paragraph (b)(3)".

K. Part 514

FDA proposed carving out designated medical gases from provisions in part 514 (21 CFR part 514) to align with the provisions specific to designated medical gases that we proposed to add to part 230. We did not receive comments on the proposed revisions and are finalizing the provisions as

proposed with minor technical changes made on our own initiative.

VI. Effective Date

This rule is effective December 18, 2025, except for §§ 4.2, 4.3, and 4.4. The effective date for §§ 4.2, 4.3, and 4.4 will be February 2, 2026.

(Comment 62) One comment supports the proposed effective date of 18 months after publication of the final rule. The comment notes that firms will need time to update labeling information to ensure compliance with the new requirements.

(Response 62) FDA acknowledges this comment, and we believe that 18 months is an appropriate time after publication of the final rule to enable firms to comply with these requirements. However, we note that the recently published final rule "Medical Devices; Quality System Regulation Amendments" (the QSRA rule), which will become effective on February 2, 2026,⁴ amends provisions of part 4 that are further revised by this rule. To prevent any confusion that may result from multiple amendments to part 4 occurring so close in time, FDA has determined that this rule's amendments to §§ 4.2, 4.3, and 4.4 will be effective on February 2, 2026, the same date the QSRA rule becomes effective.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or

safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866, section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of \$100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities.

Because this final rule will better tailor the current good manufacturing practice requirements for medical gases and medically appropriate combinations of such gases and creates small net cost savings for small entities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The 2022 threshold after adjustment for inflation is \$177 million, using the (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

This final rule establishes, within part 213, CGMP regulations specific to medical gases. These regulations include many of the same categories of requirements as the general drug product CGMP regulations but are tailored to reflect differences in how medical gases are manufactured, packaged, labeled, stored, and distributed. This rule makes limited changes to the labeling requirements of part 201, including requiring that a "no smoking" statement, a "no vaping" statement, and graphic warning symbol be added to oxygen containers to reduce the risk of fire. This rule codifies and clarifies the process for obtaining a certification to market designated medical gases. Recommendations for how to request a certification for designated medical gases are currently included in a draft guidance. This rule makes changes to postmarketing safety reporting regulations for designated medical gases that address human and animal use and more specifically reflect

⁴ See 89 FR 7496 (February 2, 2024).

the development, manufacturing, and distribution of designated medical gases.

The costs of this final rule are primarily driven by new labeling requirements, clarification leading to firms becoming compliant with existing requirements, and added CGMP requirements, including a requirement for portable cryogenic containers to have a working gauge.

The cost savings of this final rule are primarily driven by removing or relaxing CGMP requirements that do not apply to medical gases, such as removing certain building and facility

requirements, which may streamline inspections for industry and FDA.

Table 1 summarizes the estimated benefits and costs of the final rule. The annualized benefits will range from \$0.00 million to \$7.02 million with a primary estimate of \$3.51 million over a 10-year span at a 7 percent discount rate. Annualized at a 3 percent discount rate these benefits will range from \$0.00 million to \$7.43 million with a primary estimate of \$3.72 million. The annualized costs will range from \$1.52 million to \$5.30 million with a primary estimate of \$3.24 million at a 7 percent discount rate. Annualized at a 3 percent discount rate these costs will range from

\$1.36 million to \$5.11 million with a primary estimate of \$3.07 million.

The present value of the estimated benefits will range from \$0.00 million to \$56.33 million with a primary estimate of \$28.17 million at a 7 percent discount rate and from \$0.00 million to \$59.64 million with a primary estimate of \$29.82 million at a 3 percent discount rate. The present value of the estimated costs will range from \$12.23 million to \$42.49 million with a primary estimate of \$25.96 million at a 7 percent discount rate and from \$12.98 million to \$48.72 million with a primary estimate of \$29.28 million at a 3 percent discount rate.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE
(Millions of 2022 dollars)

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							Most benefits are cost savings to industry while the remaining are cost savings for FDA due to a more streamlined inspection process.
Annualized Monetized \$millions/year	\$3.51 3.72	\$0.00 0.00	\$7.02 7.43	2022 2022	7 3	10 10	
Annualized Quantified					7 3		
Qualitative	Potential small increase in safety from a reduction in fire risk from graphic warning labels on oxygen containers; flexibility in testing of components, containers, and closures; clarifies calculations of yield requirement does not apply to medical gases; clarifies medical gas salvage is allowed under certain conditions; removes requirement that labels not be susceptible to becoming worn or detached; outlines the certification request process; and clarifies adverse event reports are generally not required for reports of the death of a patient or animal who was administered oxygen and fires associated with the administration of oxygen that do not include an adverse event experienced by the patient or animal.						
Costs:							
Annualized Monetized millions/year	3.24 3.07	1.52 1.36	5.30 5.11	2022 2022	7 3	10 10	Maintaining resumes for consultants, and potential cost of relabeling medical air containers.
Annualized Quantified					7 3		
Qualitative							
Transfers:							
Federal Annualized Monetized millions/year					7 3		
From/To	From:			To:			
Other Annualized Monetized millions/year					7 3		
From/To	From:			To:			
Effects:	State, Local or Tribal Government: None. Small Business: Not significant. Wages: None. Growth: None.						

FDA conducted a regulatory flexibility analysis of the impact of the final rule on small entities. Approximately 41 percent of domestic entities that would be affected by the

final rule are small according to Small Business Administration size standards. We estimate that the highest single year cost for a firm could be as high as 0.860 percent, while the average costs to

receipts ratio is 0.007 percent. Therefore, our analysis of the impact of the final rule on small entities suggests that small firms will not be significantly affected by the final regulation.

We received one comment directed at the preliminary regulatory impact analysis (PRIA) and a few comments on the rule that we considered to be relevant to the economic analysis. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 63) One comment maintains that entering a specific percentage of oxygen in the distribution records for each medical air cylinder is not necessary, because medical air contains a range of oxygen in nitrogen.

(Response 63) FDA agrees. We removed "medical air and" from the distribution records section to clarify. This clarification ensures no additional burden for distribution records.

(Comment 64) One comment suggests that transfilling be included in the distribution records and tracked, including which lots of gas material were added and on which date.

(Response 64) FDA declines to make this change. Including transfilling in the distribution records would be burdensome, and the tracking information might be of limited use for traceability due to the use of multiple batches and commingling.

(Comment 65) One comment states that the potential burden associated with the proposed minimum data set requirements for human postmarketing safety reporting on medical gas firms could be significant based on the number of adverse event reports received and the specific information required for individual case safety reports. The comment asserts that adverse event reporting would require all registered medical gas firms to hire or have available medical professionals or contractors to evaluate potential adverse events.

(Response 65) Adverse event reporting is already required for applicants and nonapplicants. This final rule requires nonapplicants to report adverse events directly to FDA rather than reporting to the applicant who in turn would report the adverse event to FDA. The Agency believes this will be less burdensome in the context of medical gases. Our analysis does anticipate a small increase in adverse event reporting for animals as a result of clarification of the requirements applicable to industry. However, because this is not a new requirement, we believe that the small increase is an accurate estimate of the additional burden for adverse event reports.

We do not anticipate an additional burden per adverse event report as a result of the minimum data set

requirements established in the final rule. Collection of the minimum data set is already included in FDA's July 2009 guidance for industry "Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application," and the March 2001 draft guidance for industry "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines" (Refs. 4 and 5), and is industry practice.

FDA does not believe that firms will need to hire medical professionals. Reporters are not required to determine causality but only to report that an adverse event did occur. Additionally, adverse event reporting is not a new requirement.

(Comment 66) One comment maintains that the requirements do not reflect current industry practice and there may be additional economic burden on the industry that is not included in FDA's summary.

(Response 66) We appreciate the comment, but we believe we have sufficiently estimated all direct additional costs for new requirements not determined to be de minimis. We also acknowledged additional potential costs and possible sensitivities in the sensitivity analysis of the PRIA.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 6) and at <https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria>.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h), (j), and (k) 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.

IX. Paperwork Reduction Act of 1995

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

completing and reviewing each collection of information.

Title: Information Collection for Rulemaking of Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases.

Description: This rulemaking is amending existing regulations and establishing new regulatory requirements pertaining to medical gases.

Description of Respondents: Respondents to this information collection are entities who manufacture, process, pack, label, or distribute certain medical gases.

1. Product Jurisdiction and Combination Products; OMB Control No. 0910–0523—Revision

FDA recognizes that some medical gases are marketed as part of a combination product. For example, a medical gas may be marketed with a device constituent part (for example, a portable liquid oxygen unit or a pressure regulator). Combination products are subject to information collection provisions found in parts 3 and 4, which prescribe content and format requirements associated with marketing applications, together with applicable recordkeeping and reporting requirements.

FDA is revising provisions in part 4 to account for combination products that contain a medical gas, as FDA is requiring medical gases to be subject to new part 213, and to clarify (where appropriate) applicable medical gases requirements throughout part 4. We believe that the new regulations impose no new burden associated with information collection currently approved under OMB control number 0910–0523.

2. Labeling Requirements for Prescription Drugs; OMB Control No. 0910–0572—Revision

Regulations in part 201 govern the statement of ingredients and declaration of net quantity of contents with regard to prescription drug product labeling.

The new regulations require that firms identify bulk or transport containers with the name of the product contained therein and that containers be accompanied by documentation that identifies the product as meeting applicable compendial standards. Bulk or transport containers are excluded from the definition of final use containers. Because these large containers are removed from the point of care and we do not expect that patients and healthcare practitioners

will use them directly to administer a designated medical gas, FDA does not believe that firms' bulk or transport containers need to bear the information required under § 201.161(a). However, to prevent mix-ups, it is essential that the identity of the gas inside such containers is evident to individuals who handle and transport the containers. FDA expects that these requirements will help prevent mix-ups and ensure that recipients of medical gases in bulk or transport containers are provided information indicating that such gases meet applicable compendial standards.

We estimate that 1,696 firms will label 4,000 containers and anticipate firms will expend 6 minutes (0.1 hours) to identify the containers with the name of the product and place documentation that identifies the product as meeting applicable compendial standards, totaling 400 hours annually.

Section 201.328(d) provides that the owner of a designated medical gas container or a container of a medically appropriate combination of designated medical gases may be identified on the container. This statement may appear on a separate sticker or decal on the container (that is, it need not be contiguous with other labeling on the container), but if the container owner is not the manufacturer, packer, or distributor of the gas, that information shall be clearly stated. FDA recognizes the complex distribution system for designated medical gases and medically appropriate combinations of designated medical gases and the importance of each entity in the distribution chain being clearly identified so that patients and healthcare professionals can contact the appropriate entity if necessary. We intend for this provision to help ensure that appropriate entities can be contacted about quality issues or

adverse events. In addition, the labeling requirement facilitates the return of cylinders to owners who may not also be medical gas manufacturers. FDA believes that including the container owner's information will not cause the container owner to be a "relabeler" for purposes of FDA's registration and listing requirements.

We estimate that 1,696 firms will identify on a designated medical gas container or a container of a medically appropriate combination of designated medical gases the name of the container owner who may not also be the manufacturer, packer, or distributor of the gas. We estimate firms would include this label on 4,000 containers and will expend 6 minutes (0.1 hours) to perform this activity, totaling 400 hours annually.

We estimate the burden of the information collection as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity; 21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (hours)	Total hours
Labeling of bulk or transport containers used to hold designated medical gases; § 201.161(b).	1,696	2.36	4,000	0.1 (6 minutes)	400
Identify the owner of a designated medical gas container or a container of a medically appropriate combination of designated medical gases on the container label. If the container owner is not the manufacturer, packer, or distributor of the gas, identify that information on the label; § 201.328(d).	1,696	2.36	4,000	0.1 (6 minutes)	400
Total			8,000		800

¹ There are no capital costs or operating and maintenance costs associated with the information collection.

3. Current Good Manufacturing Practice for Medical Gases; OMB Control No. 0910–0906

FDA is establishing new part 213 setting forth CGMP requirements applicable to medical gases. Part 213 applies to firms that manufacture a medical gas and establishes requirements applicable to firms that subsequently combine, commingle, refill, or distribute medical gases.

The regulations also include recordkeeping requirements pertaining to personnel qualifications and responsibilities of persons who are engaged in the manufacturing, processing, packing, or holding of a medical gas.

Provisions under § 213.42(c) include recordkeeping to document the development and implementation of written procedures to ensure that firms maintain a clean condition for any building used to manufacture, process, pack, or hold a medical gas so as to ensure the safety, identity, strength, quality, and purity of the gas. Firms also need to develop written procedures that apply to recordkeeping for cleaning and

maintaining buildings. Based on available data, we estimate 1,696 firms will each develop and implement written procedures to maintain and clean buildings. We estimate it will take 13 hours to perform this activity, totaling 22,048 hours initially. Firms will also update these written procedures annually. Based on available data, we estimate 1,696 firms would each update written procedures to maintain and clean buildings and that it will take 39 minutes (0.65 hours) to perform this activity, totaling 1,102 hours annually.

Provisions under § 213.100 include development and maintenance of written procedures to ensure that production and process controls are designed to assure that medical gases have the appropriate qualities (identity, strength, quality, and purity) they are purported to possess. Based on available data, we estimate 1,696 firms will each develop and implement written procedures. We estimate it will take 13 hours to perform this activity, totaling 22,048 hours. Firms will also update these written procedures annually.

Based on available data, we estimate 1,696 firms would each update written procedures to maintain and clean buildings and that it will take 39 minutes (0.65 hours) to perform this activity, totaling 1,102 hours annually.

In concert with §§ 213.42 and 213.80, under § 213.150, firms are required to establish and follow written procedures regarding warehousing and distribution of medical gases, including procedures for the quarantine of such gases before release by the quality unit. The distribution procedures are also required to include a system by which the distribution of each lot can be readily determined, to facilitate any necessary recalls. Based on available data, we estimate 1,696 firms will each develop and implement written procedures for warehousing and distribution of medical gases. We anticipate it will take approximately 13 hours to perform this activity totaling 22,048 hours initially. Firms will also update these written procedures annually. Based on available data, we estimate 1,696 firms would each update these written procedures annually and

that it will take 39 minutes (0.65 hours) to perform this activity, totaling 1,102 hours annually.

Similarly, under § 213.208, firms are required to develop and implement written procedures for the holding, testing, and use of salvaged medical gases. Based on available data, we estimate 1,696 firms will develop and implement written procedures for the holding, testing, and use of salvaged medical gases. We estimate it will take 13 hours for firms to perform this activity, totaling 22,048 hours. In addition, based on available data, we estimate that 1,696 firms will update their written procedures (1 procedure each) for the holding, testing, and use of salvaged medical gases. We estimate it takes 0.65 hours to perform the updates, totaling 1,102 hours annually.

The regulations under § 213.25 provide that employee training be included in the firm operations. Recordkeeping would be established to demonstrate that qualified individuals conduct training on a continuing basis and with sufficient frequency to allow employees to remain familiar with applicable requirements. Based on available data, we estimate that 1,696 firms will prepare written documentation pertaining to employee training. We estimate that 10 employees per firm will create 16,960 records (10 records per firm) and that it will take 5 minutes (0.083 hours) to prepare each record, for a total of 1,408 hours annually.

Under § 213.34, records demonstrating that consultants have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained will be required. Based on available data, we estimate that 1,696 firms will maintain 571 records of consultants' education, training, and experience, or any combination thereof and expect that it will take 30 minutes (0.5 hours) to perform this activity, totaling 286 hours annually.

In addition, under § 213.67(c), we estimate that 1,696 firms will maintain 74,230 records of equipment maintenance and cleaning and anticipate it will take 15 minutes (0.25 hours) to perform this activity, totaling 18,557 hours annually. We also anticipate that, under § 213.68(d), 1,696 firms will develop and implement 11,420 written procedures for automatic, mechanical, and electronic equipment and that firms will expend 15 minutes (0.25 hours) to perform this activity, totaling 2,855 hours annually.

As provided in the new regulation under § 213.82, once a shipment of an incoming designated medical gas is

received, the firm will perform full compendial testing on the gas and record the results or verify and record that a signed certificate of analysis accompanies the shipment. If an incoming designated medical gas is obtained from a supplier other than the original manufacturer, the shipment would also need to include specific information. To ensure the reliability of appropriate assessment and testing, firms will be required to establish and maintain a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures. We estimate that 1,380 firms would verify and document records upon receipt of a designated medical gas. We anticipate that firms will maintain 575,460 records (417 records each (1 delivery per week of oxygen for 1 year (52 deliveries) plus 1 delivery per day of nitrogen for 1 year (365 deliveries))). We further estimate firms will expend 15 minutes (0.25 hours) each (104 hours in total for each firm) to perform this activity, totaling approximately 143,865 hours annually.

Section 213.89 requires that firms identify and control rejected components, containers, and closures under a quarantine system designed to prevent their use in operations for which they are unsuitable. Section 213.89 also applies to incoming designated medical gases. Quarantine systems would not need to include physical quarantining because other methods can adequately ensure that unsuitable products are not used. We estimate that 1,380 downstream firms would need to assess and document 33.4 million medical gas components, containers, and closures annually. We estimate that firms would reject 0 to 0.1 percent of all containers. These firms will maintain a total of 33,400 records of rejected components and we estimate they will expend 5 minutes (0.083 hours) to perform this activity, totaling 2,772 hours annually.

Under § 213.122(c), firms need to maintain records for each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected. Based on available data, we estimate 1,696 firms will prepare 74,230 records to document each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected. We estimate it will take 15 minutes (0.25 hours) to perform this activity, totaling 18,558 hours annually.

Under § 213.130(e), firms are required to document results of inspections concerning packaging and labeling in the batch production records. Based on

available data, we estimate 1,696 firms will document results of inspections in the batch production records in approximately 114,200 records. We estimate it will take 15 minutes (0.25 hours) per record to perform this activity, totaling 28,550 hours annually.

Under § 213.180(d), firms are required to maintain written records so that data therein can be used for evaluating, at least annually, the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures. Based on available data, we estimate 1,696 firms will prepare 457 records. We estimate it will take 15 minutes (0.25 hours) to perform this activity, totaling 114 hours annually.

Under § 213.182, firms are required to maintain a written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use. Based on available data, we estimate 1,696 firms will prepare 2,969 records documenting major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use. We estimate it will take 10 minutes (0.16 hours) to perform this activity, totaling 475 hours annually.

Under § 213.184, firms are required to maintain certain records concerning components, medical gas containers and closures, and labeling. We estimate 1,696 firms will prepare 4,454 records for components, medical gas containers and closures, and labeling. We estimate firms will expend 19.8 minutes (0.33 hours) to perform this activity, totaling 1,470 hours annually.

Under § 213.186, to ensure uniformity from batch to batch, firms are required to prepare, date, and sign master production and control records for each medical gas. We estimate 1,696 firms will prepare and maintain approximately 22,840 master production and control records and estimate that it will require 2 hours for firms to perform this activity, totaling 45,680 hours annually.

Under § 213.189, firms are required to maintain batch production and control records. These records would need to include documentation that the firm has accomplished each significant step in the manufacturing, processing, packing, or holding of the medical gas produced, including in-process and laboratory tests. We estimate 1,696 firms will prepare and maintain 37,115 batch production and control records. We anticipate it will require 78 minutes (1.3 hours) for firms to perform this activity, totaling 48,250 hours annually.

Section 213.192(a) describes production record review. Per paragraph (a), firms are required to maintain a written record of any investigation of errors, unexplained discrepancies in production, or failure of a batch or any component of a batch to meet specifications and include the conclusions and followup. We estimate 1,696 firms will prepare and maintain 4,568 laboratory records and that it will require 1 hour for firms to perform this activity, totaling 4,568 hours annually.

Under § 213.194(b) through (e), firms are required to maintain certain laboratory records. Based on available data, we estimate 1,696 firms will prepare and maintain 57,100 laboratory records and estimate it will require 30 minutes (0.5 hours) for firms to perform this activity, totaling 28,550 hours annually.

Section 213.196 describes certain requirements for distribution records. Based on available data, we estimate 1,696 firms will prepare and maintain 57,100 distribution records and estimate

it will require 15 minutes (0.25 hours) for firms to perform this activity, totaling 14,275 hours annually.

Under § 213.198, firms are required to maintain written records of each complaint regarding medical gases. We estimate 1,696 firms will maintain 11,420 records of complaints. We estimate it will require approximately 1 hour for firms to perform this activity, totaling 11,420 hours annually.

We estimate the burden of the information collection as follows:

TABLE 3—ESTIMATED ONE-TIME RECORDKEEPING BURDEN ¹

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
New Start Up SOP—Cleaning, Maintenance and Operation; § 213.42 ...	1,696	1	1,696	13	22,048
New Start Up SOP—Medical Gases Production and Process Controls; § 213.100	1,696	1	1,696	13	22,048
New Start Up SOP—Warehousing and Distribution; § 213.150	1,696	1	1,696	13	22,048
New Start Up SOP—Salvaging of Medical Gases; § 213.208	1,696	1	1,696	13	22,048
Total			6,784		88,192

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
SOP Maintenance—cleaning, maintenance, and operation; § 213.42	1,696	1	1,696	0.65 (39 minutes)	1,102
SOP Maintenance—Medical Gases Production and Process Controls; § 213.100	1,696	1	1,696	0.65 (39 minutes)	1,102
SOP Maintenance—salvaging of medical gases; § 213.208	1,696	1	1,696	0.65 (39 minutes)	1,102
SOP Maintenance—Medical Gases Warehousing and distribution; § 213.150	1,696	1	1,696	0.65 (39 minutes)	1,102
Documentation of completion of training; § 213.25(a)	1,696	10	16,960	0.083 (5 minutes)	1,408
Consultants' records of sufficient education, training, and experience, or any combination thereof; § 213.34	1,696	0.34	571	0.5 (30 minutes) ...	286
Firms' records of equipment maintenance and cleaning; § 213.67(c)	1,696	43.77	74,230	0.25 (15 minutes)	18,558
Maintain records for modifications to automatic, mechanical, and electronic equipment; § 213.68(d)	1,696	6.73	11,420	0.25 (15 minutes)	2,855
Receipt and storage of incoming designated medical gases; § 213.82(a)	1,380	417	575,460	0.25 (15 minutes)	143,865
Records of rejected components; § 213.89	1,380	24.2	33,400	0.083 (5 minutes)	2,772
Maintain records for each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected; § 213.122(c)	1,696	43.77	74,230	0.25 (15 minutes)	18,558
Document results of inspections in the batch production records; § 213.130(e)	1,696	67.33	114,200	0.25 (15 minutes)	28,550
Maintain written records so that data therein can be used for evaluating, at least annually, the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures; § 213.180(d)	1,696	0.27	457	0.25 (15 minutes)	114
Maintain record of equipment cleaning and use log maintenance; § 213.182 ..	1,696	1.76	2,969	0.16 (10 minutes)	475
Maintain records for components, medical gas containers and closures, and labeling; § 213.184	1,696	2.63	4,454	0.33 (19.8 minutes)	1,470
Maintain master production and control records; § 213.186	1,696	13.47	22,840	2 hours	45,680
Maintain batch production and control records; § 213.189	1,696	21.88	37,115	1.3 hours	48,250
Maintain record of the investigation; § 213.192(a)	1,696	2.69	4,568	1 hour	4,568
Maintain laboratory records; § 213.194(b) through (e)	1,696	33.67	57,100	0.5 (30 minutes) ...	28,550
Maintain distribution records; § 213.196	1,696	33.67	57,100	0.25 (15 minutes)	14,275
Maintain written records of each complaint; § 213.198	1,696	6.73	11,420	1 hour	11,420
Total			1,105,278		376,061

¹ There are no capital costs or operating and maintenance costs associated with the information collection.

4. Certification and Postmarketing Reporting for Designated Medical Gases; OMB Control No. 0910–0906

Section 230.50 establishes the general requirements for requesting a designated medical gas certification for all

submission types and outlines the information that must be included in certification request submissions (Form FDA 3864). The new regulations require applicants to include facility information in certification requests. Such information would include, among

others, name and address of the original manufacturing facility or facilities where the gas is or will be manufactured.

Section 230.50 also provides for the submission of additional information if FDA deems it appropriate to determine

whether a medical gas meets the definition of a designated medical gas. This information would generally be in the form of a written request by FDA for the additional information. We estimate that five respondents will submit a total of five certification requests annually, including certification forms for original and resubmissions, and each certification request will require 3 hours to prepare and submit, totaling 15 hours annually.

Under § 230.65, applicants will be allowed to withdraw a certification request that has not been deemed granted. An applicant may notify FDA that it withdraws its certification request at any time before the certification is granted. Upon an applicant's withdrawal of a certification request, FDA will retain the certification request, and if the applicant requests a copy via a Freedom of Information Act request, FDA will provide it pursuant to the fee schedule in FDA's public information regulations. Since the passage of the Food and Drug Administration Safety and Innovation Act, FDA has received several certification requests but has not received any withdrawal requests. FDA has no other data on which to provide a burden estimate. Therefore, the Agency does not expect to receive withdrawal requests except in exceedingly rare situations.

Section 230.70 requires applicants to submit a supplement if any information in the granted certification has changed. The regulation prescribes information to be included in a supplement to the marketing application. We estimate four applicants will submit supplements, and each submission will require 3 hours to prepare, totaling 12 hours annually.

Section 230.72 governs changes in ownership of a granted certification. An example of when a change in ownership could occur is during a merger or acquisition. Upon a change in ownership, the regulations require that both the new and previous owner notify FDA. Based on related submissions received by FDA over the last few years and averaged accordingly, we estimate two respondents will submit four letters or other supporting documents, requiring 2 hours to complete each of the tasks, totaling 8 hours annually.

To assist respondents with the requirements associated with § 230.80 (annual reports), we are developing an annual report form (Form FDA 5025). We estimate that 57 applicants will submit 123 annual reports to FDA. We estimate firms will expend 2 hours per report to perform this activity, totaling 246 hours annually.

Our estimate associated with requirements in § 230.205 for field alert reporting for designated medical gases is based on our prior experience with similar reports that FDA receives. We estimate that FDA will receive a total of 3 field alert reports from the pool of 1,380 applicants and nonapplicants. We anticipate the respondents will each expend approximately 8 hours to perform this activity, totaling 24 hours annually.

Section 230.210 requires that applicants and nonapplicants promptly review all safety information that the applicant or nonapplicant receives or otherwise obtains from any source (including both foreign and domestic sources). Applicants and nonapplicants will generate reports from review of the safety information and will submit the reports under §§ 230.220 and 230.230. As described in § 230.220(a) through (d), firms are required to submit ICSRs associated with the use of a designated medical gas in humans.

Section 230.220 contains requirements for submission of ICSRs associated with the use of a designated medical gas in humans. Under § 230.220(a)(1), applicants and nonapplicants are required to submit each ICSR as soon as possible, but no later than 15 calendar days from the date the applicant or nonapplicant meets the reporting criteria under § 230.220(b) and acquires a minimum data set for an ICSR for that adverse event.

Under § 230.220(a)(3), applicants and nonapplicants will submit new information they receive or otherwise obtain about an ICSR previously submitted to FDA. The regulation prescribes reporting schedules to ensure FDA becomes aware of any new information about the adverse event in a timely manner.

Section 230.220(b) describes the types of ICSRs that applicants and nonapplicants are required to report for human use. Under § 230.220(b)(1), applicants and nonapplicants would be required to submit ICSRs for serious adverse events. Under § 230.220(b)(2), upon notification by FDA, an applicant is required to report to FDA, in a timeframe established by FDA, ICSRs for any adverse events that would not be required under § 230.220(b)(1).

Section 230.220(c) and (d) include additional requirements for the content and format of human designated medical gas ICSRs. Under § 230.220(a) through (d), we estimate that 1,430 applicants and nonapplicants will submit to FDA 172 ICSRs annually. We previously estimated it would take 6 hours for respondents to perform this

activity. Upon considering recent estimates for safety reporting that describe a lower time burden (Ref. 6), we estimate it will be less burdensome than we previously expected in the proposed rule for designated medical gas applicants and nonapplicants to comply with ICSR reporting requirements. Moreover, we do not anticipate that safety reporting compliance will be more burdensome for human reports than for animal reports. Therefore, we estimate that it will take 4 hours for respondents to perform this activity, totaling 688 hours annually.

Under § 230.230(a)(1), an applicant or nonapplicant will submit serious adverse events related to the use of a designated medical gas in animals to FDA as soon as possible but no later than 15 calendar days from first receiving the information. The applicant or nonapplicant will submit the report to FDA in electronic format as described under § 230.230(b)(1), unless the applicant or nonapplicant obtains a waiver under § 230.230(b)(2) or FDA requests the report in an alternate format.

Under § 230.230(a)(2), upon notification by FDA, applicants and nonapplicants will submit reports of adverse events associated with the use of a designated medical gas in animals that do not qualify for reporting under § 230.230(a)(1). The notice will specify the adverse events to be reported and the reason for requiring the reports. We anticipate that eight records will be submitted per year. We previously estimated that it will take approximately 5 hours to perform this activity. Upon considering recent estimates for safety reporting that describe a lower time burden (Ref. 6; see also 84 FR 24798, May 29, 2019), we estimate it will be less burdensome than we previously expected in the proposed rule for designated medical gas applicants and nonapplicants to comply with adverse event reporting requirements. Therefore, we estimate that it will take 4 hours for respondents to perform this activity, totaling 32 hours annually.

Under § 230.230(b)(2), an applicant or nonapplicant may request, in writing, a temporary waiver of the electronic submission requirements under § 230.230(b)(1). An applicant or nonapplicant will provide the initial request by telephone or email to Center for Veterinary Medicine's (CVM's) Division of Pharmacovigilance and Surveillance, with prompt written followup submitted as a letter to the granted certification or certifications. FDA will grant waivers on a limited basis for good cause shown. If FDA

grants a waiver, the applicant or nonapplicant is required to comply with the conditions for reporting specified by

FDA upon granting the waiver. We estimate eight waiver requests will be submitted annually and anticipate it

will take 5 hours to prepare and submit the request totaling 40 hours annually.

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Submission of certification requests and certification form (Form FDA 3864) that includes any resubmissions and amendments to pending requests; § 230.50	5	1	5	3	15
Submission of supplements to certification requests and other changes; § 230.70	4	1	4	3	12
Submission of requests to transfer ownership of certification, including new address and the owner's submission of any change in the conditions in the granted certification; § 230.72	2	2	4	2	8
Submission of annual reports (Form FDA 5025); § 230.80	57	2.15	123	2	246
Submission of field alert reports; § 230.205	1,380	0.002	3	8	24
CDER: Submission of ICSRs (§ 230.220(a) through (d))	1,430	0.12	172	4	688
CVM: Submission of adverse event reports; § 230.230(a)	1,696	0.0044	8	4	32
CVM: Waiver request from electronic submission requirement; § 230.230(b)	1,696	0.0044	8	5	40
Total			327		1,065

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

Section 230.220(e) prescribes requirements for keeping records pertaining to human designated medical gas adverse events. For a period of 10 years from the initial receipt of information, each applicant or nonapplicant is required to maintain records of information relating to adverse events, whether or not submitted to FDA. These records must include raw data, correspondence, and any other information relating to evaluating and reporting adverse event information that is received or otherwise obtained by the applicant or nonapplicant. Upon written notice by FDA, the applicant or nonapplicant will submit any and all of these records to FDA within 5 calendar days after receipt of the notice. The applicant or nonapplicant will permit any

authorized FDA employee, at reasonable times, to access, copy, and verify the established and maintained records described in this section. We anticipate that 1,430 manufacturers will create 686 records pertaining to human designated medical gas requirements and it will take approximately 16 hours to perform this activity, totaling 10,976 hours annually.

Section 230.230(c) prescribes requirements for records to be maintained for animal designated medical gas adverse events. For a period of 5 years from the initial receipt of information, each applicant or nonapplicant is required to maintain records of information relating to adverse events, whether or not submitted to FDA. These records must include raw data, correspondence, and

any other information relating to evaluating and reporting adverse event information that is received or otherwise obtained by the applicant or nonapplicant. Upon written notice by FDA, the applicant or nonapplicant will submit any and all of these records to FDA within 5 calendar days after receipt of the notice. The applicant or nonapplicant will permit any authorized FDA employee, at reasonable times, to access, copy, and verify the established and maintained records described in this section. We anticipate that 1,696 manufacturers will create eight records pertaining to animal designated medical gas requirements and it will take approximately 5 hours to perform this activity, totaling 40 hours annually.

TABLE 6—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity; 21 CFR section	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per response (hours)	Total hours
CDER's maintenance of records for human designated medical gas ICSR requirements; § 230.220(e)	1,430	0.48	686	16	10,976
CVM's recordkeeping requirements related to adverse event reports; § 230.230(c)	1,696	0.0044	8	5	40
Total			694		11,016

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

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a

collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National

Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

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

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at <https://www.regulations.gov>. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA draft guidance for industry "Certification Process for Designated Medical Gases," November 2015, available at <https://www.fda.gov/media/85013/download>.
2. Kreiter, P., T.G. Bizjak, and R.L. Friedman, "Preventing Patients From Receiving Leaking or Empty Containers of Medical Gas: A Review of Inspection Findings From 2003 to 2021," CDER Office of Manufacturing Quality, December 2021, U.S. Food and Drug Administration.
3. FDA, Compliance Program Guidance Manual 7356.002E, "Compressed Medical Gases," March 15, 2015, available at <https://www.fda.gov/media/75194/download>.
4. FDA guidance for industry "Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application," July 2009; available at <https://www.fda.gov/media/77193/download>.
5. FDA draft guidance for industry "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines," March 2001, available at <https://www.fda.gov/media/73593/download>.
6. FDA, Final Regulatory Impact Analysis: Current Good Manufacturing Practice, Certification, Postmarketing Safety Reporting, and Labeling Requirements for Certain Medical Gases, available at <https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria> <https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria> <https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria>

[fda/economics-staff/regulatory-impact-analyses-ria](https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria).

The following standards appear in the amendatory text of this document and were approved for § 4.4 in the final rule published at 89 FR 7496 (which will be effective February 2, 2026): ISO 13485 and ISO 9000. No changes are proposed to the incorporation by reference (IBR) material.

List of Subjects

21 CFR Part 4

Biologics, Drugs, Human cells and tissue-based products, Incorporation by reference, Medical devices.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 210

Drugs, Packaging and containers.

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 213

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 230

Administrative practice and procedure, Animal drugs, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 314

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

21 CFR Part 514

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

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended as follows:

PART 4—REGULATION OF COMBINATION PRODUCTS

- 1. The authority citation for part 4 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 360l, 360hh–360ss, 360aaa–360bbb, 360ddd, 360ddd–1, 371(a), 372–374, 379e, 381, 383, 394; 42 U.S.C. 216, 262, 263a, 264, 271.

- 2. Effective February 2, 2026, revise § 4.2 to read as follows:

§ 4.2 How does FDA define key terms and phrases in this subpart?

The terms listed in this section have the following meanings for purposes of this subpart:

Biological product has the meaning set forth in § 3.2(d) of this chapter. A biological product also meets the definitions of either a drug or device as these terms are defined under this section.

Combination product has the meaning set forth in § 3.2(e) of this chapter.

Constituent part is a drug, device, or biological product that is part of a combination product.

Co-packaged combination product has the meaning set forth in § 3.2(e)(2) of this chapter.

Current good manufacturing practice operating system means the operating system within an establishment that is designed and implemented to address and meet the current good manufacturing practice requirements for a combination product.

Current good manufacturing practice requirements means the requirements set forth under § 4.3(a) through (e).

Device has the meaning set forth in § 3.2(f) of this chapter. A device that is a constituent part of a combination product is considered a finished device within the meaning of the Quality Management System Regulation (QMSR).

Drug has the meaning set forth in § 3.2(g) of this chapter and includes medical gas as defined in section 575(2) of the Federal Food, Drug, and Cosmetic Act. Medical gas includes designated medical gases as defined in section 575(1) of the Federal Food, Drug, and Cosmetic Act and medical gases approved under section 505 of the Federal Food, Drug, and Cosmetic Act. A drug other than a medical gas that is a constituent part of a combination product is considered a drug product within the meaning of the drug current good manufacturing practice (CGMP) requirements. A drug that is a medical gas that is a constituent part of a combination product is considered a medical gas within the meaning of the medical gas CGMP requirements.

Drug CGMP requirements refers to the current good manufacturing practice regulations set forth in parts 210 and 211 of this chapter.

HCT/PS refers to human cell, tissue, and cellular and tissue-based products,

as defined in § 1271.3(d) of this chapter. An HCT/P that is not regulated solely under section 361 of the Public Health Service Act may be a constituent part of a combination product. Such an HCT/P is subject to part 1271 of this chapter and is also regulated as a drug, device, and/or biological product.

Manufacture includes, but is not limited to, designing, fabricating, assembling, filling, processing, testing, labeling, packaging, repackaging, holding, and storage.

Medical gas CGMP requirements refers to the current good manufacturing practice regulations set forth in part 213 of this chapter.

QMSR refers to the requirements under part 820 of this chapter.

Single-entity combination product has the meaning set forth in § 3.2(e)(1) of this chapter.

Type of constituent part refers to the category of the constituent part, which can be either a biological product, a device, or a drug, as these terms are defined under this section.

■ 3. Effective February 2, 2026, amend § 4.3 by revising paragraphs (a), (c), and (d) and adding paragraph (e) to read as follows:

§ 4.3 What current good manufacturing practice requirements apply to my combination product?

* * * * *

(a) The current good manufacturing practice requirements in parts 210 and 211 of this chapter apply to a combination product that includes a drug constituent part other than a medical gas;

* * * * *

(c) The current good manufacturing practice requirements among the requirements (including standards) for biological products in parts 600 through 680 of this chapter apply to a combination product that includes a biological product constituent part to which those requirements would apply if that constituent part were not part of a combination product;

(d) The current good tissue practice requirements including donor eligibility requirements for HCT/Ps in part 1271 of this chapter apply to a combination product that includes an HCT/P; and

(e) The current good manufacturing practice requirements in part 213 of this chapter apply to a combination product

that includes a drug constituent part that is a medical gas.

■ 4. Effective February 2, 2026, amend § 4.4 by:

■ a. Revising paragraphs (b)(1) introductory text and (b)(2) introductory text;

■ b. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5), respectively;

■ c. Adding new paragraph (b)(3); and

■ d. Revising paragraph (e).

The revisions and addition read as follows:

§ 4.4 How can I comply with these current good manufacturing practice requirements for a co-packaged or single-entity combination product?

* * * * *

(b) * * *

(1) If the combination product includes a device constituent part and a drug constituent part, and the current good manufacturing practice operating system has been shown to comply with the drug CGMP requirements or the medical gas CGMP requirements, as applicable, the following clauses of ISO 13485 (together with the definitions in Clause 3 of ISO 9000), which is incorporated by reference into the QMSR under § 820.7 of this chapter, and certain other provisions within the QMSR must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the QMSR need be made:

* * * * *

(2) If the combination product includes a device constituent part and a drug constituent part other than a medical gas, and the current good manufacturing practice operating system has been shown to comply with the QMSR requirements for devices, the following provisions of the drug CGMP requirements must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the drug CGMP requirements need be made:

* * * * *

(3) If the combination product includes a device constituent part and a drug constituent part that is a medical gas, and the current good manufacturing practice operating system has been shown to comply with the QMSR regulation, the following provisions of

the medical gas CGMP requirements must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the medical gas CGMP requirements need be made:

(i) Section 213.84 of this chapter. Testing and approval or rejection of components, containers, and closures.

(ii) Section 213.94 of this chapter. Medical gas containers and closures.

(iii) Section 213.122 of this chapter. Materials examination and usage criteria.

(iv) Section 213.165 of this chapter. Testing and release for distribution.

(v) Section 213.166 of this chapter. Stability testing and expiration dating for medical gases marketed under applications submitted under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act.

(vi) Section 213.204 of this chapter. Returned medical gases.

(vii) Section 213.208 of this chapter. Salvaging of medical gases.

* * * * *

(e) The requirements set forth in this subpart and in parts 210, 211, 213, 820, 600 through 680, and 1271 of this chapter listed in § 4.3, supplement, and do not supersede, each other unless the regulations explicitly provide otherwise. In the event of a conflict between regulations applicable under this subpart to combination products, including their constituent parts, the regulations most specifically applicable to the constituent part in question shall supersede the more general.

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 5. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 6. Amend § 16.1 by revising paragraph (b)(2) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) The regulatory provisions are as follows:

TABLE 1 TO PARAGRAPH (b)(2)

Sections 1.634 and 1.664, relating to revocation of recognition of an accreditation body and withdrawal of accreditation of third-party certification bodies that conduct food safety audits of eligible entities in the food import supply chain and issue food and facility certifications.

Section 1.1173, relating to the revocation of recognition of an accreditation body, and the disqualification of a laboratory, with respect to food testing conducted under part 1, subpart R of this chapter.

TABLE 1 TO PARAGRAPH (b)(2)—Continued

Section 1.1174, relating to the issuance of a directed food laboratory order by FDA pursuant to § 1.1108.

Section 56.121(a), relating to disqualifying an institutional review board or an institution.

Section 58.204(b), relating to disqualifying a testing facility.

Section 71.37(a), relating to use of food containing a color additive.

Section 80.31(b), relating to refusal to certify a batch of a color additive.

Section 80.34(b), relating to suspension of certification service for a color additive.

Section 99.401(c), relating to a due diligence determination concerning the conduct of studies necessary for a supplemental application for a new use of a drug or device.

Sections 112.201 through 112.213, (see part 112, subpart R of this chapter), relating to withdrawal of a qualified exemption.

Sections 117.251 through 117.287 (part 117, subpart E of this chapter), relating to withdrawal of a qualified facility exemption.

Section 130.17(1), relating to a temporary permit to vary from a food standard.

Section 170.17(b), relating to use of food containing an investigational food additive.

Section 202.1(j)(5), relating to approval of prescription drug advertisements.

Section 230.150(b), relating to revocation of the grant of a certification for a designated medical gas.

Section 312.70, relating to whether an investigator is eligible to receive test articles under part 312 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

Sections 312.70(d) and 312.44, relating to termination of an IND for a sponsor.

Section 312.160(b), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

Section 507.60 through 507.85 (part 507, subpart D of this chapter) relating to withdrawal of a qualified facility exemption.

Section 511.1(b)(5), relating to use of food containing an investigational new animal drug.

Section 511.1(c)(1), relating to whether an investigator is eligible to receive test articles under part 511 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products; and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

Section 511.1(c)(4) and (d), relating to termination of an INAD for a sponsor.

Section 812.119, relating to whether an investigator is eligible to receive test articles under part 812 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

Section 814.46(c) relating to withdrawal of approval of a device premarket approval application.

Section 822.7(a)(3), relating to an order to conduct postmarket surveillance of a medical device under section 522 of the act.

Section 830.130, relating to suspension or revocation of the accreditation of an issuing agency.

Section 895.30(c), regarding a proposed regulation to ban a medical device with a special effective date.

Section 900.7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.

Section 900.14, relating to suspension or revocation of a mammography certificate.

Section 900.25, relating to approval or withdrawal of approval of certification agencies.

Section 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.

Section 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.

Section 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.

Section 1107.1(d), relating to rescission of an exemption from the requirement of demonstrating substantial equivalence for a tobacco product.

Section 1107.50, relating to rescission of an order finding a tobacco product substantially equivalent.

Section 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.

Section 1270.43(e), relating to the retention, recall, and destruction of human tissue.

Section 1271.440(e) relating to the retention, recall, and destruction of human cells, tissues, and cellular and tissue-based products (HCT/PS), and/or the cessation of manufacturing HCT/PS.

PART 201—LABELING

■ 7. The authority citation for part 201 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 343, 351, 352, 353, 355, 358, 360, 360b, 360ccc, 360ccc-1, 360ddd, 360ddd-1, 360ee, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 8. Amend § 201.1 by revising paragraph (b) to read as follows:

§ 201.1 Drugs; name and place of business of manufacturer, packer, or distributor.

* * * * *

(b) As used in this section, and for purposes of section 502(a) and (b)(1) of

the Federal Food, Drug, and Cosmetic Act, the manufacturer of a drug product is the person who performs all of the following operations that are required to produce the product:

- (1) Mixing;
- (2) Granulating;
- (3) Milling;
- (4) Molding;
- (5) Lyophilizing;
- (6) Tableting;
- (7) Encapsulating;
- (8) Coating;
- (9) Sterilizing;
- (10) Filling sterile or aerosol drugs into dispensing containers; and
- (11) With respect to a medical gas, fabricating the gas by chemical reaction, physical separation, compression of

atmospheric air, purification (*e.g.*, re-processing an industrial gas into a medical gas), combining two or more distinct medical gases, or other process.

* * * * *

■ 9. Amend § 201.10 by revising paragraph (d)(2) to read as follows:

§ 201.10 Drugs; statement of ingredients.

* * * * *

(d) * * *

(2) A statement of the percentage of an ingredient in a drug shall, if the term *percent* is used without qualification, mean percent weight-in-weight, if the ingredient and the drug are both solids, or if the ingredient is a liquid and the drug is a solid; percent weight in

volume at 68 °F (20 °C), if the ingredient is a solid and the drug is a liquid; percent volume in volume at 68 °F (20 °C), if both the ingredient and the drug are liquids, except that alcohol shall be stated in terms of percent volume of absolute alcohol at 60 °F (15.56 °C); and percent volume in volume if the ingredient is a designated medical gas (as defined in § 201.161(c)(1)).

* * * * *

■ 10. Amend § 201.51 by revising paragraphs (a) and (b) to read as follows:

§ 201.51 Declaration of net quantity of contents.

(a) The label of a prescription or insulin-containing drug in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement of quantity of drugs in tablet, capsule, ampule, or other unit dosage form shall be expressed in terms of numerical count; the statement of quantity for drugs in other dosage forms shall be in terms of weight if the drug is solid, semi-solid, or viscous, in terms of fluid measure if the drug is liquid, or in terms of volume measure if the drug is a designated medical gas (as defined in § 201.161(c)(1)) or a medically appropriate combination of designated medical gases in a gaseous state. When the drug quantity statement is in terms of the numerical count of the drug units, it shall be augmented to give the weight or measure of the drug units or the quantity of each active ingredient in each drug unit or, when quantity does not accurately reflect drug potency, a statement of the drug potency.

(b) Statements of weight of the contents shall in the case of prescription drugs be expressed in terms of avoirdupois pound, ounce, and grain or of kilogram, gram, and subdivisions thereof. A statement of liquid measure of the contents shall in the case of prescription drugs other than designated medical gases and medically appropriate combinations thereof be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, fluid-ounce, and fluid-dram subdivisions thereof, or of the liter and milliliter, or cubic centimeter, and shall express the volume at 68 °F (20 °C). A statement of the liquid measure of the contents in the case of insulin-containing drugs shall be expressed in terms of the liter and milliliter, or cubic centimeter, and shall express the volume at 68 °F (20 °C). A statement of the measure of the contents shall in the case of designated medical

gases (as defined in § 201.161(c)(1)) and medically appropriate combinations thereof be expressed as follows:

(1) If in a gaseous state in a high-pressure container, it shall be expressed in liters or cubic feet based on the filled pressure at 70 °F (21 °C);

(2) If in a liquefied compressed gas state in a high-pressure container, it shall be expressed in gaseous liters or by an appropriate net weight statement;

(3) If in a liquefied state in a portable cryogenic container, it shall be expressed in gaseous liters, liquid liters (if identified as a liquid measure), gallons, or by an appropriate net weight statement at the time of fill; and

(4) If in a bulk or transport container (as defined in § 201.161(c)(3)), labeling for net quantity of contents is not required.

* * * * *

■ 11. Amend § 201.105 by revising the introductory text to read as follows:

§ 201.105 Veterinary drugs.

A drug subject to the requirements of section 503(f)(1) of the act shall be exempt from section 502(f)(1) of the act if it is a designated medical gas (as defined in § 201.161(c)(1)) or a medically appropriate combination of designated medical gases and is in compliance with § 201.161, or if all the following conditions are met:

* * * * *

■ 12. Revise § 201.161 to read as follows:

§ 201.161 Medical gases.

(a) The requirements of sections 503(b)(4) and 502(f) of the Federal Food, Drug, and Cosmetic Act are deemed to have been met for a designated medical gas or a medically appropriate combination of designated medical gases if the labeling on its final use container bears the following:

(1) In the case of oxygen:

(i) A warning statement providing that uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful; that oxygen should not be used on patients who have stopped breathing unless used in conjunction with resuscitative equipment; and, in the case of oxygen that may be provided without a prescription for use in the event of depressurization or other environmental oxygen deficiency, or for oxygen deficiency or for use in emergency resuscitation when administered by properly trained personnel, a warning statement providing that oxygen may be used for emergency use only when administered

by properly trained personnel for oxygen deficiency and resuscitation, and that for all other medical applications a prescription is required.

(ii) A clear and prominent warning containing the statements “No Smoking” and “No Vaping” and a graphic symbol conveying that smoking, vaping, and open flames near oxygen are dangerous.

(2) In the case of a designated medical gas other than oxygen, and in the case of medically appropriate combinations of any designated medical gases:

(i) A warning statement providing that the administration of the gas or gas combination (as applicable) may be hazardous or contraindicated; and that the gas or gas combination (as applicable) should be used only by or under the supervision of a licensed practitioner who is experienced in the use and administration of the gas or gas combination (as applicable) and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications, and side effects and the precautions to be taken.

(ii) The symbol “Rx only.”

(3) Appropriate directions and warnings concerning storage and handling.

(b) A designated medical gas or medically appropriate combination of designated medical gases in a bulk or transport container must be identified with the name of the product contained therein and accompanied by documentation identifying the product as meeting applicable compendial standards.

(c) For purposes of this section:

(1) A *designated medical gas* means a drug that:

(i) Is manufactured or stored in a liquefied, nonliquefied, or cryogenic state;

(ii) Is administered as a gas; and

(iii) Meets the definition in section 575(1) of the Federal Food, Drug, and Cosmetic Act.

(2) A *final use container* means a container that is for direct use or access by a patient or healthcare provider to administer a designated medical gas or medically appropriate combination of designated medical gases. The term *final use container* does not include bulk or transport containers and does not include containers that are described in § 868.5655 of this chapter.

(3) A *bulk or transport container* means a container used to transport or store designated medical gases or medically appropriate combinations of designated medical gases and that is not used directly to administer such gases to a patient.

- 13. Amend § 201.328 by revising paragraphs (a) introductory text and (a)(1) introductory text and adding paragraph (d) to read as follows:

§ 201.328 Labeling of medical gas containers.

(a) *Portable cryogenic medical gas containers.* For the purposes of this section a *portable cryogenic medical gas container* is one that is capable of being transported and is intended to be attached to a medical gas supply system within a hospital, health care entity, nursing home, other facility, or home health care setting, or is used to fill small cryogenic gas containers for use by individual patients. The term excludes cryogenic containers that are not designed to be connected to a medical gas supply system, *e.g.*, tank trucks, trailers, rail cars, or small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined at § 868.5655 of this chapter).

(1) Each portable cryogenic medical gas container must be conspicuously marked with a 360° wraparound label identifying its contents. Such label must meet the requirements of § 213.94(e)(3) of this chapter and the following additional requirements.

* * * * *

(d) *Statement identifying owner or return address of medical gas containers.* Notwithstanding § 201.1, a container filled with a designated medical gas (as defined in § 201.161(c)(1)) or medically appropriate combination of designated medical gases may bear a statement identifying the name of the owner of the container or the address to which the container should be returned after use. Such statement may appear on a separate sticker or decal. If the owner of the medical gas container is not the manufacturer, packer, or distributor of the designated medical gas or medically appropriate combination of designated medical gases, that shall be clearly stated on the container. The addition of such statement shall not cause the owner of the cylinder to be a “relabeler” for purposes of registration and listing under part 207 of this chapter.

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

- 14. The authority citation for part 210 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 360ddd, 360ddd–1, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

- 15. Amend § 210.1 by revising paragraphs (a) and (b) to read as follows:

§ 210.1 Status of current good manufacturing practice regulations.

(a) The regulations set forth in this part and in parts 211, 213, 225, and 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(b) The failure to comply with any regulation set forth in this part and in parts 211, 213, 225, and 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

* * * * *

- 16. Amend § 210.2 by revising paragraphs (a) and (b) to read as follows:

§ 210.2 Applicability of current good manufacturing practice regulations.

(a) The regulations in this part and in parts 211, 213, 225, and 226 of this chapter as they may pertain to a drug; in parts 600 through 680 of this chapter as they may pertain to a biological product for human use; and in part 1271 of this chapter as they are applicable to a human cell, tissue, or cellular or tissue-based product (HCT/P) that is regulated as a drug (subject to premarket review under an application submitted under section 505 of the act or under a biologics license application under section 351 of the Public Health Service Act); shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulation specifically applicable to the drug product in question shall supersede the more general.

(b) If a person engages in only some operations subject to the regulations in this part and in parts 211, 213, 225, 226, 600 through 680, and 1271 of this chapter, and not in others, that person need only comply with those regulations applicable to the operations in which the person is engaged.

* * * * *

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

- 17. The authority citation for part 211 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 360ddd, 360ddd–1, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

- 18. Amend § 211.1 by revising paragraph (a) to read as follows:

§ 211.1 Scope.

(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products (excluding positron emission tomography drugs and medical gases as defined in § 213.3(b)(12) of this chapter) for administration to humans or animals.

* * * * *

§ 211.94 [Amended]

- 19. Amend § 211.94 by removing paragraph (e).

- 20. Amend § 211.125 by revising paragraph (c) to read as follows:

§ 211.125 Labeling issuance.

* * * * *

(c) Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 211.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with § 211.122(g)(2).

* * * * *

- 21. Amend § 211.132 by revising paragraph (c)(1) introductory text to read as follows:

§ 211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.

* * * * *

(c) * * *
(1) In order to alert consumers to the specific tamper-evident feature(s) used, each retail package of an OTC drug product covered by this section (except ammonia inhalant in crushable glass ampules or aerosol products that depend upon the power of a liquefied or compressed gas to expel the contents from the container) is required to bear a statement that:

* * * * *

■ 22. Amend § 211.170 by revising paragraph (b) introductory text to read as follows:

§ 211.170 Reserve samples.

* * * * *

(b) An appropriately identified reserve sample that is representative of each lot or batch of drug product shall be retained and stored under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics. The reserve sample consists of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated in accordance with § 211.192. The results of the examination shall be recorded and maintained with other stability data on the drug product. The retention time is as follows:

* * * * *

■ 23. Revise § 211.196 to read as follows:

§ 211.196 Distribution records.

Distribution records shall contain the name and strength of the product and description of the dosage form, name and address of the consignee, date and quantity shipped, and lot or control number of the drug product.

■ 24. Add part 213 to subchapter C to read as follows:

PART 213—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICAL GASES

Subpart A—General Provisions

Sec.

213.1 Scope.

213.3 Definitions.

Subpart B—Organization and Personnel

213.22 Responsibilities of quality unit.

213.25 Personnel qualifications and responsibilities.

213.34 Consultants.

Subpart C—Buildings and Facilities

213.42 Design and construction features.

Subpart D—Equipment

213.63 Equipment design, size, and location.

213.65 Equipment construction.

213.67 Equipment maintenance and cleaning.

213.68 Automatic, mechanical, and electronic equipment.

Subpart E—Control of Incoming Designated Medical Gas, Components, and Medical Gas Containers and Closures

213.80 General requirements.

213.82 Receipt and storage of incoming designated medical gases.

213.84 Testing and approval or rejection of components, containers, and closures.

213.89 Rejected components, incoming designated medical gases, and medical gas containers and closures.

213.94 Medical gas containers and closures.

Subpart F—Production and Process Controls

213.100 Written procedures; deviations.

213.101 Charge-in of components and incoming designated medical gases.

213.110 Sampling and testing of in-process materials.

Subpart G—Packaging and Labeling Control

213.122 Materials examination and usage criteria.

213.125 Labeling issuance.

213.130 Packaging and labeling operations.

Subpart H—Holding and Distribution

213.150 Warehousing and distribution procedures.

Subpart I—Laboratory Controls

213.160 General requirements.

213.165 Testing and release for distribution.

213.166 Stability testing and expiration dating for medical gases marketed under applications submitted under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act.

Subpart J—Records

213.180 General requirements.

213.182 Equipment cleaning and use log.

213.184 Records for components, medical gas containers and closures, and labeling.

213.186 Master production and control records.

213.189 Batch production and control records.

213.192 Production record review.

213.194 Laboratory records.

213.196 Distribution records.

213.198 Complaint files.

Subpart K—Returned and Salvaged Medical Gases

213.204 Returned medical gases.

213.208 Salvaging of medical gases.

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360b, 360ddd, 360ddd–1, 371, 374.

Subpart A—General Provisions

§ 213.1 Scope.

The regulations in this part contain the minimum current good manufacturing practice for preparation of medical gases for administration to humans or animals.

§ 213.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) *Acceptance criteria* means the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).

(2) *Batch* means a specific quantity of a medical gas or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(3) *Commingling or commingled* refers to the act of combining one lot of designated medical gas or component with another lot or lots of the same designated medical gas or component.

(4) *Component* means any ingredient intended for use in the manufacture of a medical gas, including those that may not appear in such gas. It does not include an incoming designated medical gas.

(5) *Designated medical gas* means a drug that is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; is administered as a gas; and is defined in section 575(1) of the Federal Food, Drug, and Cosmetic Act.

(6) *FDA* means the Food and Drug Administration.

(7) *In-process material* means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the medical gas.

(8) *Incoming designated medical gas* means a designated medical gas received from one source that, after receipt, is commingled with the same gas from another source, used in a medically appropriate combination of designated medical gases or in the production of another medical gas, or further distributed.

(9) *Lot* means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a medical gas produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

(10) *Lot number, control number, or batch number* means any distinctive

combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of medical gas or other material can be determined.

(11) *Manufacture, processing, packing, or holding of medical gases* includes packaging and labeling operations, testing, and quality control.

(12) *Medical gas* has the meaning given the term in section 575(2) of the Federal Food, Drug, and Cosmetic Act.

(13) *Original manufacturer* means the person that initially produces a designated medical gas by chemical reaction, physical separation, compression of atmospheric air, purification (*e.g.*, re-processing an industrial gas into a medical gas), or other means.

(14) *Quality unit* means any person or persons designated with the authority and responsibility for overall quality management and other responsibilities as defined in § 213.22.

(15) *Strength* means:

(i) The concentration of the medical gas (for example, weight/weight, weight/volume, or unit dose/volume basis); and/or

(ii) The potency, that is, the therapeutic activity of the medical gas as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

Subpart B—Organization and Personnel

§ 213.22 Responsibilities of quality unit.

(a) There shall be a quality unit that shall have the responsibility and authority to approve or reject all components, medical gas containers and closures, in-process materials, packaging material, labeling, and medical gases, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality unit shall be responsible for approving or rejecting medical gases manufactured, processed, packed, or held under contract by another company.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, medical gas containers and closures, packaging materials, in-process materials, and medical gases shall be available to the quality unit.

(c) The quality unit shall have the responsibility for approving or rejecting all procedures or specifications

impacting on the identity, strength, quality, and purity of the medical gas.

(d) The responsibilities and procedures applicable to the quality unit shall be in writing; such written procedures shall be followed.

(e) Quality unit personnel may perform other functions provided appropriate written controls are in place to ensure any other functions are performed separately from quality unit responsibilities and such other functions do not interfere with the quality unit's responsibilities or subordinate the quality unit's responsibilities to any other unit.

§ 213.25 Personnel qualifications and responsibilities.

(a) Each person engaged in the manufacture, processing, packing, or holding of a medical gas shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with current good manufacturing practice requirements applicable to them. Written documentation shall be maintained demonstrating the completion of employee training, and shall include the date of the training, the type of the training, and the results of any completion criteria, such as test results.

(b) There shall be an adequate number of qualified personnel to perform the manufacture, processing, packing, or holding of each medical gas.

(c) Only authorized personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

§ 213.34 Consultants.

Consultants advising on the manufacture, processing, packing, or holding of medical gases shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

Subpart C—Buildings and Facilities

§ 213.42 Design and construction features.

(a)(1) Any buildings and facilities used in the manufacture, processing, packing, or holding of a medical gas shall be of adequate design, including having adequate space, for the orderly placement of equipment and materials to prevent mix-ups between:

- (i) Components;
- (ii) Incoming designated medical gases;
- (iii) Medical gas containers and closures;
- (iv) Labeling;
- (v) In-process materials; or
- (vi) Medical gases.

(2) Such buildings and facilities shall also allow for adequate cleaning, maintenance, and proper operations.

(b)(1) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mix-ups during the course of the following procedures:

(i) Receipt, identification, storage, and withholding from use of components, incoming designated medical gases, medical gas containers and closures, and labeling, pending the appropriate sampling, testing, or examination by the quality unit before release for manufacturing or packaging;

(ii) Holding rejected components, incoming designated medical gases, medical gas containers and closures, and labeling before disposition;

(iii) Storage of released components, incoming designated medical gases, medical gas containers and closures, and labeling;

(iv) Storage of in-process materials;

(v) Manufacturing and processing operations;

(vi) Packaging and labeling operations;

(vii) Quarantine storage before release of medical gases;

(viii) Storage of medical gases after release; and

(ix) Control and laboratory operations.

(2) The flow of components, incoming designated medical gases, medical gas containers and closures, labeling, in-process materials, and medical gases through the buildings and facilities shall be designed to prevent contamination and mix-ups.

(c) Any building or facility used in the manufacture, processing, packing, or holding of a medical gas shall be maintained in a clean condition so as to assure the safety, identity, strength, quality, and purity of the medical gas. Written procedures applicable to the

maintenance and cleaning of buildings and facilities shall be established and followed.

Subpart D—Equipment

§ 213.63 Equipment design, size, and location.

Equipment used in the manufacture, processing, packing, or holding of a medical gas shall be of appropriate design and adequate size, and be suitably located to facilitate operations for its intended use and any necessary cleaning and maintenance.

§ 213.65 Equipment construction.

(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or medical gases shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the medical gas beyond the official or other established requirements.

(b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, containers, closures, in-process materials, or medical gases so as to alter the safety, identity, strength, quality, or purity of the medical gas beyond the official or other established requirements.

§ 213.67 Equipment maintenance and cleaning.

(a) Written procedures shall be established, maintained, and followed for adequate cleaning and maintenance of equipment used in the manufacture, processing, packing, or holding of medical gases. These procedures shall include, but are not necessarily limited to, the following:

- (1) Assignment of responsibility for cleaning and maintaining equipment;
- (2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;
- (3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;
- (4) Removal or obliteration of previous batch identification;
- (5) Protection of clean equipment from contamination prior to use; and
- (6) Inspection of equipment for cleanliness immediately before use.

(b) The procedures described in paragraph (a) of this section shall not alter the safety, identity, strength, quality, or purity of the medical gas beyond the established requirements.

(c) Records shall be kept of cleaning, maintenance, and inspection as specified in §§ 213.180 and 213.182.

§ 213.68 Automatic, mechanical, and electronic equipment.

(a) Automatic, mechanical, and electronic equipment used in the manufacture, processing, packing, and holding of medical gases shall be routinely calibrated, inspected, and checked according to a written program designed to ensure proper performance. Written procedures and records of calibration, inspections, and checks shall be maintained.

(b) Computerized systems that record, store, or use data shall be appropriately validated.

(c) A backup file of data entered into the computer system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes.

(d) Appropriate change control shall be used whenever modifications are made to computer systems to assure that any changes do not adversely affect data integrity or product quality. Records of such modifications shall be maintained.

Subpart E—Control of Incoming Designated Medical Gas, Components, and Medical Gas Containers and Closures

§ 213.80 General requirements.

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components, incoming designated medical gases, and medical gas containers and closures; such written procedures shall be followed.

(b) Components, incoming designated medical gases, and medical gas containers and closures shall at all times be handled and stored in a manner to prevent contamination and mix-ups.

(c) Lots of incoming designated medical gases or components, whether used directly as supply or commingled with an existing supply, shall be assigned a unique identification number.

§ 213.82 Receipt and storage of incoming designated medical gases.

(a)(1) Upon receipt of each shipment of each incoming designated medical gas, the firm shall either perform full compendial testing on the gas and record the results or verify and record that a signed certificate of analysis from the supplier accompanies each different designated medical gas in a shipment.

The certificate of analysis shall include the following:

- (i) Supplier's name;
- (ii) Name of the incoming designated medical gas;
- (iii) Lot number or other unique identification number;
- (iv) Actual analytical result obtained for strength, as well as the results of other tests performed;
- (v) Identification of the test method(s) used for analysis;
- (vi) New drug application and/or new animal drug application number of the incoming designated medical gas; and
- (vii) Supplier representative's signature and the date of signature.

(2) If the incoming designated medical gas is obtained from a supplier other than the original manufacturer, the shipment shall also include complete information from the original manufacturer's certificate of analysis. The firm shall establish and maintain a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures.

(b) An identity test shall be performed upon receipt of the incoming designated medical gas.

§ 213.84 Testing and approval or rejection of components, containers, and closures.

(a) Components, containers, and closures (including valves) shall be examined for conformance with appropriate written procedures and specifications, and approved or rejected, prior to the manufacturing or filling process. In lieu of such examination by the firm, a statement of verification that the component, container, or closure meets specifications may be accepted from the supplier, provided that the firm establishes and maintains a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing provisions. Any rejected items shall be handled in accordance with § 213.89.

(b) Firms shall take appropriate actions to protect against container and closure leaks, which shall include performing leak tests on containers and closures at the time of fill and after fill but prior to release.

(c) Each component shall be sampled, tested, and approved or rejected as appropriate prior to use. This requirement can be met by performing testing for conformance with written specifications or by an identity test on the component accompanied by an acceptable certificate of analysis from the supplier, provided that the firm establishes and maintains a program to ensure the reliability of the supplier's capabilities through appropriate assessment and testing procedures.

§ 213.89 Rejected components, incoming designated medical gases, and medical gas containers and closures.

Rejected components, incoming designated medical gases, and medical gas containers and closures shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable and shall be documented and assessed.

§ 213.94 Medical gas containers and closures.

(a) Medical gas containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the gas beyond the official or established requirements.

(b) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the medical gas.

(c) Medical gas containers and closures shall be clean to assure that they are suitable for their intended use.

(d) Standards or specifications, methods of testing, and, where indicated, methods of cleaning shall be written and followed for medical gas containers and closures.

(e) Medical gas containers and closures must meet the following requirements—

(1) *Gas-specific use outlet connections.* Portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (e.g., those that have been silver-brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the containers' use) except by the manufacturer. For the purposes of this paragraph (e)(1), the term *manufacturer* includes any individual or firm that fills high-pressure medical gas cylinders or cryogenic medical gas containers. For the purposes of this section, a *portable cryogenic medical gas container* is one that is capable of being transported and is intended to be attached to a medical gas supply system within a hospital, healthcare entity, nursing home, other facility, or home healthcare setting, or is used to fill small cryogenic gas containers for use by individual patients. The term excludes cryogenic containers that are not designed to be connected to a medical gas supply system, e.g., tank trucks, trailers, rail cars, or small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined at § 868.5655 of this chapter).

(2) *Gauges for certain medical gas containers.* Portable cryogenic medical gas containers as described in paragraph (e)(1) of this section and small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined at § 868.5655 of this chapter) must have a working gauge sufficient to assist the user in determining whether the container contains an adequate supply of medical gas for continued use.

(3) *Label and coloring requirements.* The labeling specified at § 201.328(a) of this chapter must be affixed to the container in a manner that does not interfere with other labeling. Each such label as well as materials used for coloring medical gas containers must be reasonably resistant to fading, durable when exposed to atmospheric conditions, and not readily soluble in water.

Subpart F—Production and Process Controls**§ 213.100 Written procedures; deviations.**

(a) There shall be written procedures for production and process controls designed to assure that medical gases have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

§ 213.101 Charge-in of components and incoming designated medical gases.

Written production and control procedures shall include the following, which are designed to assure that the medical gases produced have the identity, strength, quality, and purity they purport or are represented to possess:

(a) Except when a monograph or formulary specifies a range, the batch shall be formulated with the intent to provide 100 percent of the labeled or established amount of each medical gas. When a monograph or formulary specifies a range for the contents of a medical gas, the batch shall be formulated with the intent to provide an amount of the medical gas within such specified range.

(b) Components and incoming designated medical gases added to in-process supply or final product containers shall be weighed or measured as appropriate. In-process and final product containers shall identify the name of the component or designated medical gas or the name and percentage of each component or designated medical gas if they contain multiple components or designated medical gases, and the unique lot number assigned.

§ 213.110 Sampling and testing of in-process materials.

(a) In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality unit during the production process.

(b) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes.

(c) Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

Subpart G—Packaging and Labeling Control**§ 213.122 Materials examination and usage criteria.**

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed. Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a medical gas.

(b) Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable.

(c) Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected.

(d) Labels and other labeling materials for each different medical gas, strength,

or quantity of contents shall be stored with suitable identification to avoid mix-ups. Access to the label storage area shall be limited to authorized personnel.

(e) Labels, labeling, and other packaging materials that are obsolete, outdated, or that do not meet applicable requirements shall be destroyed.

(f) Packaging and labeling operations shall include one of the following special control procedures:

(1) Dedication of labeling and packaging lines to each different strength of each different medical gas;

(2) Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or

(3) Use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of labeling operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person.

(g) Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record.

(h) Labels may be reused if they are legible, properly affixed to the container, and otherwise meet all applicable requirements.

§ 213.125 Labeling issuance.

(a) Labeling and packaging operations must be controlled to prevent labeling and product mix-ups. Procedures shall be written and followed describing in sufficient detail the control procedures employed for the issuance of labeling.

(b) Procedures shall be used to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of medical gas and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 213.192. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance with § 213.122(f)(2). Labeling reconciliation is also waived for 360° wraparound labels on portable cryogenic medical gas containers.

(c) All excess lot number stickers or decals bearing lot or control numbers shall be discarded.

(d) Bulk or transport containers (as defined in § 201.161(c)(3) of this chapter) are exempt from this section.

§ 213.130 Packaging and labeling operations.

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for medical gases; such written procedures shall be followed. These procedures shall incorporate the following features:

(a) Prevention of mix-ups by physical or spatial separation from operations on other products.

(b) Identification and handling of filled containers of medical gas that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container.

(c) Identification of the medical gas with a lot or control number that permits determination of the history of the manufacture and control of the batch. The lot or control number of the medical gas may be identified by use of a separate identification sticker or decal.

(d) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record. Product labels, including 360° wraparound labels, can be reused provided they meet all applicable labeling requirements, all information on the label is legible, and the label is in good condition.

(e) Inspection of the packaging and labeling facilities immediately before use to assure that all medical gases have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

(f) Bulk or transport containers (as defined in § 201.161(c)(3) of this chapter) are exempt from this section provided they are identified with the name of the product contained therein and accompanied by documentation identifying the product as meeting applicable compendial standards.

Subpart H—Holding and Distribution

§ 213.150 Warehousing and distribution procedures.

(a) Written procedures shall be established, and followed, describing

the distribution of medical gases and including a system by which the distribution of each lot can be readily determined to facilitate its recall if necessary.

(b) Written procedures shall be established, and followed, describing the warehousing of medical gases, including quarantine of such gases before release by the quality unit.

Subpart I—Laboratory Controls

§ 213.160 General requirements.

(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

(b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, medical gas containers and closures, in-process materials, labeling, and medical gases conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, medical gas containers and closures, and labeling used in the manufacture, processing, packing, or holding of a medical gas. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, container, or closure that is subject to deterioration.

(2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified.

(3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for medical gases. Such

samples shall be representative and properly identified.

(4) The calibration or verification of calibration for instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

§ 213.165 Testing and release for distribution.

(a) For each batch of medical gas, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the medical gas, including the identity and strength, prior to release.

(b) Any sampling and testing plans shall be described in written procedures that shall include the method of sampling, the number of units per batch to be tested, and acceptance criteria. Such written procedures shall be followed.

(c) The accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with § 213.194(a)(2). The suitability of all testing methods shall be verified under actual conditions of use.

(d) Medical gases failing to meet established standards or specifications and any other relevant quality criteria shall be rejected.

(e) This section does not apply to the filling of a designated medical gas or medically appropriate combination of designated medical gases via liquid to liquid into a container at a delivery site.

§ 213.166 Stability testing and expiration dating for medical gases marketed under applications submitted under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act.

(a) For medical gases marketed under applications submitted under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act, any stability testing performed and any expiration date established shall be in accordance with paragraph (b) of this section, subject to the conditions established in their approved applications, if any.

(b) To assure that the medical gas described in paragraph (a) of this section meets applicable standards of identity, strength, quality, and purity at the time of use:

(1) The stability testing program shall be designed to assess the stability characteristics of the medical gas and its container closure system. The results of stability testing shall be used in determining appropriate storage conditions and any expiration date included on the label. The stability program shall include the appropriate sample size, test intervals, container closure systems, and storage conditions for samples retained for testing.

(2) Any expiration dates included on the label shall appear in accordance with the requirements of § 201.17 of this chapter.

(3) Stability shall be evaluated periodically to ensure that the medical gas continues to meet the standards for identity, strength, quality, and purity stated on the labeling to support the expiration date.

Subpart J—Records

§ 213.180 General requirements.

(a) *Record availability.* All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred and are subject to copying as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph (a).

(b) *Record requirements.* All records must be legible, stored to prevent deterioration or loss, and original or accurate reproductions of the original records.

(c) *Record retention period.* Except where otherwise provided, all records required to be maintained in compliance with this part must be maintained for a period of at least 3 years after the distribution of the batch of medical gas.

(d) *Maintenance of written records.* Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each medical gas to determine the need for changes in specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch; and

(2) A review of complaints, recalls, returned or salvaged medical gases, and

investigations conducted under § 213.192 for each gas.

(e) *Written procedure requirements.* A firm shall establish and follow written procedures to assure that responsible officials of the firm are notified in writing of any recalls, reports of inspectional observations by FDA, regulatory actions related to good manufacturing practices brought by FDA, or investigations resulting from adverse event complaints.

§ 213.182 Equipment cleaning and use log.

A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 213.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

§ 213.184 Records for components, medical gas containers and closures, and labeling.

Records for components, medical gas containers and closures, and labeling shall include the following:

(a) The results of any test or examination performed (including those performed as required by § 213.84 or § 213.122) and the conclusions derived therefrom.

(b) Documentation of the examination and review of labels and labeling for conformity with established specifications in accordance with §§ 213.122 and 213.130.

(c) The disposition of rejected components, medical gas containers and closures, and labeling.

§ 213.186 Master production and control records.

(a) To assure uniformity from batch to batch, master production and control records for each medical gas shall be prepared, dated, and signed. The preparation of master production and control records shall be described in a

written procedure and such written procedure shall be followed.

(b) Master production and control records shall include:

(1) The name and strength of the medical gas;

(2) A complete list of components and any incoming designated medical gases used in manufacturing designated by names or codes sufficiently specific to indicate any special quality characteristic;

(3) A description of the medical gas containers and closures, packaging materials, and labels; and

(4) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

§ 213.189 Batch production and control records.

(a) Batch production and control records shall be prepared for each batch of medical gas produced.

(b) These records shall include documentation that each significant step in the manufacture, processing, packing, or holding of the medical gas produced was accomplished, including:

(1) Dates of each significant step, including in-process and laboratory tests as applicable;

(2) A description of the container for the medical gas, including the number and size of the containers filled as applicable;

(3) Specific identification of each component and its source or in-process material used as applicable;

(4) Measures of components used in the course of processing as applicable;

(5) Testing results, including any in-process test results and finished product test results;

(6) Dated signature or initials of the persons performing and directly supervising or checking each significant step in the operation;

(7) Inspection of the packaging and labeling area before and after use;

(8) Complete labeling control records, including specimens or copies of all labeling used and label application and reconciliation records as appropriate; and

(9) Any investigation made according to § 213.192.

§ 213.192 Production record review.

(a) Manufacturing production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality unit to determine compliance with all established, approved written procedures before a batch is released or distributed. The quality unit must

review production records to determine whether errors or unexplained discrepancies have occurred prior to batch release. If errors or unexplained discrepancies have occurred, or a batch or any component of the batch fails to meet any of its specifications, the firm must thoroughly investigate and take appropriate corrective actions. A written record of the investigation shall be made and shall include the conclusions and followup.

(b) For production and control records of filling at a delivery site, quality unit review as described in paragraph (a) of this section shall be within one business day after fill.

§ 213.194 Laboratory records.

(a) Laboratory records related to the manufacture of a medical gas must include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows:

(1) A description of the sample, the batch or lot number to be tested, the date the sample was taken, and the date the sample was tested.

(2) The method used in the testing of the sample, the result of the test, how the results compare with established standards of identity, strength, quality, and purity for the component, container, closure, in-process materials (as applicable), and medical gas tested, a record of any calculations performed in connection with each test and any calculated results, and the unit of measurement of the result for each test. It is not necessary to provide the actual calculation where the result is evident through use of simple addition and subtraction.

(3) Where applicable, any graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, in-process material, or medical gas for each lot tested.

(4) The initials or signature of the person performing the test and the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

(b) Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method.

(c) Complete records shall be maintained of any testing and

standardization of laboratory reference standards, reagents, and standard solutions.

(d) Complete records shall be maintained of the periodic calibration or verification of calibration of laboratory instruments, apparatus, gauges, and recording devices required by § 213.160(b)(4).

(e) Complete records shall be maintained of all stability testing performed in accordance with § 213.166.

§ 213.196 Distribution records.

Distribution records shall contain the name of the medical gas, lot or batch number, name and address of the consignee, and date and quantity shipped. For medically appropriate combinations of designated medical gases, the distribution record shall include the percentage of each gas.

§ 213.198 Complaint files.

(a) Written procedures shall be established and followed for the receipt and handling of all written or oral complaints concerning a medical gas. These procedures must include quality unit review of any complaint involving the possible failure of a medical gas to meet any of its specifications and provisions for determining the need for an investigation in accordance with § 213.192 as well as determining whether the complaint represents an event that is required to be reported to FDA under part 230 of this chapter. Any complaint involving a possible leak of a container or closure must be reviewed, evaluated, and investigated in accordance with § 213.192.

(b) A written record of each complaint regarding a medical gas must be maintained. The record must include the name of the gas, the lot or batch number, the name of the complainant, the date the complaint was received, the nature of the complaint, and the response to the complaint. It must also include the findings of any investigation and followup. Where an investigation is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.

(c) Complaint files shall be maintained in a manner such that they are readily available for inspection by the firm or by FDA during an inspection. Complaint files shall be maintained for at least 1 year after the date the complaint was received or for at least 3 years after distribution of the medical gas, whichever is longer.

Subpart K—Returned and Salvaged Medical Gases**§ 213.204 Returned medical gases.**

Returned medical gases shall be identified as such and held. If the conditions under which such returned gases have been held, stored, or shipped before or during their return, or if the condition of the gas, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality, or purity of the gas, the returned gas shall be destroyed unless examination, testing, or other investigations prove the gas meets appropriate standards of safety, identity, strength, quality, or purity. Records of returned medical gases shall be maintained and shall include the name, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned gas. If the reason for a medical gas being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of § 213.192. Procedures for the holding, testing, and use of returned medical gases shall be in writing and shall be followed. This section is not applicable to the routine refilling of cryogenic medical gas containers in the normal course of business unless the cryogenic medical gas container was returned due to a quality issue.

§ 213.208 Salvaging of medical gases.

Medical gases in containers that have been subjected to improper storage conditions may be salvaged unless their containers have been subjected to adverse conditions that impact the identity, strength, quality, and purity of the gas or integrity of the container closure. Whenever there is a question whether medical gases have been subjected to such conditions, salvaging operations may be conducted only if there is evidence from laboratory tests that such gases meet all applicable standards of identity, strength, quality, and purity, and the integrity of the container closure system is not compromised. Procedures for the holding, testing, and use of salvaged medical gases shall be in writing and shall be followed.

■ 25. Add part 230 to subchapter C to read as follows:

PART 230—CERTIFICATION AND POSTMARKETING REPORTING FOR DESIGNATED MEDICAL GASES**Subpart A—General Provisions**

Sec.

- 230.1 Scope of this part.
- 230.2 Purpose.
- 230.3 Definitions.

Subpart B—Certification of Designated Medical Gases

- 230.50 General requirements for all submission types.
- 230.65 Withdrawal by the applicant of a certification request before it is deemed granted.
- 230.70 Supplements and other changes to a granted certification.
- 230.72 Change in ownership of a granted certification.
- 230.80 Annual report.
- 230.100 FDA review of submissions.
- 230.105 When a submission is deemed granted.
- 230.150 Withdrawal or revocation of approval of an application.

Subpart C—Postmarketing Quality and Safety Reporting

- 230.205 Field alert reports.
- 230.210 General reporting requirements for designated medical gas adverse events.
- 230.220 Human designated medical gas ICSR requirements.
- 230.230 Animal designated medical gas adverse event reporting requirements.

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360b, 360cc, 360ddd, 360ddd–1, 371, 374, 379e, 379k–1, 381.

Subpart A—General Provisions**§ 230.1 Scope of this part.**

This part sets forth procedures and requirements for the submission to, and the review by, the Food and Drug Administration of certifications to market designated medical gases under sections 575 and 576 of the Federal Food, Drug, and Cosmetic Act, as well as amendments and supplements to those certifications. This part also sets forth the postmarketing safety reporting requirements for designated medical gases.

§ 230.2 Purpose.

The purpose of this part is to establish an efficient process for the certification of designated medical gases and to establish an effective system for surveillance of such gases.

§ 230.3 Definitions.

(a) The definitions and interpretations contained in sections 201 and 575 of the Federal Food, Drug, and Cosmetic Act apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) *Adverse event* means any untoward medical occurrence associated with the use of a designated medical gas in humans or animals, whether or not it is considered related to the designated medical gas. An

adverse event can occur in the course of the use of a designated medical gas; from overdose of a designated medical gas, whether accidental or intentional; from abuse of a designated medical gas; from discontinuation of the designated medical gas (e.g., physiological withdrawal); and it includes any failure of expected pharmacological action.

(2) *Applicant* means any person who submits a certification request for a designated medical gas under this part, including a supplement, and any person who owns a granted certification for a designated medical gas under this part.

(3) *Certification request* means a submission under section 576 of the Federal Food, Drug, and Cosmetic Act requesting certification of a medical gas as a designated medical gas.

(4) *FDA* or *Agency* means the Food and Drug Administration.

(5) *Individual case safety report* (ICSR) means a description of an adverse event related to an individual patient or subject.

(6) *ICSR attachments* means documents related to the adverse event described in an ICSR, such as medical records, hospital discharge summaries, or other documentation.

(7) *Life-threatening adverse event* means any adverse event that places the patient, in the view of the initial reporter, at *immediate* risk of death from the adverse event as it occurred, *i.e.*, it does not include an adverse event that, had it occurred in a more severe form, might have caused death.

(8) *Minimum data set for an ICSR for an adverse event* means the minimum four elements required for reporting an ICSR of an adverse event: An identifiable patient, an identifiable reporter, a suspect designated medical gas, and an adverse event.

(9) *Nonapplicant* means any person other than the applicant whose name appears on the label of a designated medical gas container as a manufacturer, packer, or distributor.

(10) *Serious adverse event* means:

(i) An adverse event is considered “serious” if it results in any of the following outcomes:

- (A) Death;
- (B) A life-threatening adverse event;
- (C) Inpatient hospitalization or prolongation of existing hospitalization;
- (D) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; and/or
- (E) A congenital anomaly/birth defect.

(ii) Other events that may be considered serious adverse events: Important medical events that may not result in one of the listed outcomes in this definition may be considered

serious adverse events when, based upon appropriate medical judgment, they may jeopardize the patient or study subject and may require medical or surgical intervention to prevent one of the outcomes listed in this paragraph (b)(10). Examples include: Allergic bronchospasm requiring intensive treatment in an emergency department or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of product dependency or product abuse. Additional examples in animals include: Severe hypersensitivity reactions or respiratory distress.

Subpart B—Certification of Designated Medical Gases

§ 230.50 General requirements for all submission types.

(a) *Who must submit a request for certification.* (1) The certification process described in this subpart applies to designated medical gases for the indications described in section 576(a)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act. Any person who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce shall file a request for certification. The certification process is the same for all designated medical gases, regardless of whether it is intended for human use, animal use, or both. The applicant must identify its intention to market its designated medical gas for human use, animal use, or both.

(2) Any person that proposes to market a medical gas that is a new drug for human use must obtain approval under part 314 of this chapter, and any person that proposes to market a medical gas that is a new animal drug for animal use must obtain approval under part 514 of this chapter, unless—

(i) The medical gas meets the definition of a designated medical gas; and

(ii) The medical gas is proposed to be marketed alone or in combination (as medically appropriate) with another designated medical gas or other designated medical gases, for which a certification or certifications have been granted, for a use described under section 576(a)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act.

(b) *The applicant must include the following information in its certification request—*(1) *Applicant information.* The applicant must identify the name, address, telephone number, and email address of the person requesting certification. If the address of the person requesting certification is not in the

United States, the certification request is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

(2) *Type of submission.* The applicant must indicate the type of submission as one of the following:

(i) *Original certification request.* An initial request submitted by an applicant for certification of a medical gas as a designated medical gas.

(ii) *Amendment to a pending certification request.* Any submission related to a pending submission that revises existing information or provides additional information, including responses to Information Request Letters.

(iii) *Resubmission.* Any submission that has been revised and submitted again following a previous denial. If an applicant chooses to resubmit its submission, it must provide a written response to the deficiencies identified in FDA's denial letter, along with other information required for certification requests.

(iv) *Supplement to a granted certification.* Any submission that contains a change to a granted certification.

(v) *Other.* Any submission that does not fit in one of the other categories.

(3) *Description of medical gas.* A separate certification request is required to be submitted for each designated medical gas for which certification is sought. Each designated medical gas certification request must include the name of the medical gas and a certification statement from the applicant that the designated medical gas meets the appropriate compendial standard.

(4) *Facility information.* Each certification request must include the name and address of the facility or facilities where the designated medical gas will be initially produced. For each facility, include a brief description of the manufacturing or processing activities performed, the FDA Establishment Identifier, if one exists, and the Unique Facility Identifier in accordance with the requirements of part 207 of this chapter and section 510 of the Federal Food, Drug, and Cosmetic Act. For amendments and supplements, only changes to the list of facilities are required to be included.

(5) *Certification of adequate manufacture, processing, packaging, and holding of designated medical gas.* The applicant must certify that the applicant's methods, facilities, and controls used for the manufacture, processing, packing, and holding of the

designated medical gas, as applicable, are adequate to ensure its safety, identity, strength, quality, and purity.

(6) *Additional information.* The applicant must provide any other information which FDA deems appropriate to determine whether the medical gas is a designated medical gas. The applicant may also provide other information that the applicant believes will assist FDA in evaluating the request.

(c) *Where and how to submit a request for certification.* The applicant must submit a signed, completed request for certification form either in an electronic format that FDA can process, review, and archive, or in hard copy by submitting two paper copies to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Amundson Rd., Beltsville, MD 20705.

§ 230.65 Withdrawal by the applicant of a certification request before it is deemed granted.

An applicant may at any time withdraw a certification request that is not yet deemed granted by notifying FDA in writing. A decision to withdraw the certification request is without prejudice to refiling. The Agency will retain the certification request and will provide a copy to the applicant on request under the fee schedule in § 20.45 of this chapter (FDA's public information regulations).

§ 230.70 Supplements and other changes to a granted certification.

(a) The applicant must submit a supplement if any information in the certification request changes after the request has been deemed granted, including, but not limited to, the addition of a new facility manufacturing the designated medical gas, a change in contact information, or a change in the corporate name.

(b) Each supplement must include a signed, completed request for certification form with the updated information in accordance with § 230.50. The updated information must be submitted no later than 30 calendar days after the date the change occurred.

§ 230.72 Change in ownership of a granted certification.

An applicant may transfer ownership of its certification. At the time of transfer the new and former owners are required to submit information to FDA as follows:

(a) The former owner must submit a letter or other document that states that all rights to the certification have been transferred to the new owner.

(b) The new owner must submit a supplement under § 230.70 signed by the new owner describing any changes in the conditions in the granted certification and a letter or other document containing the date that the change in ownership is effective.

§ 230.80 Annual report.

(a) The applicant must submit each year within 60 calendar days of the new calendar year an annual report containing the information described in paragraph (b) of this section. The applicant must submit a signed, completed annual report form either in an electronic format that FDA can process, review, and archive, or in hard copy by submitting two paper copies to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705.

(b) The report must contain, for the prior calendar year, the following information in the order listed:

(1) *Summary.* A brief summary of significant new information that might affect the safety, effectiveness, or labeling of the designated medical gas, including any actions the applicant has taken or intends to take as a result of this new information.

(2) *Distribution data.* Information about the quantity of the designated medical gas distributed by the applicant. The information must include the National Drug Code (NDC) numbers, the quantities distributed for domestic use, and the quantities distributed for foreign use. Disclosure of financial or pricing data is not required.

(3) *Administrative changes.* Any changes to the applicant's name or contact information.

(4) *Current facilities.* A list of current facilities where the designated medical gas is initially produced, and a list of facilities that are no longer in use.

§ 230.100 FDA review of submissions.

(a) In reviewing a submission pursuant to § 230.50, FDA will consider information provided with the submission along with any other available, relevant information of which FDA becomes aware, including information obtained from State or Federal officials, FDA inspection reports, or any other source.

(b) FDA will deny a submission if FDA finds that:

(1) The medical gas that is the subject of the submission is not a designated medical gas;

(2) The submission does not contain the required information or otherwise appears to lack sufficient information to

determine that the medical gas is a designated medical gas;

(3) The applicant's methods, facilities, and controls used for the manufacture, processing, and handling of the designated medical gas, as applicable, are not adequate to ensure its safety, identity, strength, quality, and purity; or

(4) Denying the request is otherwise necessary to protect the public health.

(c) Within 60 calendar days of filing of a submission, FDA may contact the applicant to request additional information regarding the submission if it determines that required information is not included in the submission, that FDA needs such information to determine whether the medical gas is a designated medical gas, or that FDA determines such information is necessary to protect the public health. Upon receipt of an amendment to a pending certification request, this 60-day review period will restart. If FDA is not able to contact the applicant to obtain and evaluate the information within the 60-day review period, FDA may find that the submission lacks sufficient information to permit a determination that the medical gas is a designated medical gas and deny the submission. If FDA is able to contact the applicant but is not provided with the additional information requested within the 60-day review period, FDA may find that the request lacks sufficient information to permit a determination that the medical gas is a designated medical gas and deny the submission.

(d) Within 60 calendar days of filing of a submission, if FDA makes one of the findings described in paragraph (b) of this section, FDA will notify the applicant in writing that the submission is denied and provide the basis for FDA's determination.

§ 230.105 When a submission is deemed granted.

Unless FDA makes one of the findings described in § 230.100(b) and notifies the applicant within 60 calendar days of filing that the submission is denied, the certification is deemed to be granted and the designated medical gas will be deemed to have in effect an approved application under section 505 or section 512 of the Federal Food, Drug, and Cosmetic Act, or both, as applicable, for the indications described in section 576(a)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act. FDA will notify the applicant in writing.

§ 230.150 Withdrawal or revocation of approval of an application.

(a) *Withdrawal.* (1) FDA will notify the applicant, and afford an opportunity for a hearing on a proposal to withdraw

approval of the application under the procedure in § 314.200 of this chapter, § 514.200 of this chapter, or both, as applicable, if any of the following apply:

(i) The Secretary of Health and Human Services has suspended the approval of the application for a designated medical gas on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(ii) FDA finds:

(A) That clinical or other experience, tests, or other scientific data show that the designated medical gas is unsafe for use under the conditions of use upon the basis of which the application was approved; or

(B) That new evidence of clinical experience not available to FDA until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available when the application was approved, reveal that the designated medical gas is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or

(C) Upon the basis of new information before FDA with respect to the designated medical gas, evaluated together with the evidence available when the application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126 of this chapter, that the designated medical gas will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(D) That the application contains any untrue statement of a material fact.

(2) FDA may notify the applicant, and afford an opportunity for a hearing on a proposal to withdraw approval of the application under the procedure in § 314.200 of this chapter, § 514.200 of this chapter, or both, as applicable, if the Agency finds:

(i) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports applicable to designated medical gases, including under sections 505(k) and 512(l) of the Federal Food, Drug, and Cosmetic Act and this part, part 213 of this chapter, and § 314.81(b)(3) of this chapter, or that the applicant has refused to permit access to, or copying or verification of, its records.

(ii) That on the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the designated medical gas are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Agency.

(iii) That on the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the labeling of the designated medical gas, based on a fair evaluation of all material facts, is false or misleading in any particular, and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the Agency.

(iv) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the Federal Food, Drug, and Cosmetic Act.

(3) FDA will withdraw approval of an application if the applicant requests its withdrawal because the designated medical gas subject to the application is no longer being marketed, provided none of the conditions listed in paragraphs (a)(1) and (2) of this section applies to the designated medical gas. FDA will consider a written request for a withdrawal under this paragraph (a)(3) to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application under this paragraph (a)(3) is without prejudice to refiling.

(4) FDA may notify an applicant that it believes a potential problem associated with a designated medical gas is sufficiently serious that the designated medical gas should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the Agency will not make a finding under paragraph (a)(1) or (2) of this section, but will withdraw approval of the application in a notice published in the **Federal Register** that contains a brief summary of the Agency's and the applicant's views of the reasons for withdrawal.

(5) If FDA withdraws an approval, FDA will publish a notice in the **Federal Register** announcing the withdrawal of approval.

(b) *Revocation.* FDA may revoke the grant of a certification if FDA

determines, after providing the applicant with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the request for certification contains any material omission or falsification.

Subpart C—Postmarketing Quality and Safety Reporting

§ 230.205 Field alert reports.

The applicant shall submit a field alert report containing all information described in paragraphs (a) and (b) of this section about distributed designated medical gases and articles to the FDA district office that is responsible for the facility involved as soon as possible but no later than 45 calendar days from the date the applicant, or its agent or contractor, obtained information suggesting that a reportable incident has occurred. If the information suggests that the reportable incident may require a rapid response to address a public health risk, the applicant must as soon as possible, but no later than 3 working days from obtaining the information, submit a field alert report. The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: "Designated Medical Gas—Field Alert Report."

(a) Information concerning any incident that causes the designated medical gas or its labeling to be mistaken for, or applied to, another article.

(b) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed designated medical gas, or any failure of one or more distributed batches of the designated medical gas to meet established specifications.

§ 230.210 General reporting requirements for designated medical gas adverse events.

(a) *Review of safety information.* Each applicant and nonapplicant must promptly review all safety information that the applicant or nonapplicant receives or otherwise obtains from any source, foreign or domestic, such as information derived from commercial marketing experience, reports in the published scientific and medical literature, unpublished scientific papers, and reports from regulatory authorities.

(b) *Safety reporting disclaimer.* (1) A report or information submitted by an applicant or nonapplicant (and any release by FDA of that report or information) under § 230.220 or § 230.230 does not necessarily reflect a

conclusion by the applicant or nonapplicant or by FDA that the report or information constitutes an admission that the designated medical gas caused or contributed to an adverse effect.

(2) An applicant or nonapplicant need not admit, and may deny, that the report or information submitted under § 230.220 or § 230.230 constitutes an admission that the designated medical gas caused or contributed to an adverse effect.

§ 230.220 Human designated medical gas ICSR requirements.

(a) *ICSR reporting—(1) General.* Except as provided in paragraph (c) of this section, applicants and nonapplicants must submit each ICSR associated with the use of a designated medical gas in humans described in paragraph (b) of this section to FDA as soon as possible but no later than 15 calendar days from the date when the applicant or nonapplicant has met the reporting criteria described in paragraph (b) of this section and acquired a minimum data set for an ICSR for an adverse event.

(2) *Copies of ICSRs obtained from FDA.* An applicant or nonapplicant should not resubmit under this section any ICSRs obtained from FDA's adverse event reporting database or forwarded to the applicant or nonapplicant by FDA.

(3) *Followup information.* Applicants and nonapplicants must submit any new information that is related to a previously submitted ICSR or an ICSR that was sent to the applicant or nonapplicant by FDA no later than 15 calendar days after the information is received or otherwise obtained.

(b) *Reporting requirements—(1) Serious adverse events—(i) Reported to or otherwise received by the applicant or nonapplicant.* Applicants and nonapplicants must submit ICSRs for serious adverse events reported to or otherwise received by the applicant or nonapplicant (such as a report initiated by a patient, consumer, or healthcare professional, or received at the request of the applicant or nonapplicant).

(ii) *Reported from the scientific literature.* Applicants and nonapplicants must submit ICSRs for serious adverse events obtained from published scientific and medical journals either as case reports or as the result of a formal clinical trial.

(iii) *Exception to reporting requirements for serious adverse events.* Notwithstanding paragraphs (b)(1)(i) and (ii) of this section, ICSRs are not required for reports of the death of a patient who was administered oxygen, unless the applicant or nonapplicant is aware of evidence to suggest that the

death was caused by the administration of oxygen.

(2) *Other adverse event reports to be submitted upon notification by FDA.* Upon notification by FDA, applicants and nonapplicants must submit, in a timeframe established by FDA, ICSRs for any adverse events that are not required under paragraph (b)(1) of this section. The notification will specify the adverse events to be reported and the reason for requiring the reports.

(c) *Completing and submitting ICSRs.* This paragraph (c) describes how to complete and submit ICSRs required under this section.

(1) *Electronic format for submissions.* (i) ICSRs and ICSR attachments must be in an electronic format that FDA can process, review, and archive.

(ii) An applicant or nonapplicant may request, in writing, a temporary waiver of the requirements in paragraph (c)(1)(i) of this section. These waivers will be granted on a limited basis for good cause shown.

(2) *Submitting ICSRs—(i) Single submission of each ICSR.* Submit each ICSR only once.

(ii) *Separate ICSR for each patient.* The applicant or nonapplicant must submit a separate ICSR for each patient who experiences an adverse event reportable under paragraph (b) of this section.

(iii) *Coding terms.* The adverse event terms described in the ICSR must be coded using standardized medical terminology.

(iv) *Minimum data set.* All ICSRs submitted under this section must contain at least the minimum data set for an ICSR for an adverse event. The applicant or nonapplicant must actively seek the minimum data set in a manner consistent with the written procedures under paragraph (f) of this section. Applicants and nonapplicants must document and maintain records of their efforts to obtain the minimum data set.

(v) *ICSR elements.* The applicant or nonapplicant must complete all known, available elements of an ICSR as specified in paragraph (d) of this section.

(A) For adverse events, applicants and nonapplicants must actively seek any information needed to complete all applicable elements, consistent with their written procedures under paragraph (f) of this section.

(B) Applicants and nonapplicants must document and maintain records of their efforts to obtain the missing information.

(vi) *Supporting documentation.* An applicant or nonapplicant must submit the following types of supporting documentation in an ICSR, if available:

(A) A copy of the autopsy report if the patient died, or a copy of the hospital discharge summary if the patient was hospitalized. The applicant or nonapplicant must submit each document as an ICSR attachment. The ICSR attachment must be submitted either with the initial ICSR or no later than 15 calendar days after obtaining the document. English translations of foreign language documents must be provided.

(B) A copy of the published article as an ICSR attachment for each ICSR of an adverse event obtained from the published scientific and medical literature. Foreign language articles must be accompanied by an English translation of the abstract. When submitting more than one ICSR from the same published article, the applicant or nonapplicant must submit only one copy of the article with one of the ICSRs. For the remaining ICSRs not accompanied by a copy of the published article, the applicant or nonapplicant must include the cross-reference to the specific ICSR to which the article is attached.

(d) *Information reported on ICSRs.* ICSRs must include the following information, subject to paragraph (c)(2)(v) of this section:

(1) Patient information, which includes:

- (i) Patient identification code;
- (ii) Patient age at the time of adverse event, or date of birth;
- (iii) Patient sex; and
- (iv) Patient weight.

(2) Adverse event, which includes:

(i) Outcome attributed to adverse event;

- (ii) Date of adverse event;
- (iii) Date of ICSR submission;
- (iv) Description of adverse event;
- (v) Adverse event term(s);
- (vi) Description of relevant tests conducted, including dates and laboratory data; and

(vii) Other relevant patient history, including preexisting medical conditions.

(3) Suspect designated medical gas(es), which includes:

- (i) Name;
- (ii) Dose, frequency, and route of administration used;
- (iii) Therapy dates;
- (iv) Diagnosis for use (indication);
- (v) Whether the adverse event abated after the use of the designated medical gas(es) stopped or the dose was reduced;
- (vi) Whether the adverse event reappeared after reintroduction of the designated medical gas(es);

(vii) Lot number;

(viii) National Drug Code (NDC) number; and

(ix) Concomitant medical products and therapy dates.

(4) Initial reporter information, which includes:

(i) Name, address, email address, and telephone number;

(ii) Whether the initial reporter is a healthcare professional; and

(iii) Occupation, if a healthcare professional.

(5) Applicant or nonapplicant information, which includes:

(i) Applicant or nonapplicant name, address, email address, and telephone number;

(ii) Report source, such as spontaneous, literature, or study;

(iii) Date the report was received by applicant or nonapplicant;

(iv) New drug application and/or new animal drug application number;

(v) Whether the ICSR is an expedited report;

(vi) Whether the ICSR is an initial report or followup report; and

(vii) Unique case identification number, which must be the same in the initial report and any subsequent followup report(s).

(e) *Recordkeeping.* (1) For a period of 10 years from the initial receipt of information, each applicant or nonapplicant must maintain records of information relating to adverse events under this section, whether or not submitted to FDA.

(2) These records must include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse event information that is received or otherwise obtained by the applicant or nonapplicant.

(3) Upon written notice by FDA, the applicant or nonapplicant must submit any or all of these records to FDA within 5 calendar days after receipt of the notice. The applicant or nonapplicant must permit any authorized FDA employee, at reasonable times, to access, copy, and verify these established and maintained records described in this section.

(f) *Written procedures.* The applicant or nonapplicant must develop written procedures needed to fulfill the requirements in this section for the surveillance, receipt, evaluation, and reporting to FDA of adverse event information, including procedures for employee training and for obtaining and processing adverse event information from other applicants and nonapplicants.

(g) *Patient privacy.* An applicant or nonapplicant should not include in reports under this section the names and addresses of individual patients; instead, the applicant or nonapplicant

should assign a unique code for identification of the patient. The applicant or nonapplicant should include the name of the reporter from whom the information was received as part of the initial reporter information, even when the reporter is the patient. As set forth in FDA's public information regulations in part 20 of this chapter, FDA generally may not disclose the names of patients, individual reporters, healthcare professionals, hospitals, and geographical identifiers submitted to FDA in adverse event reports.

§ 230.230 Animal designated medical gas adverse event reporting requirements.

(a) *Report for adverse events.* This report provides information on each adverse event associated with the use of a designated medical gas in animals, regardless of the source of the information.

(1) *Serious adverse events.* The applicant or nonapplicant must submit serious adverse events to FDA as soon as possible but no later than within 15 calendar days of first receiving the information. The report must be submitted to the Agency in electronic format as described in paragraph (b)(1) of this section, unless the applicant or nonapplicant obtains a waiver under paragraph (b)(2) of this section or FDA requests the report in an alternate format.

(i) *Reported to or otherwise received by the applicant or nonapplicant.* Applicants and nonapplicants must submit reports for *each serious adverse event* reported to or otherwise received by the applicant or nonapplicant (such as reports initiated by a patient, consumer, veterinarian, or other healthcare professional, or received at the request of the applicant or nonapplicant), regardless of whether the applicant or nonapplicant believes the events are related to the designated medical gas.

(ii) *Reported from the scientific and medical literature.* Applicants and nonapplicants must submit reports for each serious adverse event obtained from the published scientific and medical literature regardless of whether the applicant or nonapplicant believes the events are related to the designated medical gas.

(iii) *Exception to reporting requirements for serious adverse events.* Notwithstanding paragraphs (a)(1)(i) and (ii) of this section, reports are not required to be submitted for the death of an animal that was administered oxygen, unless the applicant or nonapplicant becomes aware of evidence to suggest that the death was caused by the administration of oxygen.

(2) *Other adverse event reports to be submitted upon notification by FDA.* Upon notification by FDA, applicants and nonapplicants must submit reports of adverse events associated with the use of a designated medical gas in animals that do not qualify for reporting under paragraph (a)(1) of this section. The notice will specify the adverse events to be reported and the reason for requiring the reports.

(3) *Copies of adverse event reports obtained from FDA.* An applicant or nonapplicant should not resubmit under this section any adverse event reports obtained from FDA's adverse event reporting database or forwarded to the applicant or nonapplicant by FDA.

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

(2) *Waivers.* An applicant or nonapplicant may request, in writing, a temporary waiver of the electronic submission requirements in paragraph (b)(1) of this section. The initial request may be provided by telephone or email to the Center for Veterinary Medicine's Division of Pharmacovigilance and Surveillance, with prompt written followup submitted as a letter to the granted certification(s). FDA will grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

(c) *Records to be maintained.* (1) For a period of 5 years from the initial receipt of information, each applicant or nonapplicant must maintain records of information relating to adverse event reports under this section, whether or not submitted to FDA.

(2) These records must include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse event information that is received or otherwise obtained by the applicant or nonapplicant.

(3) Upon written notice by FDA, the applicant or nonapplicant must submit any or all of these records to FDA within 5 calendar days after receipt of the notice. The applicant or nonapplicant must permit any authorized FDA employee, at reasonable times, to access, copy, and verify these established and maintained records described in this section.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 26. The authority citation for part 314 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360cc, 360ddd, 360ddd–1, 371, 374, 379e, 379k–1.

■ 27. Amend § 314.1 by redesignating paragraph (c) as paragraph (d) and adding new paragraph (c) to read as follows:

§ 314.1 Scope of this part.

* * * * *

(c) The following provisions do not apply to designated medical gases, which are subject to the certification and postmarketing reporting requirements under part 230 of this chapter:

- (1) Sections 314.50 through 314.72;
- (2) Section 314.80;
- (3) Section 314.81, except paragraph (b)(3);
- (4) Section 314.90;
- (5) Subpart C of this part;
- (6) Sections 314.100 through 314.162;
- (7) Subpart H of this part; and
- (8) Subpart I of this part.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 28. The authority citation for part 514 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 360ddd, 360ddd–1, 371, 379e, 381.

■ 29. Amend § 514.1 by adding a sentence to the end of paragraph (a) to read as follows:

§ 514.1 Applications.

(a) * * * The following provisions do not apply to designated medical gases, which are subject to the certification requirements under part 230 of this chapter: §§ 514.1(b) and (c), 514.3 through 514.8, 514.12, and 514.15, and subpart B of this part.

* * * * *

■ 30. Amend § 514.80 by:

■ a. In the introductory text table, adding an entry after the sixth entry; and

■ b. Adding paragraph (a)(6).
The additions read as follows:

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

The following table outlines the
purpose for each paragraph of this
section:

Purpose					21 CFR paragraph and title	
*	*	*	*	*	*	*
Does this section apply to designated medical gases subject to the certification requirements under part 230?					514.80(a)(6)	
*	*	*	*	*	*	*

(a) * * *
(6) This section does not apply to
designated medical gases, which are
subject to the certification requirements

under part 230 of this chapter. Part 230
of this chapter contains requirements
related to records and reports

concerning experience with the use of a
designated medical gas in animals.
* * * * *

Dated: June 10, 2024.
Robert M. Califf,
Commissioner of Food and Drugs.
[FR Doc. 2024–13190 Filed 6–17–24; 8:45 am]
BILLING CODE 4164–01–P

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Federal Register

Vol. 89, No. 118

Tuesday, June 18, 2024

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids **202-741-6000****Laws** **741-6000**

Presidential Documents

Executive orders and proclamations **741-6000****The United States Government Manual** **741-6000**

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FEDERAL REGISTER PAGES AND DATE, JUNE

47439-47846.....	3
47847-48130.....	4
48131-48254.....	5
48255-48486.....	6
48487-48820.....	7
48821-49080.....	10
49081-49796.....	11
49797-50204.....	12
50205-50498.....	13
50499-51202.....	14
51203-51394.....	17
51395-51784.....	18

CFR PARTS AFFECTED DURING JUNE

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.

2 CFR

200.....48131

Proposed Rules:

910.....51460

3 CFR

Proclamations:

10766.....48223

10767.....48225

10768.....48227

10769.....48229

10770.....48231

10771.....48233

10772.....48233

10772.....48255

10773.....48487

10774.....49081

10775.....50203

Administrative Orders:

Presidential Permits:

Presidential Permit of

May 31, 2024.....48243

Presidential Permit of

May 31, 2024.....48247

Presidential Permit of

May 31, 2024.....48251

Memorandums:

Memorandum of May

24, 2024.....50499

Notices:

Notice of June 13,

2024.....51197

Notice of June 13,

2024.....51199

Notice of June 13,

2024.....51201

4 CFR

28.....51395

5 CFR

900.....48821

1302.....48821

1303.....48821

6 CFR

Proposed Rules:

226.....47471

7 CFR

3.....48495

800.....48257

3550.....48499

Proposed Rules:

1220.....51277

8 CFR

208.....48710

235.....48710

1208.....48710

Proposed Rules:

106.....48339

9 CFR

11.....48131

Proposed Rules:

56.....49107

145.....49107

146.....49107

147.....49107

201.....49002

10 CFR

50.....49083

52.....49083

72.....47439, 51400

430.....50205

433.....48266

12 CFR

1033.....49084

Proposed Rules:

1022.....51682

13 CFR

107.....48132

120.....48132

125.....48266

128.....48266

142.....48132

146.....48132

14 CFR

25.....51401

39.....48500, 49091, 49094,

50501, 50503, 50505, 50510,

50513, 51203, 51205, 51401

71.....47847, 47848, 48269,

48271, 48504, 48506, 50219,

50220, 50221, 50222, 50518,

50519, 50520, 51403, 51405,

51406, 51407, 51408, 51410

73.....51414

91.....51415

95.....51432

97.....48135, 48136

121.....51415

135.....51415

Proposed Rules:

21.....50241

39.....47879, 48139, 48348,

49819, 50241, 51468, 51471

71.....49118, 50536, 50537,

50540, 51279

15 CFR

734.....51644

740.....51644

744.....51644

746.....51644

774.....51644

922.....48272

16 CFR

432.....49797

Proposed Rules:	570.....50541	14.....48850	57.....50058
1218.....51475	982.....50541		58.....50058
17 CFR	26 CFR	37 CFR	59.....50058
17.....47439	1.....50524	43.....49808	61.....50058
146.....51208	Proposed Rules:	38 CFR	62.....50058
240.....47688	1.....47792, 51476	1.....51442	63.....50058
248.....47688		3.....51224	64.....50058
270.....47688	29 CFR	17.....51224, 51444	Proposed Rules:
275.....47688	102.....50223		541.....48865
Proposed Rules:	1603.....47850	39 CFR	
40.....48968	4001.....48291	20.....51446	47 CFR
18 CFR	4010.....48291	111.....49056	8.....48514
35.....49280	4022.....48291	Proposed Rules:	9.....47869
50.....47460	4041.....48291	111.....50542	10.....51265
380.....47460	4041A.....48291		20.....48514
Proposed Rules:	4043.....48291	40 CFR	64.....47869
4.....48351	4044.....48291, 50526	52.....47468, 49100, 49815,	73.....50235
5.....48351	4050.....48291	50227, 50231	Proposed Rules:
6.....48351	4262.....48291	82.....50410	1.....51284
7.....48351	4281.....48291	85.....50234	4.....48540
20 CFR	Proposed Rules:	86.....50234	11.....47891
222.....47460	1910.....49119	141.....49101	73.....47891
235.....47462	30 CFR	257.....48774	74.....47891
404.....48138	90.....50527	261.....48511	90.....51293
416.....48138	31 CFR	1036.....51234	95.....51293
21 CFR	223.....48827	1037.....51234	
1.....47463	542.....48309, 48310	1065.....51234	48 CFR
4.....51738	587.....48324, 48838, 48840	Proposed Rules:	225.....48330
16.....51738	594.....48841, 48842	52.....47474, 47481, 47504,	502.....48330
201.....51738	597.....48842	48523, 48532, 49120, 50245,	538.....48330
210.....51738		50543	552.....48330
211.....51738	33 CFR	70.....47504	Proposed Rules:
213.....51738	100.....48509, 50224	721.....49121, 49770	Ch. 99.....51401
230.....51738	165.....47464, 47467, 47854,	751.....51134	2.....48540
314.....51738	48325, 48327, 48328, 48509,	42 CFR	19.....48540, 48544
514.....51738	48844, 48846, 48848, 49808,	423.....51238	42.....48540
573.....48507	50527, 51215, 51218, 51219,	Proposed Rules:	52.....48540, 48544
Proposed Rules:	51221, 51222, 51440	412.....47884	
1.....51281	173.....47855	413.....47884	49 CFR
1308.....48515	174.....47855	431.....47884	367.....51266
22 CFR	207.....47863	482.....47884	384.....50235
303.....50521	326.....47863	485.....47884	Proposed Rules:
24 CFR	Proposed Rules:	495.....47884	571.....48359
58.....50523	151.....48515	512.....47884	
214.....49802	165.....47472, 47884	45 CFR	50 CFR
236.....47849, 49099	34 CFR	170.....51238	17.....48034
1000.....49802	Proposed Rules:	Proposed Rules:	216.....51600
1003.....49802	Ch. VI.....48356, 48517	5b.....48536	622.....47871, 48338, 49104,
1005.....50523	36 CFR	46 CFR	50529, 50530
Proposed Rules:	7.....47866	50.....50058	648.....47872, 49105, 49817
91.....50541	1225.....47467	52.....50058	679.....51448
92.....50541	Proposed Rules:	53.....50058	680.....47872
	1.....48850	54.....50058	Proposed Rules:
		56.....50058	216.....47508
			622.....51295

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion

in today's **List of Public Laws**.

Last List May 29, 2024

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